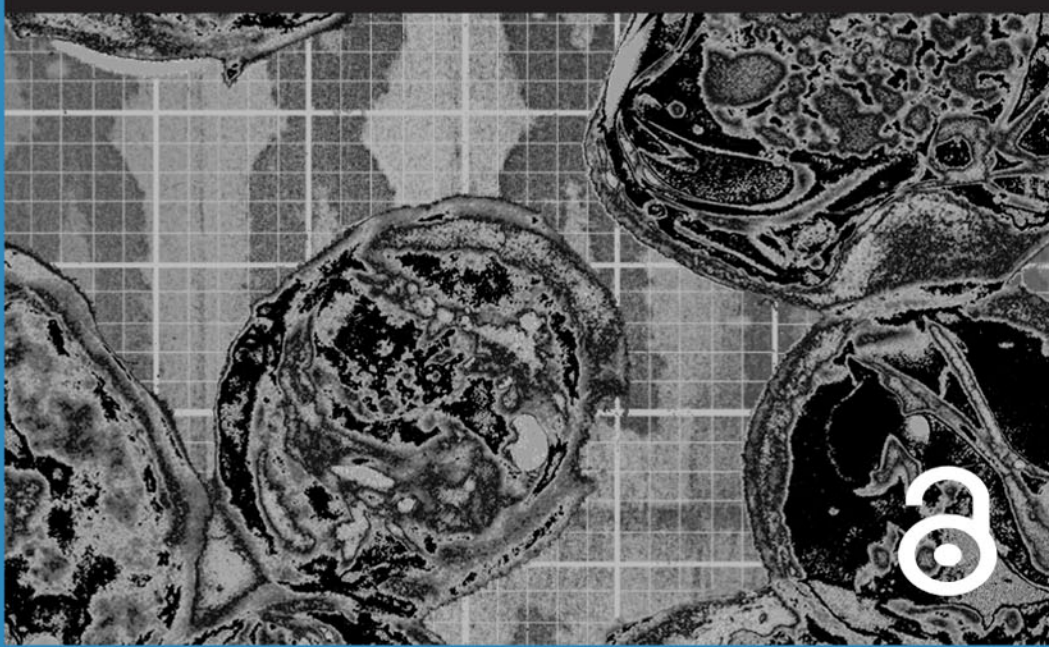
Negotiating Bioethics

The governance of UNESCO's Bioethics Programme

Adèle Langlois



Negotiating Bioethics

The sequencing of the entire human genome has opened up unprecedented possibilities for healthcare, but also ethical and social dilemmas about how these can be achieved, particularly in developing countries. UNESCO's Bioethics Programme was established to address such issues in 1993. Since then, it has adopted three declarations on human genetics and bioethics (1997, 2003 and 2005), set up numerous training programmes around the world and debated the need for an international convention on human reproductive cloning.

Negotiating Bioethics presents Langlois' research on the negotiation and implementation of the three declarations and the human cloning debate, based on fieldwork carried out in Kenya, South Africa, France and the UK, among policy-makers, geneticists, ethicists, civil society representatives and industry professionals. The book examines whether the UNESCO Bioethics Programme is an effective forum for (a) decision-making on bioethics issues and (b) ensuring ethical practice. Considering two different aspects of the UNESCO Bioethics Programme – deliberation and implementation – at international and national levels, Langlois explores:

- how relations between developed and developing countries can be made more equal;
- who should be involved in global level decision-making and how this should proceed;
- how overlap between initiatives can be avoided;
- what can be done to improve the implementation of international norms by sovereign states;
- how far universal norms can be contextualized;
- what impact the efficacy of national level governance has at international level.

Drawing on extensive empirical research, *Negotiating Bioethics* presents a truly global perspective on bioethics. The book will be of interest to students and scholars of sociology, politics, science and technology studies, bioethics, anthropology, international relations and public health.

Adèle Langlois is Senior Lecturer in Politics and International Relations at the University of Lincoln. She has conducted fieldwork in India, Kenya and South Africa. Her research interests include the regulation of human genetic and biomedical research, polio eradication and normative theories of global governance.

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For Mum and Dad

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Foreword

The research for this book springs from two sources. First, it comes from Adèle Langlois' research for a doctorate, and subsequently, her early postdoctoral work. As such, it is a perfect exemplar of what can be done by an enthusiastic, highly competent and very hard-working young researcher. But second, it shows the result of one person's commitment to learning more about the global governance of bioethics. It focuses on crucial questions, such as: Can bioethics be global? Is a UN-led intergovernmental approach the best way to construct global governance for genomic science?

The framework for this book is the science and social science of genomics from the sequencing of the human genome at the turn of the millennium. But unlike the many books already written within this context, Adèle Langlois has chosen to focus, unusually, if not uniquely, on intergovernmental relations, but more particularly, on relations between developed and developing countries. She also goes a step further by researching intergovernmental relations around ethical issues, and the even more tricky ethical questions concerning the ethics of life: stem cells, human cloning, and so on.

There is plenty to mull over and debate in the chapters of this book, and I have picked out a few issues that had cadence for me – but there are many others. In particular, one insight I gained is that crucial issues can be both 'high-level' think issues, while also relatively mundane and grounded.

At a 'higher' level, there is the question of whether the focus of research on the international politics of ethics should be different in the South from the North. The book suggests that bioethics in the South are closely intertwined with the ethics of poverty and global power. Langlois shows us that ethics committees are not new to Africa – that there have been ethics committees for many decades in South Africa and Nairobi. It would be easy to jump to conclusions about how poor countries deal with ethics, but relative weakness in terms of professional bioethical skills does not translate as having no capability or evidenced argument. There are voices with something important to contribute. It is important to listen – as Adèle has done.

At a more 'mundane' level, Adèle points to the unequal relations within UNESCO, part of the UN intergovernmental system. At one level there is 'equal' representation of groups of nations. But if poorer nations have lower human and

financial resources they will not be able to travel to 'join' the tables of 'equals'. Adèle addresses this and similar issues through the 'lens' of her detailed studies of South Africa and Kenya.

Other important ethical issues go well beyond the resources to travel and engage in UN bodies, such as the huge gap between research on diseases of the poor and diseases of the more affluent, and how to avoid poorer countries becoming a 'research sweat shop' for clinical trials that are no longer placed in developed countries.

Langlois' research fits squarely into the category of 'engaged research'. She shows here that she is an 'expert' engager among experts of many types (UN, scientists, social scientists, ethicists, policy-makers). Such engagement did not come at the end of her research process but at the beginning. This has influenced her rigorous collection of data of various kinds, including large volumes of published and grey materials and extensive observations at meetings, and enriched her research analysis and results.

The chapters of this challenging book will engage those who are serious about the important details of how to build global governance of science and technology, but it is also a key text for those who want to know more about the international politics of treaty negotiation, and those who are keen to learn about bioethics issues in developing countries. Every reader will find something of importance in these pages, and something to debate with their colleagues.

David Wield
Director, ESRC INNOGEN Centre,
Open University and the University of Edinburgh

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At a personal level, I am deeply indebted to Helen Yanacopulos and Joanna Chataway, my PhD supervisors, for steering me in the right directions with good advice and great humour. I would also like to thank my friends and colleagues at Innogen, DPP and SSPS for all the innumerable ways they have helped and supported me during my doctorate and early research career. David Wield, Hazel Johnson, Kelvin Jones, Jacqui Briggs and Hugh Bochel deserve a special mention here. Emily Briggs at Routledge has been an incredibly helpful and patient editorial assistant. All mistakes are my own. Finally and very importantly, I must thank all those who kindly gave their precious time to participate in my research, whether in 2005–6 when I was a green PhD student, or in 2011–12 when revisiting my findings, or both. Your insights have been invaluable in adding colour and life to my analysis.

To my friends in Lincoln, Cambridge, Milton Keynes, London, Guernsey and elsewhere, I offer my heartfelt thanks for your unerring support. Sport, music and

church have been the mainstays that have allowed me to break out from the rigours of academic life once in a while and thus stay relatively sane. I give thanks to God for this and every blessing. And lastly I come to my family, who have always offered their unconditional love, through this and every endeavour. Mum, Dad, Doug, Jenny and everyone in the Langlois, McKinnon and Setters clans, you are my rock – thank you for everything.

Sections of the book draw from an earlier publication: 'The global governance of bioethics: negotiating UNESCO's Universal Declaration on Bioethics and Human Rights (2005)', *Global Health Governance*, 5(1). I am grateful to *Global Health Governance* and the John C. Whitehead School of Diplomacy and International Relations, Seton Hall University, for allowing me to reproduce elements of the article here.

Abbreviations

ABC	Assisting Bioethics Committees
ABSF	African Biotechnology Stakeholders Forum
AGEI	Africa Genome Education Institute
AMANET	African Malaria Network Trust
AMCOST	African Ministerial Council on Science and Technology
ARESA	Advancing Research Ethics Training in Southern Africa
BioAWARE	National Biotechnology Awareness Initiative
BMJ	*British Medical Journal*
BRIC	Biotechnology Regional Innovation Centre
CAB	Community Advisory Board
CIOMS	Council for International Organizations of Medical Sciences
CITI	Collaborative Institutional Training Initiative
COMEST	World Commission on the Ethics of Scientific Knowledge and Technology
DACST	Department of Arts, Culture, Science and Technology
DNA	Deoxyribonucleic acid
DSA	Daily subsistence allowance
ECOSOC	Economic and Social Council
EDCTP	European and Developing Countries Clinical Trials Partnership
EEP	Ethics Education Programme
ESC	Embryonic stem cell
ETTC	Ethics Teachers' Training Course
EU	European Union
GAEIB	Group of Advisers on the Ethical Implications of Biotechnology
GEObs	Global Ethics Observatory
GGI	Global Genomics Initiative
GMO	Genetically modified organism
GPPN	Global Public Policy Network
H3Africa	Human Heredity and Health in Africa Initiative
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
HPCSA	Health Professionals Council of South Africa
HSSC	Health Sciences Specialist Committee

HUGO	Human Genome Organisation
IAEE	International Association for Ethics in Education
IBC	International Bioethics Committee
IDHGD	International Declaration on Human Genetic Data
IGBC	Intergovernmental Bioethics Committee
IGE	Intergovernmental meeting of experts
IGO	Intergovernmental organization
IOS	Internal Oversight Office
iPSC	Induced pluripotent stem cell
IRENSA	International Research Ethics Network for Southern Africa
ISAAA	International Service for the Acquisition of Agri-biotech Applications
JACOB	Joint Action for Capacity Building in Bioethics
KEMRI	Kenya Medical Research Institute
KNH-UoN	Kenyatta National Hospital-University of Nairobi
MARC	Mapping African Research Ethics Review Capacity
MEA	Multilateral environmental agreement
MoU	Memorandum of Understanding
MRC	Medical Research Council
NBAC	National Biotechnology Advisory Committee
NBC	National Bioethics Committee
NC	National Commission
NCST	National Council for Science and Technology
NEPAD	New Partnership for Africa's Development
NGO	Non-governmental organization
NHREC	National Health Research Ethics Council
NIH	National Institutes of Health
ONEC	Opinions submitted by National Ethics Committees
PCSBI	Presidential Commission for the Study of Bioethical Issues
PD	Permanent Delegation
PUB	Public Understanding of Biotechnology
REC	Research ethics committee
RNA	Ribonucleic acid
SAHGP	Southern African Human Genome Programme
SAREN	Southern African Research Ethics Network
SARETI	South African Research Ethics Training Initiative
SCNT	Somatic cell nuclear transfer
SIR	System of implementation review
TIA	Technology Innovation Agency
UDBHR	Universal Declaration on Bioethics and Human Rights
UDHGHR	Universal Declaration on the Human Genome and Human Rights
UK	United Kingdom
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNESCO	United Nations Educational, Scientific and Cultural Organization

UNU-IAS	United Nations University's Institute of Advanced Studies
US	United States (of America)
USD	United States dollar
WHO	World Health Organization
WMA	World Medical Association

1 Introduction

The sequencing of the entire human genome has opened up unprecedented possibilities for healthcare, but also ethical and social dilemmas about how these can be achieved, particularly in developing countries. How competently such dilemmas are managed will dictate whether the fruits of genetic and other biomedical research exacerbate or reduce inequalities of health between North and South. UNESCO, the United Nations Educational, Scientific and Cultural Organization, addresses such issues through its Bioethics Programme, established in 1993. Over the past two decades the Programme has negotiated bioethics in two ways. First, it has navigated the twists and turns of an evolving moral discourse, in tandem with developments in science and technology, particularly in relation to the human body. Second, at the formal intergovernmental level, it has formulated three international declarations on human genetics and bioethics. This book examines how these declarations have come about, their impact on bioethical thinking and practice and the future prospects of the Bioethics Programme.

Although the term 'bioethics' can be used to cover ethical issues across a broad spectrum, UNESCO has focused mainly on the human impact, as the titles of its three declarations demonstrate: the *Universal Declaration on the Human Genome and Human Rights* (1997); the *International Declaration on Human Genetic Data* (2003); and the *Universal Declaration on Bioethics and Human Rights* (2005). Each declaration embraces well-established bioethical principles, such as autonomy and informed consent, as well as newer ideals of knowledge sharing and capacity building between developed and developing countries. These norms and principles are designed to deal with pressing issues in genetics and bioethics. Genetics presents new ethical problems, or at least new perspectives on existing ones. That members of families and communities may share genes poses a challenge to the recognized bioethical principles of privacy and confidentiality, for instance. Relatedly, if the human genome is the common 'heritage of humanity' (as UNESCO terms it), this begs the question how the benefits that might accrue from genetic research should be distributed. At the same time, understandings of what constitutes a bioethical concern are broadening. As inequalities in access to medicine and healthcare between North and South enlarge, what should be the focus of research becomes in itself an ethical question (aside from how it should be carried out). Most recently, UNESCO has been

asking this question in the context of whether human reproductive cloning should be banned worldwide.

UNESCO is one of several organizations working in the area of bioethics. This raises another question: is the UNESCO Bioethics Programme an effective forum for (a) decision-making on bioethics issues and (b) ensuring ethical practice? The book seeks to answer this question both theoretically and empirically. Based on original research conducted at UNESCO headquarters and in member states, it draws on international relations theory to assess the efficacy of the Bioethics Programme. International relations theory, in its various forms, seeks to explain world affairs and expound how they might, if possible, be better governed. Governance, in this respect, constitutes decision-making on the management of collective issues and the subsequent implementation of regulations and policies to effect those decisions. At national level, these tasks are often undertaken by governments. At international level, governance is conducted in the absence of a formal world government, partly through institutions such as UNESCO. Effective governance of human genetic and biomedical research would contribute to the protection of individual research participants and, more broadly, the harnessing of this research to tackle global health needs. It would entail, first, high-quality decisions on how these goals could be achieved and, second, comprehensive implementation of those decisions.

Fieldwork data, collected in 2005–6 during doctoral studies and followed up in 2010–12, will shed light on whether the Bioethics Programme provides effective governance. Fieldwork included the following: close observation of meetings of UNESCO's International Bioethics Committee and Intergovernmental Bioethics Committee (which discussed, *inter alia*, the drafting of the 2005 *Universal Declaration on Bioethics and Human Rights* and the possibility of a convention to ban human reproductive cloning); analysis of official records of these and other bioethics meetings within the organization, as well as national policy documents from Kenya and South Africa; 77 interviews with UNESCO staff and delegates, policy-makers in relevant government ministries, geneticists, ethicists, members of civil society organizations and industry professionals; and questionnaires.

2005–6 saw 30 interviews conducted in Kenya, 33 in South Africa, two in the United Kingdom (with people involved in the negotiation of the 2005 declaration) and two in France (at UNESCO headquarters in Paris). Seven further interviews in Kenya in 2011 augmented the initial findings. Questionnaires sent to former interviewees and other key stakeholders from Kenya and South Africa in 2012 sought to gauge their views on (a) progress in genetics and bioethics at national level (b) UNESCO's capacity-building activities in ethics and (c) human reproductive cloning. Kenya and South Africa were chosen as the major fieldwork destinations because of their significant activities and involvement in bioethics and genetics locally, nationally, regionally and internationally. In Kenya, the Kenya Medical Research Institute carries out vaccine and drug trials for diseases such as HIV/AIDS, malaria and leprosy, while in South Africa geneticists are conducting research of both medical and evolutionary interest. Both countries have a long history of ethical review. The Human Research Ethics Committee of

the University of the Witwatersrand (Johannesburg), established in 1966, is one of the oldest in the world. Not far behind, the joint Kenyatta National Hospital and University of Nairobi Ethics and Research Committee was set up in 1974. Questionnaires were also sent to the UNESCO National Commissions and Paris-based Permanent Delegations of 23 English-speaking sub-Saharan African countries. Seven National Commissions and three Permanent Delegations replied.

The book considers two different aspects of the UNESCO Bioethics Programme – deliberation and implementation – at international and national levels. Chapter 4 charts the international negotiation processes for the three declarations, focusing on the power dimensions between (a) developed and developing countries and (b) UNESCO member states and other actors, namely United Nations agencies working in related fields, non-governmental organizations and independent experts in bioethics. Power differentials between North and South surfaced in spite of formal procedures aimed at containing them and several non-state actors felt excluded from the process. Chapter 5 examines the take-up of the declarations around the world and how this has been influenced by their content, their non-binding status (in international law, declarations are by nature non-binding) and UNESCO's efforts to encourage implementation through dissemination and capacity building. It also explores the relationship between UNESCO and other international bodies working in bioethics, particularly the World Health Organization. The choice of non-binding declarations enabled consensus among member states, but the pay-off is that adherence is harder to ensure. Engaging with stakeholders at national level is vital if the declarations are to have meaningful impact.

Chapters 6 and 7 peel back a layer to assess the impact of the declarations in Kenya and South Africa specifically. Chapter 6 asks who decided on each country's negotiating position during the drafting of the declarations, how the declarations are perceived by the respective bioethics and scientific communities and whether they have been incorporated into national laws, regulations and policies. Chapter 7 outlines UNESCO's capacity-building endeavours in Kenya and how these have been received, whether similar activities would be welcome in South Africa and the ethical challenges each country must confront. While the impact of the Bioethics Programme in each has been markedly different – Kenya has embraced it wholeheartedly, whereas in South Africa it barely features – both countries have instituted similar systems to improve ethical review of research. They also face similar challenges, in terms of protecting vulnerable populations, ensuring the benefits of research are shared equitably, training researchers and ethics committee members and educating and engaging with the public in ethical and scientific debate.

In examining deliberation and implementation within the UNESCO Bioethics Programme, from these two different levels, the book addresses the following broad issues: how relations between developed and developing countries can be made more equal; who should be involved in global level decision-making and how this should proceed; how overlap between initiatives can be avoided; what can be done to improve the implementation of international norms by sovereign

states; how far universal norms can be contextualized; and what impact the efficacy of national level governance has on that at international level. In this light, Chapter 8 reviews the strengths and weaknesses of the UNESCO Bioethics Programme, drawing on international relations theory to suggest how the latter might be addressed. It also considers the implications of the book's findings for the future of the human cloning debate and makes some practical recommendations on how the Bioethics Programme might move forward. First, though, Chapters 2 and 3 outline the parameters of the analysis to follow. Chapter 2 introduces the fields of bioethics and human genetics, the governance dilemmas they raise and how the UNESCO Bioethics Programme tackles these. Chapter 3 then presents a theoretical framework through which UNESCO's endeavours in bioethics governance can be investigated.

2 Bioethics

Human genetic and biomedical research ethics at UNESCO and beyond

> Every scientific revolution brings with it a host of ethical and social questions. The so-called genetics revolution is no exception, giving rise to a broad international debate on how the undoubted benefits of progress in this area can be reconciled with certain core human values.
>
> (UNESCO 2002a: 1)

Bioethics

Bioethics as a field has evolved from two separate disciplines: medical ethics and moral philosophy. Concern for ethics in terms of patient welfare first appeared in the form of the Hippocratic oath, while moral philosophers have come to reflect on dilemmas faced by modern society alongside more abstract meta-ethics (Harris 2001: 1–2). Bioethics is now seen to cover a wide range of issues, including genetics, reproductive technologies and biomedical research. John Harris (ibid: 4) gives a succinct definition in his introduction to *Bioethics*, part of the *Oxford Readings in Philosophy* series: 'In short, bioethics investigates ethical issues arising in the life sciences (medicine, health care, genetics, biology, research, etc) by applying the principles and methods of moral philosophy to these problems.'

At international level, research ethics were first laid down in regulatory form in 1947, in the Nuremberg Code. This codification was a response to the human rights abuses that had taken place through experimentation on human subjects under the Nazi regime of World War II and enshrined a key principle in bioethics, that of informed consent: a person agreeing to take part in research should do so voluntarily and with sufficient knowledge and understanding of what is involved (Fluss 2004: 596–7; National Institutes of Health 2009). The Code also encompasses what have come to be known as the 'four principles' or 'Georgetown principles', formulated by philosophers Tom Beauchamp and James Childress in the 1970s, namely respect for autonomy, non-maleficence, beneficence and justice. Although contested, these principles provide a normative framework that is widely used by researchers and medical practitioners (Beauchamp 2001: 479–80; Holm 2001: 494–5).

There have been several further attempts to codify good research practice, to ensure, as far as possible, that the rights of those who take part in research are

protected. In 1964, the World Medical Association produced the *Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects*, which reflects the four principles. Updated regularly, most recently in 2008, this is generally considered the foremost document globally on medical research ethics (Carlson *et al.* 2004: 695; World Medical Association 2008). The 2008 version presents a significant change in that it binds physicians to its provisions above all other international and national ethical, legal and regulatory requirements (the 2000 version set itself above only national obligations) (Rid and Schmidt 2010: 143 and 145). The Council for International Organizations of Medical Sciences' *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (CIOMS 2002) are intended to complement the Helsinki declaration. They give guidance on how its principles can be applied, particularly in developing countries. At other levels, many countries and research institutions have their own legal or regulatory instruments on bioethics, albeit usually based to a large extent on one or more of the international documents. The UNESCO declarations are the latest additions to this array.

Governance issues in bioethics

One of the main requirements of these various instruments will usually be that proposed research projects should be reviewed by a research ethics committee (REC). To ensure that a research project will be conducted ethically, RECs must determine whether the procedures for obtaining informed consent and the predicted risk/benefit ratio will be conducive to the protection of research participants, in terms of privacy, confidentiality, autonomy and safety (Benatar 2002b: 1134). How such concerns should be met has warranted renewed reflection in recent years, in the context of the growing frequency of research projects involving more than one country, including developing ones. The need to build capacity for ethical review in developing countries has also been noted. The extension of biomedical research beyond national borders renders international standards on bioethics necessary, so that research participants are treated equally and fairly, whichever country they are in (Gevers 2001: 293; Benatar 2002b: 1135; Berlinguer 2004: 1087; Isasi and Knoppers 2006: 24).

Since these universal norms are likely to be realized in different cultures, it is important that their application be contextualized (Ateudjieu *et al.* 2010: 95). The Nuffield Council on Bioethics (2002: 51), an independent body based in the United Kingdom (UK), highlights the difficulties that ensue if sponsors fail to familiarize themselves with the cultural traditions of the countries in which they fund research. Solomon Benatar and Peter Singer (2000: 826) recommend that international researchers should be sensitive to local social, economic and political contexts, while Zulfiqar Bhutta (2002: 116) suggests that communities should be involved in decision-making about research to be conducted in their locales.

Elsewhere, Benatar (2004: 576) stipulates that contextualization should only go so far: 'respect for democracy should take precedence over the preservation of cultural traditions that undermine democracy and human rights'. Other ethicists

would disagree, believing the idea that universal norms exist at all to be erroneous. 'Agreement at the level of general norms has no inherent practical significance since it is possible to derive markedly divergent policies and practices from the "same" principle, maxim, or moral intuition', writes Leigh Turner (2003: 195). He argues that historical and anthropological evidence for a common morality (including the notion of universal human rights) is scarce (ibid: 194 and 197). Similarly, modern bioethics has been criticized for deeming universal what some consider to be merely Western notions of ethics (Benatar 2004: 575).

Ruth Macklin (2003: 475) highlights the need for effective oversight of research: 'If a country lacks a mechanism for identifying and sanctioning researchers who violate laws, regulations, or fundamental ethical standards in carrying out the research, then all research subjects are potentially vulnerable.' Singer and Benatar (2001: 747), in an article on the World Medical Association's *Declaration of Helsinki* (the 2000 version), contend that building capacity in research ethics will have far more impact on ethical standards than 'revisions of this or any other research ethics code'. Similarly, Bhutta (2002: 117–18) argues that strengthening local capacity in bioethics is key to promoting ethical health research in developing countries. Benatar (2002b: 1136–8) also stresses the need for research to be effectively monitored once it has been approved. He and Christopher Vaughan (2008: 439) cite lack of resources and expertise as the two main barriers to effective ethical oversight in Africa. Several studies conducted over the last decade on African RECs and national bioethics committees bear this out (Kirigia *et al.* 2005; Kass *et al.* 2007: 28; Nyika *et al.* 2009: 189; Rwabihama *et al.* 2010: 248; Ijsselmuiden *et al.* 2012: 1).

Capacity within RECs is not the only issue. Joses Kirigia *et al.* (2005), Sylvester Chima (2006: 849), Nancy Kass *et al.* (2007: 29) and Jean-Paul Rwabihama *et al.* (2010: 248) all found that committees need national as well as international level guidelines and policies to steer them, which do not always exist in developing countries. In the context of genomics research, Dave Chokshi and Dominic Kwiatkowski (2005: 12) link the need for local capacity with the need to contextualize universal principles: 'Improving local capacity in bioethics in developing countries is essential to ensure that the philosophical principles of genomics ethics are informed by a practical understanding of what will work at the local level.' With regard to developing capacity for research itself, as well as its review, Bhutta (2002: 114) suggests that developing countries should be enabled to carry out research relevant to their needs. Petros Isaakidis *et al.* (2002: 4) assert that local researchers should play a substantial role in defining what these needs are, rather than have research priorities dictated to them by the global North. Kirigia and Wambebe (2006), in a review of health research policy in 10 African countries, recommended that governments should develop strategic plans for health research, in collaboration with stakeholders from the public and private sectors.

Medical research is largely market driven, to the detriment of those in poor parts of the world where infectious diseases are rife. Debates in research ethics thus spill over from micro level regulatory concerns to the broader issue of how

inequalities of health between North and South should be addressed. Bhutta (2002: 118) deems these 'vital components of the same equation', as does Benatar (2001: 337): 'Medical research, health care, conditions of life around the world and how humans flourish may seem separate, but they are all interdependent. Taking such a comprehensive global perspective adds complexity to the task of crafting universal research ethics guidelines.' In 2000, in what was considered a radical article in the *British Medical Journal* (*BMJ*), Benatar and Singer advocated 'a new, proactive research ethics', aimed at addressing the global health inequities they see as being the greatest ethical challenge (Benatar and Singer 2000: 826). Writing in *The Lancet* a few years later, Harold Varmus (2002: s4), former director of the National Institutes of Health (NIH) in the United States (US), expressed a similar view.

Like many commentators, Benatar and Singer (2000: 824) referred to the '10/90 gap': in 1990, approximately 90 per cent of annual health research funding was concentrated on only 10 per cent of the global disease burden. Similarly, a well-known study by Médecins Sans Frontières and the Drugs for Neglected Diseases Initiative showed that of the 1,556 drugs marketed between 1975 and 2004, only 21 are for diseases mainly affecting the global South (Chirac and Torreele 2006: 1560). The figures have changed significantly for the better in the last 20 years, through the efforts of, *inter alia*, the World Health Organization (WHO), The Wellcome Trust, NIH, the European Union and the Bill and Melinda Gates Foundation, but the 'gap'remains symbolic (Benatar and Singer 2010: 194; Global Forum for Health Research 2011; Ijsselmuiden 2012: 74). In a follow-up to their *BMJ* paper, Benatar and Singer (2010: 195) acknowledged the improvements, but maintained that 'the global medical research agenda remains skewed away from the needs of poor people'.

While those in developing countries have, until recently, seen relatively little benefit from medical research, they may well have participated in it. Factors including open access to patients, lower costs and fewer regulations conspired to produce what Benatar has termed a 'research sweat shop' (Benatar 2001: 337; Emanuel *et al.* 2004: 930). Some people in countries with poor healthcare provision may have become research participants in order to receive treatment to which they would not normally have had access (Nuffield Council on Bioethics 2002: 4). Giovanni Berlinguer (2004: 1087) has thus warned against medical research becoming a new form of exploitation. But if research in developing countries was to stop, for fear of abusing vulnerable populations, even fewer resources would be devoted to addressing their health concerns than is currently the case (Macklin 2003: 478; Clarke and Egan 2008: 44). The challenge is to develop means by which ethical research in developing countries can continue and grow.

Benatar and Singer (2000: 826), in their *BMJ* article, suggested as criteria that any proposed research should be relevant to the host country and likely to be of long-term benefit. In the 2010 follow-up they called for intensified efforts to ensure that research promotes social justice, through improved research capacity and healthcare in poor countries (Benatar and Singer 2010: 194–6). 'Benefit

sharing' agreements, by which funders and researchers commit to sharing any gains from scientific or technological research with participants or the wider community, whether directly in terms of profit or product or indirectly through capacity building and healthcare provision, may be one way to achieve this (UNESCO 2005s: article 5). Berlinguer (2004: 1088) summarizes the need for such measures as follows: 'Benefit-sharing and equal access to advances in biomedical science are now urgent and *universal* issues' [italics added].

Genetics and genomics

The term 'genomics' derives from the word 'genome'. A genome is the sum total of all the DNA (deoxyribonucleic acid) in any given individual or organism. DNA is made partly from four chemicals or bases, adenine, guanine, cytosine and thymine (abbreviated to A, G, C and T), which are sequenced in pairs along a genome. The human genome, for example, contains around 3 billion base pairs (Metcalfe *et al.* 2001: 71; US Department of Energy Office of Science 2011). Humans have approximately 99.9 per cent of their genome in common with each other, with differences in the remaining 0.1 per cent being responsible for genetic variation between individuals (Schmidt 2001: A26).

Genes are particular sequences of DNA within the genome that determine certain characteristics of an organism, such as eye colour and contribute to others, such as health and behaviour (Metcalfe *et al.* 2001: 8). There are just over 20,000 genes within the human genome, accounting for less than 2 per cent of the genome's DNA (Richards and Hawley 2011: 421 and 427). Some of the residual DNA supports genes by, for example, activating them at the correct time (Metcalfe *et al.* 2001: 105–6). Geneticists have now discovered 'some sort of function' for around 80 per cent of the genome, but there is much still to learn (Maher 2012: 46).

Geneticists can determine the order in which base pairs appear in a genome through a process called DNA sequencing. The end result is a 'map' of where each gene is positioned, as well as the supporting and non-functioning DNA. The most famous example of DNA sequencing is the Human Genome Project, which published drafts and a completed version of the human genome sequence in 2000, 2003 and 2006 respectively (US Department of Energy Office of Science 2006).

Some are keen to draw a clear distinction between genomics and genetics, as follows:

> Genomics is the comprehensive examination of an organism's entire set of genes and their interactions (as distinct from genetics, which is the study of a single gene or a small number of genes to determine specific gene roles in diseases or physical characteristics of an individual).
>
> (Smith *et al.* 2004: 385)

Since, however, a genome contains genes (as well as the other types of DNA) the terms are often used somewhat interchangeably. In 2004, for example, the World Health Assembly, the decision-making body of the WHO, adopted by resolution

WHA57.13 the following definition: 'genomics is the study of genes and their functions, and related techniques' (WHO 2004: 21). Similarly, the Human Genome Organisation describes itself as 'the international organization of scientists involved in human genetics' (HUGO 2012). For the sake of simplicity, this book henceforth uses 'genetics' as a collective term for both genetics and genomics.

Genetics in developing countries

Genetics has the potential to transform health and healthcare, in both developed and developing countries. As knowledge of both the nature and functions of the human genome increases, genetic influences on human disease patterns will be identified (Giallourakis *et al.* 2005: 399). While the principal cause of many diseases may be environmental, a growing pool of molecular data has led to the belief that there is a genetic component to almost all human diseases. A decade ago Kwiatkowski (2002: 1) predicted,

> For example, genetic variation may partly explain why one child develops fatal cerebral malaria, or kwashiorkor, while other children living in the same compound are equally exposed to malaria parasites and to poor diet but do not develop these severe clinical syndromes. A huge amount of scientific effort is now being put into investigating the many different genetic factors that influence susceptibility to common diseases, in the hope that this will provide fundamental insights into molecular pathogenesis and ultimately lead to better methods of disease prevention.

Infectious diseases such as malaria, HIV/AIDS and tuberculosis may involve several hundred genes, interacting both with each other and environmental risk factors. Genome-wide research enables the study of these complex diseases, affording valuable information concerning the molecular and cellular basis of disease in the search for effective vaccines and treatments (ibid; Kwiatkowski 2000: 1062).

Benatar (2002a) questions whether biotechnology will really help the poor, if drugs that have already been developed have not been made available to the very many people in the global South that need them. With Gopal Sreenivasan, he advocates a more holistic approach, predicting that scientific advances in biotechnology will have little impact if broad disparities in wealth and health are not addressed with equal enthusiasm (Sreenivasan and Benatar 2006: 3). This was also the finding of a 2002 WHO report entitled *Genomics and World Health*. The report, which received considerable attention worldwide,[1] stated that 'the science of genomics holds tremendous potential for improving health globally', but stressed the importance of 'fundamental overarching strategies to improve health', such as poverty alleviation, health systems development and education, alongside genetic science (WHO 2002: 3). Thus the value of any investment in genetics must be assessed relative to current approaches to healthcare and medical

research, such that these more conventional mechanisms are not neglected (WHO 2003: 1–2).

The report also cautioned that it would take time for the possible health benefits of genetic research to come to fruition and that, because these are likely to be expensive, they have the potential to increase disparities in health. This was all the more concerning because most developing countries did not have 'either the technological capacity or skill base to reap the potential benefits of genomics research and apply them to their health care needs'. Hence the report recommended that developing countries should develop clinical genetic services, which would be the simplest means of building the necessary capacity, as they use well-established DNA technologies. These services would also enable early intervention to control hereditary diseases such as sickle-cell anaemia, which is particularly prevalent in sub-Saharan Africa (WHO 2002: foreword, 6, 83, 187 and 189). A 2010 WHO consultation on community genetics in low and middle income countries found that provision is still inadequate (WHO 2010: iv).

Like the WHO report, bioethicists Abdallah Daar and Singer have warned that biotechnology could widen the gap between rich and poor. In a 2001 article in *Science*, they campaigned for an increase in investment, infrastructure and expertise to enable developing countries to capitalize on the promise of biotechnology and thus prevent a 'genomics divide' (Singer and Daar 2001: 87). Although the number of studies on non-Western populations (particularly African ones) is still comparably low, the last decade has seen an increased interest in genomics in developing countries (Hardy *et al.* 2008b: S23; Séguin *et al.* 2008: 487; de Vries and Pepper 2012: 474). The African Ministerial Council on Science and Technology (AMCOST), established in November 2003 to coordinate and implement the science and technology programmes of NEPAD (the New Partnership for Africa's Development) and the African Union, under *Africa's Science and Technology Consolidated Plan of Action*, sees great potential in genetics (and the life sciences in general) to fight diseases such as malaria and contribute to poverty reduction and economic growth (NEPAD 2005).

AMCOST has also identified factors that could constrain the development potential of genetics and biotechnology, including insufficient scientific and technical capacity, infrastructure and funding. To address these, NEPAD established the African Biosciences Initiative in 2005, consisting of four regional networks of centres of excellence (NEPAD 2005; NEPAD Office of Science and Technology 2005: 7–9 and 2006: 5–6). In August 2007, a High-Level African Panel on Modern Biotechnology (set up, like AMCOST, under the auspices of the African Union and NEPAD) suggested that each African region should specialize in a particular area of biotechnology through 'long-term "biotechnology missions"', reflecting existing expertise. Southern Africa could thus focus on health biotechnology and East Africa on livestock (Juma and Serageldin 2007: iii and xvii).

The most prominent programme on human genetics in Africa is the Human Heredity and Health in Africa Initiative (H3Africa), sponsored by The Wellcome Trust and NIH (de Vries and Pepper 2012: 475). This grew out of a proposal for an African Genome Project at the 2007 meeting of the African Society of Human

Genetics (Newport and Rotimi 2009: 251). The initiative has a budget of USD 70 million for 2012–19 and aims to 'catalyse' genomics research in Africa, through investment in infrastructure, training, research projects and clinical services, in existing institutions and new centres of excellence. Collaborative networking will also be key. The ultimate goal is to improve health, by increasing understanding of the genetic and social determinants of communicable and non-communicable diseases common in Africa (H3Africa 2011; H3Africa Working Group 2011: 1–2).

Why genetics needs governance

Human genetic research, like biomedical research in general, stretches beyond national borders: 'An orders-of-magnitude increase in scale of genetic data collection has created the need for establishing diffuse international partnerships, sometimes across developed- and developing-world countries, with ramifications for assigning research ownership, distributing intellectual property rights, and encouraging capacity-building' (Chokshi and Kwiatkowski 2005: 1). While genetics holds great promise, then, it also carries new ethical dilemmas, concerning both individuals and communities, which require international governance. Governance at national level may also be an issue. The WHO report *Genomics and World Health* found that many developing countries did not have regulatory, ethical or policy frameworks in place to deal with genetics (WHO 2002: 187–8).

One general concern in genetics is to balance freedom of research with individual rights. Anne-Marie Duguet (2001: 203) expresses this concern thus:

> An acknowledged principle in our democratic societies, freedom in research, is viewed as inherent to freedom of thinking and it is therefore accepted that its finalities be unrestricted. However, genetic research explores a very sensible domain. Indeed, what is under investigation is a person's intimate inheritance, origins, future and progeny.

Fears of discrimination on the basis of the information their genome contains may render some people reluctant to participate in genetic research. Thus confidentiality must be protected (Reilly 2000: 489; Anderlik and Rothstein 2001: 404–5). A complicating factor is that, while each person's genome is unique, it also carries information about their families (and possibly communities) (Knoppers 2002: 86). This has consequences for how far someone's right to autonomy should allow them to control personal genetic information (Laurie 2001: 1).

Other issues requiring guidance include the transfer of samples and data across national borders and the ensuing implications for ownership, particularly given the increase in international research projects. This affects developing countries disproportionately, as they have less capacity for in-house analysis. Standardization of procedures would enable both better protection of individual rights and further transnational research cooperation (Godard *et al.* 2003: S104). One trailblazer is the MalariaGEN project, a network of malaria researchers

across 21 countries. The project has set up rigorous materials transfers agreements between partners, as well as training for young researchers from all sites and the development of software enabling data analysis from anywhere in the world, without the need for expensive infrastructure (Parker *et al.* 2009: e1000143; de Vries *et al.* 2011).

Chokshi and Kwiatkowski (2005: 1) capture a major dilemma in genetic research with the question, 'What is the structure of an equitable and fair system for distributing the financial and scientific rewards of research?' Some scientists are concerned that the patenting of gene sequences, including human ones, could be detrimental to both scientific advancement and healthcare provision (Andrews 2002: 803). Researchers may be reluctant to share findings for fear of precluding possible patents, while the cost of licence fees for gene-based products could render some treatments unaffordable. Others argue that, without the legal protection of intellectual property, there will be little incentive for companies to invest in research (Schmidt 2001: A29). The human genome itself is in the public domain, but data on the products derived from the information therein may not be. Richard Dahl (2001: A32) writes, 'the mapping of the human genome opens huge potential markets for pharmaceutical and biotechnologic product developments, which take time and money. The question is, how much patent protection should those efforts enjoy?'

Some are concerned with the idea of gene sequencing at a more fundamental level. Eike-Henner Kluge argues that the patenting of human genes is 'ethically indefensible and amounts to an unjustified appropriation of a general human heritage' (Kluge 2003: 119). The characterization of the human genome as the 'common heritage of humanity' (HUGO Ethics Committee: 2002) promotes the idea of benefit sharing (Knoppers and Chadwick 2005: 77). Who exactly deserves to benefit is complicated, however, given that several parties will have contributed to the process of deriving a gene-based health product, from those who have given genetic samples, through to those who take it to market. Chokshi and Kwiatkowski (2005: 10–11) give the following example:

> It is . . . unclear who deserves to gain financially from, for instance, the discovery of a novel anti-malarial molecule from studies of national genetic diversity. Any of at least five groups can make a claim: the subjects themselves, the health professionals who diagnosed and treated them, the epidemiologists who managed the study, the geneticists who produced the result, and the company that makes the end product. As Chadwick and Berg have pointed out, while our moral intuitions may sympathize most with the subjects' claim, it is the scientists who have actually made the subjects' samples 'valuable'.

They thus advocate a broad approach to benefit sharing in genetics:

> If we assert first that the reference human genome sequence belongs to mankind and second that, given the positive-externality effects of vaccines and therapies for infectious diseases, research is of potential benefit to all, it

> follows that the aims of benefit-sharing should shift from purely local interests to broader interests.
>
> (Chokshi and Kwiatkowski 2005: 11)

Between 2001 and 2006, Daar and Singer, with colleagues at the Toronto Joint Centre for Bioethics, promoted the idea of a global governance mechanism to ensure the benefits of genomics are enjoyed equitably. This was to sit outside the traditional intergovernmental structures of the UN, which were seen to be too slow-moving to keep pace with genomic innovation. The proposals went through various iterations, from a commission on genomics and global health, to a network-based Global Genomics Initiative. The idea was to bring together stakeholders from various sectors – industry, academia, governments and civil society – to promote global dialogue, collaboration and norm-setting (Singer and Daar 2001; Acharya *et al.* 2004a and 2004b; Dowdeswell *et al.* 2003, 2005 and 2006). Although the initiative never formally took off, Daar, Singer and colleagues (now at the Sandra Rotman Centre for innovation in global health at Toronto) continue to publish widely on ways to promote science and technology, including genomics, for development. Ruha Benjamin (2009: 346) credits the Centre with establishing the field of public health genomics, stating, 'Through tremendous visibility and strategic collaboration, this relatively small group of health policy entrepreneurs is playing a principal role in the growing political will among governments to sponsor genomic initiatives and implement genomic sovereignty legislation' (that is, legislation to protect the DNA of their populations).

The UNESCO Bioethics Programme

UNESCO (the United Nations Educational, Scientific and Cultural Organization) is a long-standing agency of the United Nations, comprising 195 member states. It was founded in 1945, aiming to 'build peace in the minds of men' through education, science, culture and communication. Its remit has now expanded to include poverty eradication, sustainable development and intercultural dialogue, in line with the Millennium Development Goals. It has a mandate to advise member states on developing national capacities (UNESCO 2007f; UNESCO 2011e). UNESCO 'functions as a laboratory of ideas and a standard-setter to forge universal agreements on emerging ethical issues' (UNESCO 2011q). The ethics of science and technology is a priority within Social and Human Sciences, one of UNESCO's five specialized sectors. UNESCO aims to consolidate the universal values of justice, freedom and dignity, while acknowledging pluralism: 'scientific and technological progress must be placed in a context of ethical reflection rooted in the cultural, legal, philosophical and religious heritage of all our communities' (UNESCO 2012j).

The UNESCO Bioethics Programme,[2] part of the Division of Ethics and Global Change, began in 1993 with the formation of the International Bioethics Committee (IBC). Then Director-General of UNESCO, Federico Mayor, decided

that the organization should set up this committee so that it could 'reply to the main ethical preoccupations raised by advances in the life sciences' (UNESCO 1994). An Intergovernmental Bioethics Committee (IGBC) followed in 1999. Each committee has 36 members, the former made up of independent experts and the latter of representatives from selected member states (UNESCO 2012b). UNESCO also provides the secretariat for the UN Inter-Agency Committee on Bioethics, established in 2001 (UNESCO 2011a). Beyond UNESCO Headquarters in Paris, many of UNESCO's activities are administered through National Commissions in each member state (UNESCO 2004m: 6).

One of UNESCO's key activities is the setting of international standards, on which member states can subsequently draw to establish regulatory or legal frameworks at national level. Koïchiro Matsuura, Director-General of UNESCO from 1999 to 2009, expressed the need for standards within science and technology in terms of transnational practices and benefit sharing:

> Present-day scientific practices cross national borders. Hence the imperative need to take action together at the international level – not to erect barriers against these practices, but to provide the necessary oversight so that the benefits of science may be enjoyed by all humanity. . . .
>
> (UNESCO 2004n: 10)

UNESCO sees itself as particularly well-suited to standard setting in bioethics, as the only UN organization with competencies in both human and social sciences (ten Have 2005: 745; UNESCO 2012k). Publications, speech transcripts and the UNESCO website all emphasize its unique or leading role in this field. As science and technology advance, its 'ethical watch mandate' becomes more and more pertinent (UNESCO 2012b).

The UNESCO declarations

In recent years UNESCO has produced a series of declarations on bioethics and genetics: the 1997 *Universal Declaration on the Human Genome and Human Rights* (UDHGHR), the 2003 *International Declaration on Human Genetic Data* (IDHGD) and the 2005 *Universal Declaration on Bioethics and Human Rights* (UDBHR). These declarations have stemmed from the tremendous increase in the profile of genetics and the extension of biomedical research beyond national borders. The three declarations are to be 'treated integrally'; indeed, there is much common ground between them (UNESCO 2005a: 3). As a set, they prescribe how human genetic and biomedical research can be conducted ethically and encourage capacity building and knowledge sharing in science and ethics, particularly between North and South.

The IBC's first task was to prepare an international instrument on the human genome (the eventual UDHGHR). It appointed a Legal Commission to propose what form and substance the instrument should take, which met regularly between April 1994 and December 1996. An international consultation was launched in

May 1995. After receiving a progress report in November 1995, the twenty-eighth UNESCO General Conference requested that a draft declaration be developed, to be finalized by a committee of government experts appointed by member states (as per established protocol within the UN). The resultant draft was adopted 'unanimously and by acclamation' at the twenty-ninth General Conference, in November 1997. A year later the UDHGHR was endorsed by the UN General Assembly (UNESCO 1999a: IV, 1–2 and 67).

The UDHGHR was adopted in order to facilitate a balance between progress in genetics and protection of human rights. The preamble states:

> The General Conference, . . . recognizing that research on the human genome and the resulting applications open up vast prospects for progress in improving the health of individuals and of humankind as a whole, but emphasizing that such research should fully respect human dignity, freedom and human rights, as well as the prohibition of all forms of discrimination based on genetic characteristics, proclaims the principles that follow and adopts the present Declaration.
>
> (UNESCO 1997)

Although the declaration covers human genetic data in a general sense, it was felt that their collection, processing, storage and use needed to be addressed more specifically and as a matter of urgency. Growth in the number of human genetic databases and international research programmes, increasing private sector involvement and the need to protect vulnerable populations were all contributing factors to this decision. The IBC had already produced two reports on this subject when the Director-General requested in May 2001 that it look into drafting an international instrument thereupon. The thirty-first General Conference endorsed the initiative the following November and the IBC duly set up a drafting group. After widespread written and verbal consultations and further scrutiny by various UNESCO bodies – the IBC, the Executive Board (elected by the biennial General Conference and constituting 58 member states), an intergovernmental meeting of experts and a working group – the draft IDHGD was adopted 'unanimously and by acclamation' on 16 October 2003, at the thirty-second General Conference, as 'an extension of and means of implementing' the UDHGHR (UNESCO 2000a; UNESCO 2002a; UNESCO 2003c: 1 and 3; UNESCO 2012i).

In 2001 the General Conference had invited the Director-General to look into the possibility of elaborating a universal instrument on bioethics. On the basis of the IBC's subsequent report, the 2003 General Conference declared the setting of universal standards in bioethics to be 'imperative and desirable' (Berlinguer 2004: 1088). The drafting process for the UDBHR was launched in January 2004. As with the previous two declarations, a drafting group was appointed and an extensive consultation process initiated, involving UNESCO, member states and other stakeholders. It was decided that universal guidelines on 'all issues' in bioethics were needed (UNESCO 2003h: 2; UNESCO 2004o; UNESCO 2005q).

The UNESCO website (2012e) has for several years defined bioethics as follows:

> Stem cell research, genetic testing, cloning: progress in the life sciences is giving human beings new power to improve our health and control the development processes of all living species. Concerns about the social, cultural, legal and ethical implications of such progress have led to one of the most significant debates of the past century. A new word has been coined to encompass these concerns: bioethics.

The final text of the UDBHR contains no reference to issues such as stem cells, however, because they proved too controversial to enable consensus. Thus the original aim proved over-ambitious. Illustrating a complete reversal, a 2005 report described the IBC's final draft text as 'far from attempting to resolve all the existing bioethics issues' (UNESCO 2005h: 7). Henk ten Have, Head of UNESCO's Division of the Ethics of Science and Technology (the predecessor to the Division of Ethics and Global Change) from 2003 to 2010, explained, 'Research into stem cells and cloning does not for now affect the lives of most people. They remain a hope for the future, but right now, people are dying because of poor health conditions. We must concentrate on this problem' (Tousni 2006). Rather than trying to address the large and ever-growing number of specific bioethics issues, he wrote in 2006, the declaration provides a 'basis' or 'frame of reference' for states developing legislation or policies on bioethics (ten Have 2006: 341). The declaration was adopted 'by acclamation' by the General Conference, on 19 October 2005 at its thirty-third session (UNESCO 2005r).

All three UNESCO declarations aim to promote human dignity, human rights and fundamental freedoms in the context of bioethics and genetics, while at the same time embracing principles of responsibility, solidarity, equality and justice, as affirmed in the preamble of each. They cover both medical and research ethics; article 5 of the UDHGHR refers to 'research, treatment or diagnosis affecting an individual's genome', for example (UNESCO 1997). Each contains articles on informed consent, risks and benefits, confidentiality, freedom of research, ethics committees and bioethics education and training. The IDHGD (2003) and the UDBHR (2005) also cover transnational practices and the monitoring and management of research. As well as these general provisions, the two genetics declarations include principles specific to their context; both, for example, condemn discrimination on the basis of genetic characteristics and genetic reductionism. The UDHGHR (articles 1 and 4) also disallows reproductive cloning and states that the human genome, the 'heritage of humanity', in its natural state should not enable financial gain (UNESCO 1997).

The declarations also contain several principles that are particularly pertinent to developing countries. The UDHGHR (1997, article 17) promotes research on genetically influenced endemic diseases, while the UDBHR (2005, articles 6(3), 8 and 12) endorses community engagement, the protection of individuals and groups of special vulnerability and due regard for cultural diversity and pluralism.

All three display a strong commitment to benefit sharing, knowledge exchange and capacity building. Article 18 of the UDHGHR, for example, reads:

> States should make every effort . . . to continue fostering the international dissemination of scientific knowledge concerning the human genome, human diversity and genetic research and, in that regard, to foster scientific and cultural co-operation, particularly between industrialized and developing countries.
>
> (UNESCO 1997)

Article 18 of the IDHGD (2003) is very similar, the only difference being that it reads 'human genetic data and human proteomic data' rather than 'human genome, human diversity and genetic research' (UNESCO 2003b).

The UDBHR (2005) is different again, as follows (article 24 (2)):

> Within the framework of international cooperation, States should promote cultural and scientific cooperation and enter into bilateral and multilateral agreements enabling developing countries to build up their capacity to participate in generating and sharing scientific knowledge, the related know-how and the benefits thereof.
>
> (UNESCO 2005s)

The UDBHR also directly addresses inequalities of health. Article 14, on social responsibility, pertains to social and economic rights as bioethical issues. Citing the promotion of health and social development as 'a central purpose of government', it states that progress in science and technology should advance access to healthcare, nutrition, water and improved environmental and living conditions and reductions in marginalization, illiteracy and poverty (ibid). These were considered important elements of the proposed declaration from an early stage. The IBC's 2003 report on the possibility of a new bioethics instrument notes, 'Our global society must face the responsibility to use science and technology to promote public health and to equalize access to healthcare and medicines' (UNESCO 2003h: 4). (Berlinguer was rapporteur to the working group that compiled the report.)

Relation to other bioethics instruments

UNESCO's status as an intergovernmental UN agency is a key factor in its justification for its bioethics activities. Noëlle Lenoir, Chair of the IBC from 1993 to 1998, claims that UNESCO played a 'major role in laying the foundations of international bioethics' through the UDHGHR (1997), in a paper titled 'The first legal and ethical framework at the global level' (Lenoir 1998–9: 546). The UNESCO website describes the UDHGHR as having been 'the only international instrument in the field of bioethics' at the time of its endorsement by the UN General Assembly in 1998 (UNESCO 2012b). Similarly, Koïchiro Matsuura, then

Director-General, declared in June 2005 that the UDBHR would 'close a wide gap at the international level' (UNESCO 2005m: Annex II, 1–2) and ten Have (2006: 342) has described the governmental commitment enshrined in the bioethics declaration as its 'innovative dimension'. All this implies that ethics guidelines produced by professional organizations, such as the World Medical Association (WMA) and the Council for International Organizations of Medical Sciences (CIOMS), are not truly 'inter-national', because they have not been agreed by nation-states (although CIOMS is in official relations with the WHO). Yet, where the WMA's *Declaration of Helsinki* is formally directed at physicians or researchers, the CIOMS guidelines, like the UNESCO declarations, are intended to be used in the designing of national policy on biomedical research ethics, particularly in developing countries.

Unusually, the UDBHR (2005) notes these non-UN documents in its preamble. The declaration is also considered unique in scope, as it is not confined to medical or research ethics (UNESCO 2005h: 6). Justice Kirby, who chaired the UDBHR drafting committee, purports, 'It lifts the eyes of bioethicists from the patient's bedside and the hospital ward to a new insistence on the relevance to the bioethics discipline for society, the community, humanity, all living beings and the biosphere' (Kirby 2010: 794). ten Have (2006: 341) goes even further:

> The Declaration on Bioethics thus opens perspectives for action that reach further than just medical ethics and reiterates the need to place bioethics within the context of reflection open to the political and social world. Today, bioethics goes far beyond the code of ethics of the various professional practices concerned. It implicates reflection on the evolution of society, indeed world stability, induced by scientific and technological developments. The Declaration on Bioethics paves the way for a new agenda of bioethics at the international level.

UNESCO and human cloning

After three declarations within a decade, at the end of 2005 UNESCO decided to take a 'normative pause' and instead concentrate on supporting the implementation of the existing declarations at regional and national levels (UNESCO 2005a: 4). It was not long, however, before it started to think about a fourth instrument. Despite ten Have's words about the limited relevance of stem cell research and cloning to the majority of the world's population, in 2008 the IBC set up a working group to examine whether there was any call for an international convention on human cloning.

What is cloning?

Human cloning inspires strong views, but also confusion about what exactly the term means and why the practice appears to be universally condemned. There are two types of cloning: 'reproductive' cloning and 'therapeutic' or 'research'

cloning. None of these terms are strictly accurate scientifically, but are widely used. They derive from when the only means of cloning were embryo splitting and somatic cell nuclear transfer (SCNT). SCNT is the process by which a single nucleus from a somatic (body) cell is transferred into an enucleated egg. The resulting embryo can be used for either reproductive or research purposes. Reproductive cloning sees the embryo being implanted into a female for gestation. Dolly the Sheep was the first mammal to be cloned by this method in July 1996. Therapeutic cloning sees the embryo being harvested rather than gestated, to glean stem cells (embryonic stem cells or ESCs). These cells are pluripotent, meaning they have the capacity to develop into various types of specialized cells. They occur naturally only in the early stages of embryonic development. Stem cells harvested from a cloned embryo are likely to be particularly useful in therapeutic terms, because they will be compatible with the originator's immune system (Wilmut *et al.* 1998: 21; Bowring 2004: 402–3; Isasi *et al.* 2004: 628; UNU-IAS 2007: 6).

Therapeutic cloning is seen to have great potential as a means of replacing damaged tissue and organs, but it remains controversial on several fronts. Some oppose the utilitarian creation of embryos purely for research, while others are concerned about the risks to egg donors. The strongest objection is to the destruction of embryos entailed in harvesting, on the grounds that they are morally equivalent to human persons. For those who believe human life begins at conception, even therapeutic cloning is reproductive (Isasi *et al.* 2004: 628; Lo *et al.* 2010: 17). In 2006 a new method was developed that avoids destroying embryos, by re-engineering somatic cells to become pluripotent (induced pluripotent stem cells or iPSCs). This may circumvent the moral objections to therapeutic cloning by SCNT, but it opens up new possibilities for human reproductive cloning, through tetraploid complementation (a method used to clone mice) and artificial gamete production (Meyer 2008: 851; Lo *et al.* 2010: 16; UNESCO 2010g: 2).

Arguments for and against human reproductive cloning

Since the cloning of Dolly the Sheep made human reproductive cloning seem feasible within the near future, a plethora of authors – mainly bioethicists and lawyers rather than scientists – have argued for and against the development of this technology. Those in favour take a liberal position, in the name of reproductive freedom. They also see cloning as a promising means to combat infertility. Those against are concerned for the psychological health of the clone and society more broadly. Where there is near universal consensus is on the safety issue (Galton and Doyal 1998: 279; J. Robertson 1998: 1372 and 1410; de Melo-Martín 2002: 248; Cheshire *et al.* 2003: 1010; Gogarty 2003: 84; Harris-Short 2004: 333; Tauer 2004: 209). Most scientists and philosophers agree that, as technology stands, it would be unethical to attempt human reproductive cloning. Fears for the physical health of both the clone and the mother are grounded in the poor record in animal cloning. Dolly was the only one of 277 attempts to survive to birth. Success rates in mammals remain very low and genetic abnormalities are common (Elsner 2006: 597). Even if these issues could be resolved, say some, there would

still be moral objections to cloning (Cheshire *et al.* 2003: 1010; Polkinghorne 2004: 593).

Fears for the psychological health of a human clone are rooted in two related concepts. First, having a unique identity is seen as an inherently human quality, which a clone would be unable to enjoy. Second, they would be denied their right to ignorance (as articulated by Hans Jonas), or to an open future (Joel Feinberg), if they knew about the life of the person from whom they were cloned, or were expected by their 'parents' to conform to a particular life pattern (J. Robertson 1998: 1411 and 1415–16; Burley and Harris 1999: 110; de Melo-Martín 2002: 249–50; Gogarty 2003: 85; Harris-Short 2004: 344; Tauer 2004: 209; Tannert 2006: 239; Mameli 2007: 87; Morales 2009: 43). These fears are seen by several scholars as speculative, with no basis in science. Nestor Morales (2009: 48) has reviewed analogous psychological studies (of twins, for example) and concluded that there is no evidence that individuals produced through reproductive cloning 'could display the characteristics of their donors to the extent of compromising uniqueness'. To believe otherwise, say the critics, is to engage in a crude genetic determinism that does not take sufficient account of environmental factors.

A clone would not be an exact copy of their 'original' in all respects, but would simply have the same genetic code, as do 'identical' twins, who are considered to have unique personalities nevertheless. Since environment plays an important part in development, 'time-separated twins' would be less similar than monozygotic twins, whose psychological well-being is not of major concern (Harris 1997: 353–4; Brock 1998: 152; J. Robertson 1998: 1415; de Melo-Martín 2002: 249–50; Pearson 2006: 658; Camporesi and Bortolotti 2008: e15; Morales 2009: 44–45; Ahlberg and Brighouse 2010: 541; Aloni 2011: 57). But the time delay is the significant factor, say Evelyne Shuster (2003: 520) and David Jensen (2008: 620), not least because of the implications for notions of parenthood if one's mother or father is also one's genetic 'twin'. For Christof Tannert (2006: 239), by contrast, the important point is that the similarity between monozygotic twins has occurred by chance rather than deliberate decision.

Inmaculada de Melo-Martín (2002: 251), like Justine Burley and Harris (1999: 111), argues that policies should not be based on public misunderstandings about what cloning really entails. Finn Bowring (2004: 405) agrees that the problem lies in a false premise rather than the probable impact of cloning on identity *per se*, but believes this will lead to genetic determinism all the same:

> The effects of eugenic technologies like human cloning are mediated by a cultural attachment to genetic determinism which both underpins and is consolidated by those same technologies. The problem is not that the autonomy and uniqueness of individuals will be lost, and hence they will be undeserving of the respect and dignity normally accorded to human beings. It is, rather, that the respect, love and recognition ideally expressed by adults towards the child will be subverted by their expectation that they have ordered a predetermined product, and this expectation will in turn promote the misrecognition or repression of the child's attempts to assert its autonomy and uniqueness.

John Robertson (2000–01: 41) sees these concerns as based on a misreading of parental motivations, at least in the case of an infertile couple who simply desire a genetically similar child, rather than to dictate the every move of their offspring. Any danger of psychological harms could thus be minimized through information and counselling. Joyce Havstad (2010: 74 and 76) agrees with Bowring that misconceptions of reality or fact have real consequences, which cannot be ignored, but also suggests information and monitoring as a means to mitigate these. A further counter-argument to Bowring is that there have always been parents who try to influence their children in an overbearing or less than perfect way, without this warranting interference in parenting styles (Harris 1997: 358; Camporesi and Bortolotti 2008: e15; Ahlberg and Brighouse 2010: 542).

Concerns about identity and 'human-ness' also extend to the societal level. Some believe reproductive cloning would violate human dignity (GAEIB 1997: 351; Cheshire *et al.* 2003: 1011; Shuster 2003: 522–3; Harris-Short 2004: 352). A somewhat nebulous concept, human dignity encompasses ideas of intrinsic worth, self-determination and autonomy. Many equate it with Immanuel Kant's categorical imperative that people should always be treated as ends not means; that is, they should not be commercialized or instrumentalized (S. Robertson 1998: 282; Tannert 2006: 239). Shuster (2003: 524) has suggested that cloning could lead to a new form of slavery, in the form of 'genetic bondage'.

The very mechanics of cloning are also seen as a threat to humanity. Reproductive cloning would be different to other forms of assisted reproductive technologies because it would mimic asexual rather than sexual reproduction and thus be 'unnatural'. If part of being human is that one is the unique and unplanned result of the combination of two separate chromosomes, then reproductive cloning would mean nothing less than a redefinition of what it means to be human (J. Robertson 1998: 1410; S. Robertson 1998: 282; Cheshire *et al.* 2003: 1011; Häyry 2003: 456–7; Shuster 2003: 521; Aloni 2011: 56). This distinction between the natural and the unnatural has been criticized as arbitrary. As David McCarthy (1999: 99) points out, marriage between racial groups has been deemed unnatural by some jurisdictions in the past. John Polkinghorne (2004: 597) similarly reminds us that much of routine medicine is unnatural.

Another societal level threat that cloning is perceived to carry is reduced human genetic diversity (Gogarty 2003: 84; Aloni 2011: 5). Jaime Ahlberg and Harry Brighouse (2010: 541) refute this possibility, as it is predicated on the highly unlikely scenario of vast numbers of clones with the same genetic code being created. In the eyes of several bioethicists, the idea of an army of clones is unfeasible, futile and the stuff of science fiction. The reality will be far more mundane, with cloning being the last resort for such a small number of (honourably intentioned) people that the impact on genetic diversity will be negligible (Harris 1997: 356–7; Harris-Short 2004: 359; Elsner 2006: 596; Camporesi and Bortolotti 2008: e15). Furthermore, they argue, we cannot ban behaviours or techniques because they might be open to abuse. If we did this consistently, the implications for human society would be enormous (Harris 1997: 356; McCarthy 1999: 99; Camporesi and Bortolotti 2008: e15).

Reproductive freedom, or procreative autonomy, is one of the key arguments in favour of allowing human reproductive cloning. If safety issues can be resolved, this principle would allow people to use cloning technology as and when they wish – to replace a dead loved one, for example (Harris 1997: 358; J. Robertson 1998: 1381 and 1391; de Melo-Martín 2002: 253–4; Häyry 2003: 450; Harris-Short 2004: 333; Tauer 2004: 209; Aloni 2011: 68). Authors differ on how broadly the right to reproductive freedom should be interpreted. Dan Brock (1998: 143) and Havstad (2010: 73) frame it as a negative right to non-interference in one's reproductive choices, not a positive right to reproductive assistance. Sonia Harris-Short (2004: 334) finds a similar reading of states' obligations in international human rights law (the International Covenant on Civil and Political Rights and the Convention on the Elimination of All Forms of Discrimination against Women, for example). She thus concludes that there is no reproductive right to cloning: 'under international law, no one has an absolute right to procreate in any way they choose' (Harris-Short 2004: 359). In a US context, John Robertson (1998: 1441) argues for a constitutional right to fertility treatment, to include cloning if and when this becomes feasible. Cheshire *et al.* (2003: 1011), by contrast, also writing from a US perspective, contend that reproductive liberty is not an inalienable right, nor is it a purely private matter. In the case of cloning, they argue, individual autonomy does not outweigh the public interest.

Closely linked with the reproductive freedom argument is the hope that reproductive cloning could help infertile couples and others who are unable to conceive 'naturally' (lesbian or gay couples, for example), or who are carriers of conditions such as Huntington's disease, to have genetically related children (Harris 1997: 357; J. Robertson 1998: 1378 and 1445; de Melo-Martín 2002: 253; Häyry 2003: 449; Harris-Short 2004: 333; Tauer 2004: 209; Pearson 2006: 658; Havstad 2010: 72; Aloni 2011: 22). Neil Levy and Mianna Lotz (2005: 232) and Robert Sparrow (2006: 308) cite the potential to combat infertility as the strongest argument there is for reproductive cloning. If cloning is the only means by which an individual or couple could have a genetically related child, the argument that they should be able to use this technology to exercise their reproductive freedom is much stronger than a general appeal to autonomy and does not carry the usual concerns of parental narcissism or clonal armies taking over the world. Several authors support the use of cloning as an infertility treatment if scientific concerns about the safety of the procedure can be addressed (J. Robertson 2000–01: 35; Strong 2008: 130). Going ahead even with a higher than normal chance a child could be born with birth defects or abnormalities might not be unethical, unless the child's life would not be worth living (J. Robertson 2000–01: 40; Elsner 2006: 597 and 600; Lane 2006: 135). The 'life worth living' argument has also been applied against concerns about psychological harms to the clone (Burley and Harris 1999: 113; Havstad 2010: 74).

Some ethicists counter the argument for cloning as a fertility treatment on the grounds that, like the arguments about identity and uniqueness, it is based on a genetic fallacy (Sparrow 2006: 308). Levy and Lotz (2005: 232) believe that the importance attached to genetic relatedness is a societal construct. If environmental

factors are at least as important as genetic ones in determining a person's identity, as those in favour of cloning argue, how can cloning to enable parents to have genetically similar children be justified? J. Robertson (1998: 1373), who supports reproductive cloning (if safe), recognizes this tension:

> The desire to clone arises precisely because genes are viewed as highly important, if not crucial, in making people who they are. Assigning significance to genes, however, risks becoming a crude form of genetic essentialism or determinism. At the same time that one grants genes their due, one also must guard against expecting too much from them.

Implications for regulation and research

With very few exceptions, philosophers and scientists are agreed that human reproductive cloning should not currently be allowed: 'Unlike many other areas of reproductive technology and indeed biotechnology, the practice has been near unanimously condemned by the scientific, medical, ethical, and general communities' (Gogarty 2003: 84). As Roger Brownsword and Matti Häyry point out, however, this consensus is a 'happenstance convergence' (Brownsword 2004–5: 538), or a 'happy constellation' (Häyry 2003: 459) that masks the conflicting principles bubbling under the surface. There is a fundamental difference in outlook between those who oppose reproductive cloning on safety or pragmatic grounds and those who see it as inherently wrong. John Robertson falls into the first category. In an oft-cited paper of 1998, in which he systematically reviewed the arguments for and against cloning, he concluded that a complete ban on human reproductive cloning could not be justified. He wrote, 'When carefully analyzed, the alleged harms of cloning tend to be highly speculative, moralistic, or subjective judgments about the meaning of family and how reproduction should occur' (J. Robertson 1998: 1441). Yet the view that cloning should be allowed once safety concerns have been resolved is itself speculative, as it is premised on a hypothetical level of sufficient evidence that attempting human cloning would carry an ethically acceptable degree of risk (Galton and Doyal 1998: 279).

de Melo-Martín (2002: 246–7) claims that arguments both for and against reproductive cloning fail to stand up to scrutiny, because they ignore context. The reality, she says, is that we live in a world where overpopulation, poverty and ill-health are rife:

> When one reads analyses of this technology, one has the impression that we live in a society where our most serious and pressing problems are the pleas of infertile people, or the requests of those who want to replace their dead loved ones; a world where genetic disease is the main cause of preventable deaths, where individuality is threatened, where one of the worst things that can happen to children is that their parents have too many expectations because of their genetic make up, and where resources are all but limited.
>
> (de Melo-Martín 2002: 264)

Sparrow (2006: 318) similarly argues that moral arguments against cloning are not strong enough to trump reproductive autonomy, but asks whether pursuing cloning research would be an ethical use of scarce resources. Others baulk at the expense, given the lack of scientific or medical justification for the risks involved (GAEIB 1997: 351; Gogarty 2003: 85). McCarthy (1999: 98) contends that the 'it's expensive' argument usually masks moral objections, but for Rosalind McDougall (2008: 259), like Sparrow, the expense is in itself a moral issue. She claims that investing in reproductive cloning would be an affront not to the dignity of the clone, but to the dignity of all those who are deprived of their basic rights and liberties through ill-health. Myfanwy Williams (2009: 331) directly counters this claim, citing the fact that we cannot know what the fruits of research will be. The question of how to balance meeting basic needs with the possibilities technological advancement brings goes far beyond the cloning debate, to the very heart of the scientific endeavour.

How human cloning is currently regulated

Given the albeit strained consensus that human reproductive cloning would be unethical under current conditions, it might be expected that this would be reflected in international and national laws. This is only partially the case. Many countries, but by no means all, have enacted legislation to ban reproductive and/or therapeutic cloning. Often this legislation refers to SCNT rather than cloning more generally and thus does not cover the newer technologies (Lo *et al.* 2010: 16). At regional and international level, in the wake of Dolly, several measures were brought out. UNESCO's 1997 *Universal Declaration on the Human Genome and Human Rights* (UDHGHR) is unequivocal: 'Practices which are contrary to human dignity, such as reproductive cloning of human beings, shall not be permitted' (UNESCO 1997: article 11). The WHO passed resolutions in 1997 and 1998 stating that human reproductive cloning is contrary to human dignity and urging member states to prohibit it (WHO 1998: 1). The Council of Europe's *Additional Protocol to the Convention on Human Rights and Biomedicine, on the Prohibition of Cloning Human Beings*, adopted in 1998, similarly prohibits reproductive cloning in all circumstances (articles 1 and 2), as does the European Union's 2000 (amended 2007) *Charter of Fundamental Human Rights* (article 3). None of these constitute an absolute ban, however: the UDHGHR, as a declaration, is by definition non-binding, the Council of Europe's Protocol has been ratified by only 21 of its 47 member states (Council of Europe 2012) and the European Union (EU) Charter applies to its members only when enacting EU law (Europa 2010). This hole in the international canon prompted the UN General Assembly to look towards a binding convention in 2001. The end result was the *United Nations Declaration on Human Cloning* of 2005.

The circumstances surrounding the adoption of the *UN Declaration on Human Cloning* have been thoroughly documented by several authors (Isasi and Annas 2003 and 2006; Arsanjani 2006; Cameron and Henderson 2008). In 2001, in response to claims by some scientists that they would soon attempt human

reproductive cloning, France and Germany proposed a convention to ban the reproductive cloning of human beings to the UN General Assembly. They decided on the UN rather than UNESCO, which had already proscribed the practice in its 1997 UDHGHR, because of its wider membership (crucially, the US was not at the time a member of UNESCO) and its status as the premier global legislative forum. Moreover, as cloning is cross-cutting, touching on science, ethics, health and human rights, they felt it could not be dealt with fully by any one of the UN's specialized agencies (Isasi and Annas 2003: 405; Arsanjani 2006: 164–5; UNU-IAS 2007: 16; Cameron and Henderson 2008: 153). It was expected that drafting and adopting a convention would be a relatively straightforward endeavour, as there was consensus among member states that human reproductive cloning was undesirable (Arsanjani 2006: 166; Cameron and Henderson 2008: 157). What followed was four years of dispute and discord, as rival factions fought their corners. The divergence was not over reproductive cloning, but therapeutic cloning (or, more specifically, whether there is really a significant difference between these two procedures, as both involve human embryos).

Some states felt that if only reproductive cloning were to be outlawed, this would implicitly endorse therapeutic cloning (that is, the creation and destruction of embryos), which would be unacceptable for those who believe human life begins at conception. Pragmatically, they worried that allowing therapeutic cloning could create a 'slippery slope' towards reproductive cloning and that it would be difficult to prevent rogue researchers implanting embryos that had originally been created for research purposes. There were also concerns about the impact on women, particularly in developing countries, who might be enticed to undergo risky procedures in order to produce large numbers of eggs for money. The US and Costa Rica led this faction, which grew to almost 70 states, including Kenya, Nigeria, Zambia and several other developing countries (Isasi and Annas 2003: 408–10; Isasi and Annas 2006: 61; Arsanjani 2006: 167–72; Cameron and Henderson 2008: 160–3).

Commentators differ on how interested or involved developing countries were in the debate. According to Nigel Cameron and Anna Henderson (2008: 171), these countries were 'particularly vocal' regarding the exploitation of women. Led by Tanzania and Nigeria, they also successfully lobbied for the inclusion of an article that resembles in spirit Article 14 of the UDBHR (2005) on social responsibility, encouraging states to consider 'the pressing global issues such as HIV/AIDS, tuberculosis and malaria, which affect in particular the developing countries' when allocating research funding (United Nations 2005a; Isasi and Annas 2006: 65). Rosario Isasi and George Annas (2006: 62) put this down to the political manoeuvring of the US and Costa Rica, which used this issue to broker the support of developing countries for a comprehensive ban. For Mahnoush Arsanjani (2006: 178), the inclusion of this article, which makes no mention of cloning, demonstrates the 'remoteness' of the issue for many developing countries.

On the other side, feelings ran equally strong. Those states in favour of therapeutic cloning would not countenance a holistic ban. This smaller group, led by the UK and Belgium, argued for an immediate international prohibition of

reproductive cloning, to prevent unscrupulous scientists finding sanctuary in states without appropriate jurisdiction, to be followed by further measures on therapeutic cloning as and when these could be agreed. This option, in turn, was unacceptable to those in favour of a complete embargo. Realising proceedings were at deadlock, in November 2003 the Organization of the Islamic Conference proposed discussions should be postponed for two years, in the hope that consensus might be possible at a later date. (There had already been a year long pause in negotiations in 2002–3 (Isasi and Annas 2003: 410–12; Arsanjani 2006: 172).) The General Assembly agreed to a delay of one year. As stances remained firm after the hiatus, in November 2004 it decided to opt for a declaration rather than a convention, in the vain hope that states would be able to agree on a non-binding instrument (Isasi and Annas 2003: 413; Isasi and Annas 2006: 62).

The *UN Declaration on Human Cloning* was adopted by the General Assembly on 8 March 2005, but by no means unanimously. Only 84 voted in favour, with 34 against and 37 abstentions. (Later, seven states informed the UN Secretariat they had intended to vote in favour, one that they would have voted against and two that they would have abstained.) The reason why so many states felt they could not support the declaration was its ambiguous wording (Arsanjani 2006: 165–6 and 176). The declaration calls on states to 'prohibit all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life' (United Nations 2005a). The UK confirmed that it had voted against the declaration because it 'can be interpreted as a call for a total ban on all forms of human cloning. We cannot accept such an ambiguous declaration, which may sow confusion about the acceptability of that important field of research' (United Nations 2005b: 4–5). Nikola Biller-Andorno (2005: 63), in a *Journal of Medical Ethics* editorial, reports that an insider said the declaration was 'ambiguous enough to please everybody', but this strategy clearly backfired, given the ambivalent voting.

That the declaration is ambiguous is disputed by some authors. This depends on whether one reads the phrase 'inasmuch as' to mean 'to the extent that' or 'because' (note that the French and Spanish translations of the declaration use the former sense). Arsanjani (formerly Director of the Codification Division of the UN's Office of Legal Affairs) believes the phrase was used deliberately to enable selective interpretation (Arsanjani 2006: 178), but Cameron (who advised the US delegation in 2002) and Henderson disagree. They maintain that the legislative intent of the General Assembly was clear and thus the only legitimate interpretation is to see the declaration as a comprehensive ban on all forms of cloning (Cameron and Henderson 2008: 195). Similarly, the *UN Chronicle* (United Nations 2005c: 28) states that, at the final vote, the General Assembly had 'urged Member States to prohibit all forms of human cloning, including cloning of human embryos for stem cell research'. A more subjective reading would mean that the declaration allows states to engage in reproductive cloning if they do not see this as violating human dignity (Cameron and Henderson 2008: 195). In sum, the end result was highly unsatisfactory – a weakly worded document that enjoys only ambivalent support from states. It is seen as too weak

to either prevent renegade research or support legitimate scientific investigation (Isasi and Annas 2006: 63).

UNESCO enters the fray

UNESCO's decision to investigate the possibility of a convention on human cloning came on the back of a 2007 report by the United Nations University's Institute of Advanced Studies (UNU-IAS), entitled *Is Human Reproductive Cloning Inevitable: Future Options for UN Governance*. One option identified by the report was that the IBC take up the issue of cloning regulation. Another was, 'Dissemination, discussion and debate on cloning issues at the international level, such that all countries including the developing and least developed countries can participate and put forward their concerns regarding this new technology' (UNU-IAS 2007: 26). Koïchiro Matsuura, Director-General of UNESCO, requested that the IBC examine the report. The IBC duly formed a Working Group on Human Cloning and International Governance for 2008–9. The Group's task was to 'explore whether the scientific, ethical, social, political and legal developments on human cloning in recent years justify a new initiative at international level', rather than to analyse ethical or scientific aspects of human cloning *per se* (UNESCO 2008d: 1).

In its September 2008 interim report, the Working Group recommended a legally binding convention to ban reproductive cloning (UNESCO 2008h). It redrafted the report in the light of discussions at the IBC and joint IBC–IGBC sessions in October 2008 and, in the final version (2009), recommended intensified international dialogue on the issue, rather than a convention (UNESCO 2009e: 7–8). The Working Group continued its work in 2010–11, but the IBC was unable to agree to its draft 'final statement', which again recommended a ban. The topic has now been all but abandoned, as it will simply be monitored by one or two IBC members under the IBC's Work Programme for 2012–13 (UNESCO 2011f: 4; UNESCO 2012m). Chapters 4 and 5 explore what led to this outcome and its implications.

Human genetic and biomedical research clearly has the potential to contribute towards addressing the pressing global problem of inequalities of health between North and South. If this potential is to be realized ethically, adequate protection of individual research subjects must be ensured. On a grander scale, sufficient resources will be needed to fund research directed towards the health needs of developing countries and the provision of any interventions consequently developed. Aside from external factors, UNESCO's efficacy in meeting these challenges will depend partly on its systems of decision-making and implementation. The next chapter asks what insights international relations theory might offer into how successful UNESCO's endeavours are in this regard.

3 Global governance

A conceptual framework for analysing bioethics at UNESCO

The field of international relations, in simple terms, explores why, how and to what degree states and other actors engage with each other at international level. International relations theory falls into several schools, realism and liberalism being the two longest standing. The realist paradigm, which purports that nation-states are the key actors in the international arena, was dominant until the end of the Cold War. It is chiefly concerned with the quest for power (Dougherty and Pfaltzgraff 1996: 58). Realists view the international system as one of anarchy, where moral considerations have no place. (A variant on this theme, the concept of an anarchical international society, was introduced by Hedley Bull in 1966: 'Whereas men within each state are subject to a common government, sovereign states in their mutual relations are not. This anarchy it is possible to regard as the central fact of international life and the starting point of theorizing about it' [Bull 2000: 77].) Conflicts between states are seen as inevitable, as each will seek to defend its national interest (defined in terms of 'survival, security, power, and relative capabilities' [Holsti 1995: 37]), primarily through military power (Kegley 1995: 4–5). States must exercise self-sufficiency, as dependence on another actor would leave them open to exploitation. Thus international organizations and international law are thought to be of limited use (ibid; Genest 1994: 71). Neorealism (or structural realism), as championed most famously by Kenneth Waltz, differs from classical realism in that it sees the international system as more than the sum of its parts, its very structure driving states towards certain actions and restricting them from others (Waltz 1995: 74).

The main opposition to realist theory within international relations has come from liberalism. Generally, liberals argue that realists place too much emphasis on conflict and too little on cooperation (Grieco 1995: 151). Security is often defined more broadly than under realism, to include elements such as health and education (Holsti 1995: 43). In a post-Cold War and globalizing world, liberalism has gained ground as an alternative explanation of world affairs, as scholars have paid increasing attention to influences beyond or below the state. Like realism, it has a 'neo-' successor, which synthesizes these two traditionally antithetical approaches (Hasenclever *et al.* 1996: 196). Neoliberal institutionalists assume that self-interested states are the principal international actors and that power differentials are important. While acknowledging the existence of anarchy, however, they hold

that international institutions can 'transcend the basic structural characteristics of the anarchic international system' (Dougherty and Pfaltzgraff 1996: 62).

Constructivism, another school of international relations, has grown greatly in prominence in recent years. Martha Finnemore and Kathryn Sikkink, two of its core proponents, see constructivism as 'a different kind of theory' to realism and liberalism, as it makes no claims about the nature of agents (that is, individuals or institutions) or the content of structures. Rather, as a social theory, it investigates social life and social change. They summarize this approach as follows: 'Constructivists focus on the role of ideas, norms, knowledge, culture, and argument in politics, stressing in particular the role of collectively held or "intersubjective" ideas and understandings on social life' (Finnemore and Sikkink 2001: 391–3). Thus constructivism sees rules and practices as being created and sustained by mutual agreement. State sovereignty, as an institution, provides an example. Reflecting common understandings about the characteristics of states, it allows these actors to recognize one another (Ellis 2002: 273–4).

This chapter explores on three specific approaches to governance within international relations theory: regime theory, government networks and cosmopolitan democracy. Regime theory draws on all three core schools of thought and networked governance and cosmopolitan democracy encompass elements of both neoliberalism and constructivism. Although differing in the significance they attach to concepts of power, sovereignty and the state, each has collaboration and cooperation at an international level as a central theme. Thus they all fall within a concept that has in recent years become central to the study of international relations: global governance.

Global governance

The term 'global governance' derives from the Commission on Global Governance, which met in 1995 to report on the future of the UN (Commission on Global Governance 1995). It refers to governance within and as an output of the international system, aimed at addressing those issues that have the potential to affect everyone, irrespective of national borders. As Robert Goodin (2003: 80) puts it, 'Cross-boundary spillovers – political and moral, as well as economic and environmental – are now absolutely endemic.' Alongside states, transnational actors such as UN agencies, large corporations and civil society organizations are important actors in how (and how well) these spillovers are managed (Keohane 2003: 130–2; Ruggie 2003: 117). 'Global governance' has both descriptive and normative connotations in this regard. Robert Keohane (2003: 132) describes it as rule-making and the exercise of power on a global scale, by entities not necessarily authorized to act by general consensus (with ensuing implications for legitimacy). James Rosenau (1992: 4) used the same premise, but from a different angle: because governance systems lack the traditional legitimacy conferred by democratic election, for example, they can only be effective if the great majority of those they cover agree to them. In this sense, then, governance has an inherent normative purpose; it is derived from shared goals rather than formal authority.

Regime theory

Pierre de Senarclens, a regime scholar, has commented that the notion of governance in international relations theory emerged 'in the aftermath of the debate about "regimes"' (de Senarclens 1998: 92). Regime theory (or, more accurately, theories of regimes [Vogler 1995: 25]) has much to offer in terms of describing how international bodies work and how they might do so more effectively. International regimes encompass varying levels of institutional development. They arise from efforts to develop collaborative arrangements, formally or informally, around fairly well-defined issues, such as world trade or environmental concerns (de Senarclens 1993: 456; Dougherty and Pfaltzgraff 1996: 436). Stephen Krasner and colleagues, in the seminal book *International Regimes*, defined them as 'sets of implicit or explicit principles, norms, rules and decision-making procedures around which actors' expectations converge in a given area of international relations' (Krasner 1983: 2). Although deemed vague and woolly by critics, this definition remains the most widely used (Strange 1983: 342; Kratochwil 1984: 685; Young 1989: 195; Simmons and Martin 2002: 193).

Traditionally state-centric, regime theory is particularly pertinent to intergovernmental organizations (IGOs) such as UNESCO (Young 1997: 6). States may choose to join such arrangements if they feel a given problem could be addressed more efficiently through an institution. Different theorists put forward power, interests or knowledge as defining variables in regimes, echoing the realist, neoliberal and constructivist schools of thought (Hasenclever *et al.* 1996: 178). Realist regime theory sees regimes as formed around and influenced by the power and interests of a dominant state, or group of states. Since states are seen as being primarily concerned with power plays and the vulnerability that interdependence brings, international cooperation is believed to occur infrequently (Zacher, with Sutton 1996: 2–3). Neoliberal regime theory, the mainstream approach to regimes, does not disregard power differentials, but portrays states as 'rational egoists' who pursue absolute rather than relative gains. States will therefore cooperate to realize common interests (ibid: 2; Hasenclever *et al.* 1996: 183–4). Cognitive (or constructivist) regime theory recognizes that cooperation is affected not only by power and interests but also by values, beliefs and knowledge. As regimes are based on shared principles and understandings, they are intersubjective; the issue areas around which they converge are not pre-ordained. Thus cognitive approaches help to explain the evolution and content of regimes (Kratochwil and Ruggie 1986: 764; Haggard and Simmons 1987: 509–10).

The neoliberal and cognitivist approaches do not have to be mutually exclusive. In *After Hegemony*, Keohane (1984: 63) wrote:

> But regimes can also affect state interests, for the notion of self-interest is itself elastic and largely subjective. Perceptions of self-interest depend on actors' expectations of the likely consequences that will follow from particular actions and on their fundamental values. Regimes can certainly affect expectations and may affect values as well.

Similarly, Oran Young (1999: 4) states, 'it is perfectly possible to adopt the view that actors and institutions are mutually constitutive'. In terms of UNESCO, all three approaches are relevant. We can ask, how much did differences in power between states influence the outcome of negotiations on the declarations and cloning? How did states and other actors go about securing their interests? And how did key principles in bioethics shape the formation of the declarations and vice versa?

Networked governance

Intergovernmental regimes have often been perceived to be slow-moving and ineffective. This has led some international relations theorists to examine alternative deliberative structures to see whether they might be more successful in implementing positive change. Wolfgang Reinicke and colleagues, for example, have analysed what they call Global Public Policy Networks (GPPNs). Reinicke (1999–2000: 44) charts the emergence of networks such as the Global Environment Facility and the Roll Back Malaria initiative from the 1990s onwards, defining them as 'loose alliances of government agencies, international organizations, corporations, and elements of civil society such as nongovernmental organizations, professional associations, or religious groups that join together to achieve what none can accomplish on its own'. Those who proposed the Global Genomics Initiative (GGI) (see p. 14) drew on the work of various network theorists. One of their earlier plans was based on Jean-François Rischard's Global Issues Networks, a highly specified form of GPPN, which Rischard has suggested as a means to address the 20 foremost problems faced by the world within 20 years (Rischard 2002: 66 and 224–5). Under this equitable model the GGI was to comprise representatives from governments, industry, academia, non-governmental organizations (NGOs) and civil society (Acharya *et al.* 2004a: 5). In a later proposal they shifted their focus slightly, citing the influential work of Anne-Marie Slaughter on government networks. The GGI was still to include NGOs, businesses and other sectors, but it would be 'underpinned by governments' in order to garner legitimacy and accountability (Dowdeswell *et al.* 2006: 138 and 140).

The importance of the part played by government actors in global networks lies at the heart of Slaughter's 2004 book, *A New World Order*, in which she analyses how government officials network at a global level, to exchange information and coordinate activities. These government networks are, Slaughter writes, 'a key feature of world order in the twenty-first century, but they are underappreciated, undersupported, and underused to address the central problems of global governance' (Slaughter 2004: 1). Slaughter's premise is that the state, contrary to the model assumed by many international relations theorists and multilateral negotiators alike, is not a unitary actor. Rather, it is disaggregated, primarily along legislative, regulatory and judicial lines; members of distinct domestic government institutions are increasingly involved in activities beyond national borders, interacting with their counterparts in other countries and at supranational level (ibid: 5–6, 12–13 and 31).

Slaughter (2004: 14) defines a government network broadly, as 'a pattern of regular and purposive relations among like government units working across the borders that divide countries from one another and that demarcate the "domestic" from the "international" sphere'. At present, government networks 'contribute' to world order by stimulating policy convergence among states, encouraging adherence to international treaties and promoting international cooperation (ibid: 24). In future, Slaughter suggests, this remit could be expanded. She envisages a form of networked governance that would include non-state actors such as international organizations, corporations and civil society organizations, but with government actors at the core. Slaughter claims that viewing the world as one of disaggregated states enables the imagining of 'a genuinely new set of possibilities for a future world order', the 'building blocks' of which would not be states but parts of states (ibid: 6). She describes what shape this conceptual framework might take thus:

> A disaggregated world order would be a world latticed by countless government networks. These would include horizontal networks and vertical networks; networks for collecting and sharing information of all kinds, for policy coordination, for enforcement cooperation, for technical assistance and training, perhaps ultimately for rule making. They would be bilateral, plurilateral, regional, or global. Taken together, they would provide the skeleton or infrastructure for global governance.
>
> (ibid: 15–16)

Cosmopolitan democracy

More ambitious still is 'cosmopolitan democracy', a model for global governance most prominently advocated by political theorists David Held and Daniele Archibugi. Archibugi (2004: 438) pithily captures the purpose of cosmopolitan democracy as follows: 'to globalize democracy while, at the same time, democratizing globalization'. The aim is to respond to global concerns in an integrated manner. Archibugi detects a strong call for global regulation of issues such as immigration, human rights, the environment, financial flows and development aid, but observes that at present each of these areas is serviced to a greater or lesser extent by its own regime. Cosmopolitan democracy offers a framework to connect what are currently disparate governance efforts (ibid: 451). The idea hinges on the premise that the world is made up of 'overlapping networks of power' and 'overlapping communities of fate' that do not fit neatly within state boundaries, causing strain in the current global system. The fates of distant communities are interwoven, to the extent that local level economic, social or environmental issues and events can have global ramifications and vice versa (Held 2003: 161–2 and 167). The ensuing risk that national level democracy will be 'hollowed out', as Archibugi (2002: 28) puts it, begs the question why democracy must be contained within domestic borders.

Held (2003: 169) articulates the three fundamental principles of cosmopolitanism as follows: individuals, as opposed to states or other entities, are 'the ultimate units of moral concern'; everyone's equal worth must be acknowledged; and rules

and principles must be impartial and thus universally shared. *Cosmopolitan* democracy would particularly address those issues that are difficult to regulate effectively at state level alone. Importantly, a global government *per se* is not envisaged. Rather, democracy would be promoted at several mutually supportive levels – inside nations, among states and transnationally – and involve both state and non-state actors (Archibugi 1998: 209; Archibugi 2002: 28–29 and 34). Held (2004b: 115) outlines the need for a multilayered approach thus:

> Today, if people are to be free and equal in the determination of the conditions that shape their lives, there must be an array of fora, from the city to global associations, in which they can hold decision-makers to account. If many contemporary forms of power are to become accountable and if many of the complex issues that affect us all – locally, nationally, regionally and globally – are to be democratically regulated, people will have to have access to, and membership in, diverse political communities.

These different approaches to global governance – regime theory, networked governance and cosmopolitan democracy – have points of convergence and divergence on two key themes that are pertinent to the governance of the UNESCO Bioethics Programme: deliberation and implementation. Taken together, these themes provide a conceptual framework for the analysis of the Programme in later chapters.

The deliberative process: representation, legitimacy and accountability

Whether UNESCO is considered as a legitimate arbiter of bioethics will depend partly on whether stakeholders and experts see it as a representative and accountable body. Allan Buchanan and Keohane (2006: 407) write:

> It is important not only that global governance institutions be legitimate, but that they are perceived to be legitimate. The perception of legitimacy matters, because, in a democratic era, multilateral institutions will only thrive if they are viewed as legitimate by democratic publics.

Held (2004b: xiii and 141) describes IGOs (of which UNESCO is one) as facing a 'crisis of legitimacy' on two counts: relations between strong and weak states are unequal and 'chains of delegation' from the international to the national are too long. On the first issue, Held (ibid: xiii) states, 'Increasingly, these institutions appear to speak for the powerful, or to be cast aside by these very same forces if they fail to fall into line with their will.'

Drawing on the work of Pamela Chasek and Lavanya Rajamani, Held (2004b: 95–6) points to the power imbalances between states during international

negotiations by way of example. These can be both qualitative and quantitative; some countries can afford to make available large delegations of experts to back up their official representative, while others may only be able to send one person, who may not be a specialist in the field. Slaughter (2004: 221) makes a similar observation with regard to less formalized relations between states, highlighting concerns with inequalities in power between rich and poor countries as government officials become increasingly involved in global governance: 'shifting authority to technocrats means privileging the views of those nations that *have* technocrats – inevitably the most developed nations'. She also notes that networks are sometimes criticized on the grounds that their informality can allow more powerful states to dominate, because the constraints found in traditional IGOs are absent (ibid: 28–9).

Chasek and Rajamani outline specific difficulties faced by developing countries during international negotiations. Further to the problems concerning the size and expertise of delegations highlighted by Held, they describe how some delegates will arrive at meetings with 'hollow mandates', having not received clear instructions as to what their countries' negotiating positions should be. Moreover, if they attend only later sessions, they will not only have missed out on agenda setting, but will also lack 'institutional memory' and the corresponding leverage to influence proceedings. This can be compounded for those countries without easy access to background documentation through high-speed internet connections (Chasek and Rajamani 2003: 246–9 and 258–9).

The two analysts propose several practical means by which developing countries could be better represented at international meetings and thus have stronger mandates and bargaining positions. Echoing Robert Putnam's notion (1998) that international negotiations are 'two-level games', involving the domestic as well as the international sphere, they suggest that national policy debates, strategic consultations and greater coordination between relevant ministries would 'make for more effective delegations'. Second, regional preparatory meetings would aid networking among developing countries. Broad coalitions can be powerful, but given the diversity of national concerns and priorities, Chasek and Rajamani recommend that these should be complemented by smaller groups focusing on special issues. Finally, fast and reliable internet access would help improve both coordination among countries and availability of information. All these measures might be realized through a participation fund (Chasek and Rajamani 2003: 246, 255 and 258–9).

The second crisis of legitimacy that Held identifies, the 'chains of delegation', he attributes to weak and obscure mechanisms of accountability, particularly with regard to international negotiations (Held 2004b: 141–2). Raffaele Marchetti (2006: 291) makes a similar observation, describing the system of 'double representation' in international organizations, whereby individuals are represented by national parliaments, which in turn elect an international representative, as producing 'an almost insurmountable barrier to engaging in public international life'. Nayef Samhat and Jaye Ellis argue, separately, for greater public engagement in the international system, to deal with the accountability issue. They propose

that regimes (formal and informal) be considered as public spheres, characterized as frameworks within which interests and identities are constituted and actors engage in discussion and deliberation.

Samhat (2005: 180 and 186) believes the 'democratic potential' of international regimes is growing as they involve a broadening range of actors, thus forming 'transboundary political communities' around specific issues. For Ellis (2002: 274), discourse within regimes enables 'the articulation of international rules and norms grounded in consensus and therefore enjoying legitimacy'. Both writers see the inclusion of civil society as the key element of regimes as public spheres. Ellis (ibid: 288) recommends that negotiations be made more open and thus 'more permeable to influence from civil society'. This is already happening, according to Samhat. Documentation of international meetings is becoming increasingly public and civil society actors are now participating 'across the gamut of regime and norm-building processes', from agenda setting to compliance monitoring. He sees these actors as representative agents and thus the means by which a rudimentary form of global democracy or global citizenship is practised, as a precursor to cosmopolitan democracy (Samhat 2005: 182–3 and 186).

Slaughter, by contrast, while not explicitly taking the line that civil society organizations and businesses are given too much space in international fora relative to states, gives voice to those who do (Slaughter 2004: 9–10, 224–5, 240 and 262). She argues that government networks, as they exist currently, have an advantage over the more equitable global networks advocated by former UN Secretary-General Kofi Annan, Reinicke, Rischard and others, in that, being composed of democratically appointed or elected officials, it is clear who is exercising power on whose behalf. The broader policy networks of Slaughter's vision of networked governance would thus enjoy legitimacy through having these accountable government networks, responsible for final decisions, at their core. Long chains of delegation would be avoided because those negotiating agreements would also be responsible for their implementation (ibid: 28–9, 224, 231 and 263).

Slaughter proposes 'global deliberative equality' as the foundational norm of global governance. By this she means that all those individuals and groups affected by common problems should be able to participate in collective deliberation about how to solve them, under a 'presumption of inclusion'. Participation would be indirect, through government representatives. Slaughter acknowledges that government officials are often seen as unelected technocrats acting on behalf of vested interests, but suggests ways in which such perceptions could be mitigated; namely, government networks could host common websites, engage systematically with counterpart networks of corporations and civil society organizations and promote enhanced accountability at domestic levels (Slaughter 2004: 28–9, 220–1, 235, 245–6 and 266). She envisages a system in which government officials would be explicitly recognized as having both domestic and international duties:

> National officials are responsible to national constituencies for their domestic and . . . their transgovernmental activities. At the same time . . . government networks constitute a global governance system, which must somehow be

> accountable to the global community as a whole, comprising both states and individuals whose collective interests stem from a common humanity.
>
> (ibid: 218)

Held (2004b: 173–4) and Archibugi (1998: 204–5 and 211–12), like Samhat, advocate that individuals should be entitled to take part in policy formation at the global level as fully-fledged cosmopolitan citizens, rather than through government representatives. Which individuals and groups might come together to hold to account relevant parties over a certain issue would be dictated less by geographical proximity than by whether they fell within, to use one of Held's recurring phrases, 'overlapping communities of fate'. In a similar vein to Slaughter's norm of 'global deliberative equality', Held (2004b: 97) holds that 'those who are significantly affected by a global good or bad should have a say in its provision or regulation'. Likewise, Archibugi (2004: 443–4) argues that 'cross-border issues' should be dealt with under a democratic principle that 'everyone affected is able to take part in the decision-making'. Where this does not happen, there is an accountability gap (Held 2004a: 383; Held 2004b: 99–100).

Under cosmopolitan democracy, new forms of accountability would complement those afforded by democratic elections. A full-blown cosmopolitan polity would involve an 'overarching network of democratic public fora', whereby people would be members of several different communities, according to the issues affecting them and would be able to engage politically in those issues in a variety of ways (Held 2004b: 109). These would include forms of both direct (local) and representative (global) democracy, but also novel democratic arenas such as stakeholder consultations and collective decision-making through impartial deliberative examination of opinion and informed participation (if indeed impartiality of opinion and information can ever be guaranteed) (Held 2003: 175–6). Such fora, construed within or without the UNESCO system, could perhaps help to improve global decision-making on bioethics.

The implementation process: realizing and enforcing norms

UNESCO has a stated purpose to promulgate universal norms on bioethics. How these are implemented and enforced will depend on both their nature and content. In a world of sovereign states, any international system relies ultimately on self-regulation by members, urged on by the perceived threat of reciprocal action and national concerns with status and reputation (Vogler 1995: 41). As Ellis (2002: 292) puts it, 'States are both subjects and instruments of international law, being both the addressees of international norms and the agents responsible for their domestic implementation and enforcement.'

Young (1999: 47 and 103) describes the conception and revision of regimes as 'messy processes'. Norms are often drafted ambiguously rather than to 'coherent institutional designs', representing compromise positions reached through hard bargaining and consensus-based decision-making. Negotiations aimed at binding

accords, in particular, sometimes suffer a 'lowest common denominator' effect. Non-binding instruments, which allow for fluctuating levels of compliance and are thus less threatening to reluctant states, may therefore be preferred (Stokke 1997: 50). These generally have the added advantages over binding agreements of being quicker to negotiate, more flexible in application and more open to future adjustments (Victor *et al.* 1998: 8 and 18). The corresponding disadvantages lie in their modest enforcement power, which is seen to render them weaker than binding agreements. This 'conventional wisdom' is challenged by David Victor *et al.* in their study of international environmental regimes, published in 2000. They found that binding instruments that set low standards, even if fully complied with, may have negligible impact on a given problem. By contrast, non-binding agreements enshrining high standards, even if only partly met, may effect significant behavioural change (Raustiala and Victor 1998: 685 and 705; Victor *et al.* 1998: 7).

While regimes usually coalesce around fairly well-defined issues, ambiguity concerning ownership of and responsibility for problems can result in overlapping or contradictory norms, functions and mandates among different international bodies. Lack of coherence can also lead to issues falling between agencies, or uncertainty as to whether action should be taken at global or national levels (Reinicke 1997: 136–7; Hurrell 2002: 143; Held 2004b: 94 and 97). Bioethics provides an example. As the previous chapter illustrated, several international organizations, UN-based and otherwise, have produced guidelines or standards for ethical biomedical research. Sjef Gevers (2001: 297) is critical of this proliferation:

> Before elaborating and publishing their 'own' standards, international organizations should really ask themselves what the 'added value' is of their contribution in terms of further convergence and better protection. A mere proliferation of standards is of no use to anybody, but may only lead to confusion or even "shopping" between different international documents.

From a different perspective, Young notes that, as much as organizations having similar mandates raises the possibility of overlap and congestion, it also enables positive connections and mutual reinforcement (Young 1999: 122). A too strictly delineated remit may also deny linkages with those working on related issues (Haggard and Simmons 1987: 497).

Rischard (2002: 42–4, 157, 170 and 181) deplores what he sees as rigidity in traditional IGOs and concludes that they need to become flatter, leaner and faster. What he does not take into account is that some of the advantages of international cooperation take time to be realized. Regimes confer a degree of stability in international relations by allowing reciprocal expectations and mutual information networks to develop. Liberal regime theorists hold that states will enter into multilateral agreements on the understanding that it will be to their long-term advantage (Smouts 1993: 445 and 447). The longer parties remain in a regime, the more interconnected they become and the harder it is to withdraw. Peer pressure

may induce conformity over time. 'So even though it might formally seem as if treaty regimes have no real power over member states,' writes Robert Goodin (2003: 82), 'the informal reality is that they typically provide an awful lot of leverage.'

One way to encourage adoption of regimes at national level may be through systems of implementation review (SIRs). According to Victor *et al.* (1998: 18), SIRs enhance transparency and accountability and lessen the chance of non-binding commitments being ignored. Young (1999: 119) similarly remarks, 'Well-constructed SIRs are important in almost every case as methods of retaining the attention of policymakers and avoiding the onset of "out of sight, out of mind" syndrome.' SIRs do have their limitations; Victor *et al.* found poor data reporting to be a chronic problem, in terms of both quantity and quality. More positively, they showed that active and effective implementation review often evolves informally, after an agreement has entered into force. They also observed that states were becoming more open even to external review, in the interests of international cooperation (Raustiala and Victor 1998: 677–8, 680 and 695; Victor *et al.* 1998: 18).

Where norms are not being upheld by member states, IGOs have two approaches to encouraging implementation: enforcement and management. Which is deemed appropriate will depend on whether non-compliance is attributed to self-interested choice or incapacity (Raustiala and Victor 1998: 681). John Vogler (1995: 70) writes, 'They [governments] may simply lack the technical personnel and data gathering facilities to fulfil their obligations under a regime.' Young (1999: 81, 95–6 and 100) judges IGOs to be 'notoriously weak' in applying enforcement measures such as sanctions and thus considers initiatives like UNESCO's capacity-building activities, aimed at strengthening those desiring to comply, a better option in many cases. Victor *et al.* found that a combined approach can prove effective; the threatened withdrawal of managerial assistance, for example, might be a powerful enforcement tool. The likely success of either or both methods will depend partly on a system's capacity to apply them (Raustiala and Victor 1998: 683–4). Young (1999: 119) notes that organizations administering regimes often struggle for sufficient material resources, especially for programmes aimed at developing countries.

Whether a regime is adopted at national level and, if so, how successfully, may be as dependent on internal dynamics and pressures as on IGO enforcement or management mechanisms. Where international arrangements disrupt or are incompatible with local procedures, their efficacy may be impaired (Young 1999: 122–3). This is particularly pertinent to bioethics, given the debate over universal versus pluralist, culturally determined values. Slaughter endorses pluralism, under the constitutional norms of 'legitimate difference' and 'checks and balances'. Legitimate difference would restrain government networks from attempting to cover over differences in fundamental values. Instead, they would draw up compilations of best practices, for regulators to adapt to local circumstances. Similarly, horizontal and vertical checks and balances would enshrine 'an affirmative norm of friction and constructive ambiguity' (Slaughter 2004: 31–2, 249–50 and 254–5).

These pluralistic norms would contrast directly with the third principle of cosmopolitanism, which states that rules and principles must be universally and impartially shared; those that cannot be must be rejected. Held (2003: 169–71) gives broad examples of what such rules might comprise, in terms of avoiding harm and meeting urgent needs. He acknowledges that how these should be interpreted could not be specified 'once and for all', but would depend on temporally determined cultures and traditions. Samhat (2005: 187–8) takes a balanced approach, seeing regimes as a means to resolve tension between universalism (or 'solidarism', as he puts it, defined as consensus on the moral standards states must uphold) and pluralism within the international system, on an issue by issue basis. Progress is generally incremental in this regard, as norms and principles stemming from initially different perspectives are scrutinized and revised. Encapsulated in these different perspectives is a question that UNESCO, with its aim of fostering respect for cultural diversity alongside respect for universal human rights, must answer: how far can universal principles be adapted to suit particular contexts before they lose all potency? At what point, in fact, do they become plural?

Which government agency takes on responsibility for implementing a regime may also be a key factor in the translation of internationally agreed principles to the national context. Slaughter (2004: 247) believes that networks would work most effectively if they were targeted: 'government networks should be explicitly designed to engage, enmesh, and assist specific government institutions'. What she appears not to recognize is that some issues are cross-cutting. Bioethics, for example, could involve ministries of health, science and technology, industry and education, to name a few. Echoing Slaughter's disaggregated state, Young (1999: 94) observes, 'Regimes ordinarily become the property of specific public agencies within governments rather than of the government as a whole.' Thus it is essential for IGOs to identify and liaise with the most appropriate national bodies (ibid: 48). Samhat and Ellis concur. Although they believe international regimes have the potential to expand democracy beyond the state as global public spheres, they appreciate that strong states are needed to administer whatever rules and norms are agreed upon (Ellis 2002: 280; Samhat 2005: 179–80 and 189). Young (1999: 94–5 and 105) sees unofficial groups as of 'even greater importance' in this regard. Where regimes trigger active communities willing to give time and energy to their fulfilment, they cannot be shunted aside or simply fade from the collective conscience through apathy. It might be expected that involving relevant constituencies in negotiations would harness their subsequent support, but this does not necessarily follow. Victor *et al.* found that including practitioners in decision-making led to better-crafted agreements, but had little impact in terms of encouraging participation in their realization (Raustiala and Victor 1998: 665).

Sceptical of current systems for inducing adherence to international norms and principles, Slaughter and Held suggest alternatives. These range from variations on the enforcement and management approaches to new understandings of sovereignty. Slaughter's plans for augmenting governance through government networks, both horizontal and vertical, would mirror current regime arrangements in that the norms developed would have little potency unless implemented at

domestic level. Horizontal networks would employ 'soft power' (Nye 2004: x) on a continuum running from information to socialization to persuasion to discussion and debate, to foster national level adherence (Slaughter 2004: 27, 213 and 263). Vertical networks would see international organizations directly marshalling the legislative, regulatory or judicial power of their domestic counterparts in order to achieve maximum efficacy. 'Absent a world government,' writes Slaughter, 'it is impossible to grant supranational officials genuine coercive power' (ibid: 13–14 and 20).

To promote implementation, costs and prestige would be attached to failing or meeting respectively a network's norms and standards. To this end, Slaughter introduces a new conception of sovereignty: disaggregated sovereignty. At present, she avers, there is a 'conceptual blind spot' in international law and politics, whereby separate government institutions are not formally recognized independently of the unitary state. To address the myopia, Slaughter suggests, these institutions should individually bear the rights and responsibilities of sovereignty. Each would have a discrete mandate to meet international legal obligations (which could lead to duplication and confusion should institutions with overlapping responsibilities separately apply these instruments at national level). Sovereignty would be newly understood in terms of capacity to take part in transgovernmental networks (Slaughter 2004: 25, 33–4 and 266–9). This new notion of sovereignty has not gone uncriticized. Berkowitz (2005: 75) writes, 'One should not underestimate the radicalism of Slaughter's proposal, encapsulated in her casual exercise in redefinition – as if one could disguise the rejection of a fundamental principle by keeping the name while changing the meaning.' Anderson (2005: 1299–1300) likewise comments that Slaughter's argument 'operates by pure definitional fiat', such that she has 'redefined sovereignty to mean engaging in activities characteristic of giving up traditional sovereignty'. He believes she has confused sovereign power with the international benefits it can be used to secure.

Like those of the management school of regime theory, Slaughter sees compliance with international norms as being as much about capacity as willingness. She particularly cites developing countries as lacking this capacity and suggests that government networks could provide technical assistance in helping them to build it (Slaughter 2004: 4, 26 and 261). She also recognizes that network effects take time to develop. She believes discussion and argument are the key to creative, legitimate and high-quality solutions to complex problems and that if the positive nature of conflict could be harnessed in this way the result would be long-term, trusting relationships (ibid: 27 and 214). Again, her ideas have not escaped criticism. Perju (2005: 475 and 480) describes Slaughter's plans for high-quality dialogue as 'romanticized'. In reality, he says, power relations do not get 'filtered out'. He also objects to the dialogue- and discussion-heavy approach on the grounds that it can represent a subtle means for strong states to dominate weak ones, observing, 'the current global conversation is far less global than we should expect it to be'.

Like Slaughter's government networks, cosmopolitan democracy would entail a new understanding of sovereignty. Where traditionally states have been protected

from external accountability by the national sovereignty principle, Held (2003: 168) and Archibugi (2004: 452) argue that allowing them to act with impunity simply because they sit within certain borders is incompatible with democracy; states should not be considered 'ontologically privileged' (Held 2004a: 391). The two theorists frame their proposed alternatives differently. Held (2004b: 119 and 131) sees a 'liberal international sovereignty' already emerging in the international arena. Under cosmopolitan democracy, this would entrench powers and constraints, rights and duties that might sometimes conflict with national laws. States would thus forfeit their right to sovereignty if they violated standards of international order, understood in terms of human rights and democracy. Archibugi (2004: 452) endorses a similar ethos, but argues that the canon of sovereignty should be done away with altogether and supplanted by that of 'global constitutionalism', which would see conflict resolved by jurisdictional bodies acting under a constitutional mandate.

Held (2003: 179–80) stresses that cosmopolitan democracy would not necessitate a diminution of state power and capacity *per se*, but it is difficult to envisage how it would be possible to have effective supranational levels of governance without state sovereignty being adversely affected. At present, states can assert that international norms to which they would rather not adhere lack democratic legitimization, a claim that would be invalid under cosmopolitan democracy (ibid). In its present form, the UN struggles to persuade states to uphold international law, both in spite and because of their ultimate sovereignty. To convince states to give up this sovereignty would be a task more difficult by an order of magnitude. Like Slaughter's, Held's views on sovereignty have been castigated for being unrealistically benign (Chandler 2003: 339 and 343; Desai 2005: 68–9; Slaughter and Hale 2005: 128; Wolf 2005: 41). Lupel (2005: 122) writes, 'States, as the major actors in the international arena, have a strong interest in maintaining their *de jure* sovereignty; sovereign status remains the foundation of state identity and agency in the international arena. This is never to be given up lightly.'

Held (2004b: 107) and Archibugi (2004: 465–6) recognize that cosmopolitan democracy is not immediately implementable as a *fait accompli*. It would likely be achieved through many 'little steps forward', writes Archibugi, rather than a one-off, momentous shift, with campaigns pursuing limited objectives eventually leading to the desired world order. Whether such little steps can be taken in the area of bioethics and genetics are a prime consideration. The combination of non-binding agreements and state sovereignty does not augur well for the implementation of the norms and principles of the UNESCO declarations. At issue is whether efficacy can more realistically be achieved by changing the nature of sovereignty or by finding ways to govern in spite of it.

Application to the UNESCO Bioethics Programme

The previous sections have presented a broad theoretical framework for thinking about global governance. In Chapters 4 to 7 the analysis turns to the governance of bioethics and genetics and, more precisely, the actual and potential efficacy of

the UNESCO Bioethics Programme, particularly in developing countries. The analysis will be anchored in the questions laid out here, which ask how far the Programme correlates with explanatory approaches to global governance and normative suggestions for its improvement, in terms of deliberation and implementation.

The UNESCO declarations, as a set of principles and norms on bioethics and genetics decided upon according to certain rules and procedures, can be considered an international regime under Krasner's classic definition. Hence we can ask, to what extent do they reflect or shape the powers, interests and values of states and other stakeholders? Like many international agreements, the declarations are housed in an IGO. Held has identified two crises of legitimacy currently faced by these organizations: unequal power between developed and developing countries and long chains of delegation from international to national levels. Chapter 4 will explore whether his assessment can be applied to the UNESCO Bioethics Programme in the context of the bioethics and genetics declarations and the deliberations on human cloning. Did negotiation sessions bear out Chasek and Rajamani's findings about disparities in delegation size, expertise and preparedness? How far were any power differentials mitigated by procedural norms on the right to speak? Has UNESCO fulfilled the democratic potential of IGOs by including civil society actors, as Samhat might expect?

Chapter 5 will examine the content and implementation of the UNESCO declarations. Did their non-binding nature render them relatively quick to negotiate and amenable to future adaptation? Are they characterized by the ambiguity and compromise common to many regimes? Are they weaker than binding instruments, as per conventional regime interpretations, or do they enable states to strive for higher standards, like the environmental agreements Victor *et al.* examined? On the management side, how effective is the Bioethics Programme in encouraging states to adopt and adhere to the declarations? Are its capacity-building activities hampered by constrained finances, in line with Young's observations? With regard to enforcement, how effective are the declarations' reporting mechanisms?

Chapters 6 and 7 turn to the national level. Has the Bioethics Programme been able to engage with the appropriate ministries and departments? Have government-appointed officials adequately represented their constituents at UNESCO meetings, thus garnering the legitimacy Slaughter believes them to carry? Or have geneticists, ethicists and relevant interest groups in Kenya and South Africa had little opportunity to contribute to the negotiating positions taken by their countries at international level? Have the declarations made an impact on states' laws, regulations or policies, particularly Kenya's and South Africa's? In what ways have their principles been tailored to local contexts and in which areas is implementation lacking? How far does consultation take place between government, experts and the general public on domestic policy on bioethics and genetics?

Where the empirical data highlight that the governance of bioethics and genetics might be improved, the concluding chapter will discuss whether this could be achieved by changing elements of the regime that is the decision-making

procedures and declarations of the UNESCO Bioethics Programme. Might measures similar to those recommended by Chasek and Rajamani for increasing the participation of developing countries in international negotiations be applied to UNESCO? Would any of the suggestions for increasing the involvement of experts and civil society put forward by Samhat, Ellis, Slaughter or Held and Archibugi be practicable? Not only an organization's membership but also the nature and number of its rules and procedures will affect the type and content of any norms it elaborates. To mitigate against interest-based bargaining, Held promotes an ethos of impartiality, while Slaughter, Samhat and Ellis emphasize the value of discussion and deliberation. Would such measures lead to improved deliberation and stronger agreements within UNESCO?

The question of how best to secure the implementation of the UNESCO declarations revolves around the issue of state sovereignty. If this is to remain sacrosanct, how might any states that have not yet adopted the declarations be persuaded or encouraged to do so? Could a Slaughter-like network foster inter-state peer pressure, the declarations' norms becoming gradually socialized through ongoing discussions among officials? At another level of abstraction, what would happen if states were to relinquish a part or the whole of their sovereignty? This would see UNESCO as the hub of a vertical network in a disaggregated world order, or as an institution empowered to enforce human rights under cosmopolitan democracy. Is either scenario in any way likely, given the powers, interests and values of UNESCO's member states?

4 Deliberating bioethics

UNESCO's standard-setting activities

UNESCO is a traditional IGO in that it is comprised of member states. It is these states which make final decisions on the organization's activities, including the elaboration and adoption of international declarations. In this sense, then, UNESCO's declarations on bioethics and human genetics form a state-centric regime. Non-state actors were involved in their drafting, however, notably UNESCO's International Bioethics Committee. This chapter explains the infrastructure of the Bioethics Programme, before exploring relations between member states of UNESCO in the drafting of the three declarations and the debate on the governance of human cloning, as well as the roles played by other actors, such as UNESCO's sister UN agencies and NGOs. Lenoir, first President of the IBC, wrote in 1996 that 'to involve the developing countries in the debate [on bioethics] is itself an ethical imperative' (Lenoir 1996). The extent to which this imperative has been met is a major focus of the analysis.

The infrastructure of the UNESCO Bioethics Programme

The main bodies within the UNESCO Bioethics Programme are the International Bioethics Committee (IBC) and the Intergovernmental Bioethics Committee (IGBC). These are supported by a secretariat based in Paris. The IBC was the prime actor in the elaboration of the text of all three declarations. Although one of the committee's defining characteristics is that it is made up of independent experts, its authority is seen to derive from the fact that it sits within an intergovernmental body. Hence during the drawing up of the UDHGHR (1997) it was considered to be 'the only international body working in the field of bioethics' (UNESCO 1999a: 1). The IBC has various functions, including promotion of reflection and education around ethical issues, cooperation with IGOs, NGOs and bioethics committees and follow-up on the three declarations (UNESCO 1998c: 1; UNESCO 2003b; UNESCO 2005s). Some of these tasks are carried out by smaller working groups, which focus on particular topics.

The whole committee meets once a year. Members are selected by the Director-General according to recommendations by member states, but as independent advisors:

> The Director-General appoints the IBC's 36 members to serve in their personal capacities for four year terms. The selection is made taking into account cultural diversity, balanced geographical representation and nominations from States of qualified specialists in the life sciences and in the social and human sciences, including law, human rights, philosophy, education and communication.
>
> (UNESCO 2004h)

Achieving this cultural, geographical and disciplinary diversity can be a challenge. Whether a nominee is appointed will depend partly on whether they meet the necessary profile to secure a balanced membership. In the early years there was a high proportion of legislators, but there has since been a shift towards health. For the two-year period during which the UDBHR (2005) was elaborated, the committee had several medical experts but would have welcomed more bioethicists (interviews with F_01 and F2_03). At the seventeenth IBC session in Paris in October 2010, the IBC Chair was glad to note the increased membership from Africa (UNESCO 2011i: 1).

The IGBC's mandate, as agreed by the Executive Board in 1998, is to 'examine the advice and recommendations of the IBC, including those concerned with the follow-up of the Universal Declaration' (that is, the 1997 UDHGHR). According to the IBC's statutes, the IGBC is to inform the IBC and the Director-General of its opinions, including options for following up on the work of the IBC, which the Director-General may then submit to member states, the Executive Board and the General Conference (UNESCO 1998c: 3). More informally, at the committee's second session in 2001, then Chair Najib Ouariti suggested that 'the IGBC must act as an essential relay between the IBC and all the Member States on the one hand and between the IBC and civil societies on the other' (UNESCO 2001c: 1). The IGBC converges every two years, with meetings open to the public unless it decides otherwise. States hold seats for four years, half the membership being elected at each biennial General Conference (for example, 18 members served terms from 2005–2009 and 18 from 2007–2011) (UNESCO 1998c: 3; UNESCO 2011h: 2).

With 36 seats, under a fifth of states are directly represented on the IGBC (Kenya was a member during the elaboration of the 2003 and 2005 declarations but South Africa was not, for example). This is mitigated by seats being allocated according to UNESCO's regional groupings, in accordance with 155 EX/Decision 9.2 (1998) of the Executive Board, where the seats are allocated in the same way. Which states from each group get the seats is subject to a certain amount of 'political wheeling and dealing' (interview with F_01 [quoted]; informal conversation, IGBC meeting, September 2011). The composition of the committee is as follows:

- Group I: Western European and North American states, 7 seats (from 27 members);

- Group II: Eastern European states, 4 seats (25 members);
- Group III: Latin American and Caribbean states, 6 seats (33 members);
- Group IV: Asian and Pacific states, 7 seats (44 members);
- Group Va and Vb: (a) African and (b) Arab states, 8 and 4 seats respectively (64 members) (UNESCO 1998a: 67; UNESCO 2006b; UNESCO 2012d: 64–6).

Drafting and negotiating the declarations

The Universal Declaration on the Human Genome and Human Rights (1997)

The elaboration of the UDHGHR (1997) has been documented in detail elsewhere and need not be revisited here. A previous volume in this book series, *The International Legal Governance of the Human Genome* (2009), by Chamundeeswari Kuppuswamy, carefully analyses the IBC's reports of its meetings during the negotiating period, while UNESCO's own book, *Birth of the Universal Declaration on the Human Genome and Human Rights* (1999a), includes the proceedings of the Legal Commission (the group of IBC members charged with drafting the outline text), its make-up in terms of membership and the various drafts of the declaration. A broad range of state and non-state actors participated in the elaboration process. At its second meeting, the Legal Commission decided that 'one of the major objectives of the IBC is to set back the debate on ethics into a planetary context, by giving the opportunity to representatives of countries from the global South to voice their concerns, often neglected in such discussions' (UNESCO 1999a: 37). Roberto Andorno (2003: 106) notes that 81 member states sent representatives to the 1997 intergovernmental meeting of experts that finalized the draft of the declaration adopted by the General Conference later that year. Non-state actors were given the opportunity to share their opinions in a 'vast and informal' consultation in 1995–6, in line with then Director-General Federico Mayor's wish that the declaration be used as 'an instrument of intercultural dialogue' (Lenoir 1996). The outline text was sent to around 300 institutions and individuals, including other UN agencies, national bodies, NGOs, ethics committees, universities and prominent intellectuals. Responses were discussed in detail by the Legal Commission and the IBC and formed the basis of the preliminary draft of March 1996 (ibid; UNESCO 1999a: 57–8, 61 and 67).

The International Declaration on Human Genetic Data (2003)

Although the idea of a separate declaration on human genetic data was mooted in 2001, two years after the establishment of the IGBC, the committee appears to have played no role in the drafting of the declaration (UNESCO 2003j: 19). Nevertheless, member states of UNESCO were able to contribute to the elaboration process on various occasions. The first opportunity came in January 2003, with the launch of an international consultation. An outline of the draft declaration and a questionnaire were sent to international, regional and national organizations and

more than 100 bioethics experts, as well as states. Very few replies were received at first, so the deadline for submission was extended. 42 member states eventually responded, 10 from Group I (out of 27 members), eight from Group II (24), six from Group III (33), six from Group IV (42) and 12 from Group V (64). Proportionally, then, there were more replies from developed countries than developing ones. Replies were also received from the Office of the United Nations High Commissioner for Human Rights, 12 NGOs (including the Council for International Organizations of Medical Sciences, the Human Genome Organisation and the Joint Programme Commission on Science and Ethics, which then had 32 member organizations), 22 ethics bodies, six data protection agencies and 21 'eminent personalities' or former IBC members (UNESCO 2003e: 1 and 12–15).

The consultation was followed by a Public Hearings Day in Monaco in February 2003, at which Pierre Sané, Assistant Director-General for the UNESCO's Social and Human Sciences sector, stressed 'the importance that should be attached to the involvement of civil society in the bioethical debate and the transparency of the IBC's work'. Speakers representing interest groups, developing country researchers and international bodies such as the World Medical Association (WMA), as well as insurance and pharmaceutical companies, duly made statements. These were discussed by a broad audience, comprising the drafting group and some 30 observers attending in a personal capacity or on behalf of member states or other IGOs, including the World Health Organization (WHO). The drafting group then took these discussions into consideration at its subsequent meeting (UNESCO 2003g: 1 and Annex II, 3–5). In light of both the Public Hearings Day and the returned questionnaires, it refined the draft declaration in preparation for the intergovernmental meeting of experts (IGE meeting) in June 2003, with greater emphasis placed on issues pertinent to developing countries, such as benefit sharing and international cooperation (UNESCO 2003e: 1–2 and 11).

The IGE meeting was poorly attended. Only 57 member states sent delegates, of whom 34 took part in the meeting's general debate. The reason for this low attendance is not clear; perhaps some states did not consider the draft declaration of particular relevance to their national needs or interests. Group I was more strongly represented than the other four, despite its being one of the smaller regional groupings (UNESCO 2003c: 1). Furthermore, consonant with Chasek and Rajamani's findings, the larger delegations were chiefly from Group I states. While most countries sent one or two representatives, the US (at the time not even a member of UNESCO) sent six, Germany five, France six and, as an exception to the rule, Tunisia five (UNESCO 2003d). The meeting supported the revised provisions on benefit sharing and international cooperation, particularly those concerning donor communities and scientific researchers in developing countries. Some delegates wanted to see these provisions strengthened further, but others objected, foreseeing clashes with the patent system and national standards for sample donation and research. As is often the case in regime negotiations, a compromise was reached: the draft text was retained, with the addition of a clause stressing the need to build the capacity of developing countries to collect and process human genetic data (UNESCO 2003c: 6–7).

The Universal Declaration on Bioethics and Human Rights (2005)

As for the IDHGD (2003), the first contributions by states to the drafting of the bioethics declaration were made through a written consultation. A questionnaire on what the declaration's aims, structure and content should be was sent to all member states, associate member states and permanent observer missions in January 2004 (UNESCO 2005j: 1). Of the 67 questionnaires returned, 21 were from Group I, 10 from Group II, six from Group III, eight from Group IV, 21 from Group V and one from a permanent observer (UNESCO 2005q). The greater number of responses to this questionnaire in comparison to that for the IDHGD is thus mainly attributable to states in Groups I and V. Cheryl Macpherson (2007: 588), in an article provocatively titled 'Global bioethics: did the Universal Declaration on Bioethics and Human Rights miss the boat?', laments that neither the questionnaire nor the results have been made available online, as they might 'contribute significantly to the bioethics literature regarding global and universal bioethics'. Such an impact is unlikely, however, as the questionnaire was very basic, with only yes/no questions (Snead 2009: 207–8).

Participation by member states at meetings on the UDBHR was ostensibly fair and equal. The IBC and IGBC held a week of separate and joint meetings in January 2005. (The IGBC met to discuss the draft declaration on 24 and 25 January 2005. On 26 and 27 January it continued this discussion at a joint meeting with the IBC. On 28 January the IBC held a further meeting, attended by several IGBC representatives, to revise the draft in light of the week's discussions.) The chairs of these meetings went to great pains to ensure that members had equal opportunities to contribute, as enjoined by the IGBC rules of procedure: 'The Chairperson shall call upon participants in the order in which they signify their wish to speak' (personal observations, IBC and IGBC meetings, January 2005; UNESCO 2011h: 2). This practice was also stipulated for the IGE meetings held in April and June 2005 (UNESCO 2005d: 3; UNESCO 2005n: 3). An attendee confirmed these were conducted in said fashion: 'From my own observations everybody had a right to say whatever he or she wanted to say. After all, they were representing their states' (interview with K_01). Nevertheless, some participants played a greater part in these sessions than others. At the January 2005 IBC and IGBC meetings, representatives from Germany, the US, the Russian Federation, Brazil and Egypt each made fifteen or more comments, whereas those of Malawi, Mozambique and Togo made none at all (personal observations). Furthermore, some attendees at the IGE negotiations commented in interviews that the coffee breaks were when things were really decided, which also seemed to be the case at the January meetings (ibid; interviews with UK_01 and UK_02).

A Kenyan participant at the IGE meetings felt that those countries that had a long history in bioethics had an advantage over those just starting in the field (interview with K_01). This mirrors the concerns of Chasek, Rajamani and Held about differences between countries in levels of expertise at international negotiations. Some also felt ill-prepared. One African delegate to the January 2005 joint IBC and IGBC sessions described how it had been difficult for them to

access the relevant documents before the meetings because their office did not have an internet connection (informal conversation). In terms of numbers, the lists of delegates reveal that, as for the IDHGD (2003) negotiations, some countries were able to send bigger entourages than others to both the January IBC and IGBC sessions and the two IGE meetings. A conference on biodiversity was being held in the same week as the former, with at least one African delegate obliged to cover both at once; representatives of other African countries were not present for significant periods of the meetings (interview with F_02; personal observations, IBC and IGBC meetings, January 2005; UNESCO 2005f). Of the 75 and 90 states that attended the April and June IGE meetings, 59 and 68 respectively sent only one or two delegates. By contrast, Canada, France and the US sent six, seven and eight delegates respectively to the April meeting and five, eight and nine to the June meeting (UNESCO 2005e and 2005o). The chief South African representative at the June meeting commented, 'I was left as the sole representative from South Africa (unlike other countries that were much more organized and had a panel of experts representing them).' They went on to say, 'The bigger boys came with a whole network of people that spoke and contributed to each thing. . . I felt uniquely alienated. . . without that intensive support' (interview with SA_23).

Some countries sent no representative at all. Of UNESCO's 190 member states at the time, exactly half attended the April or June meetings. As at the IGE meeting for the IDHGD (2003), there were proportionately more countries from Group I than from the other four groups, as Table 4.1 shows. Some developing countries may have considered bioethics to be a First World issue and therefore of little importance to them. One West African delegate at the January 2005 IBC and IGBC meetings commented anecdotally that bioethics was not of general concern in their country, as people had more immediate problems to deal with. Several representatives from developed countries would have had the double bonus of greater funding for travel combined with a shorter distance to cover, compared with their developing country counterparts.

A member of the Kenya National Commission for UNESCO, who had attended a number of meetings in Paris on different issues, noted that, in general, 'The participation from the developing countries is quite low.' This can be problematic, they said, because if countries do not participate in negotiations their interests

Table 4.1 Number of member states attending the April and June 2005 IGE meetings, by regional group

Group	*Region*	*April*	*June*
Group I	Western Europe and North America	20 (74%)	22 (81%)
Group II	Eastern Europe	8 (32%)	13 (52%)
Group III	Latin America and Caribbean	17 (52%)	20 (61%)
Group IV	Asia and Pacific	9 (20%)	12 (27%)
Group V	Africa/Arab states	21 (33%)	23 (36%)

Sources: UNESCO (2005e and 2005o).

cannot be addressed (interview with K_16). The Kenyan UNESCO Chair in Bioethics, who attended the April and June IGE meetings, made a similar observation, citing lack of resources as the reason why several African countries could not send representatives. (For both the IGBC and IGE meetings, states had to cover their attendance costs.) They thought it would be harder for these states to visualize how to implement the declaration, having not been involved in its elaboration (interview with K_01). Although not the poorest country, South Africa's first real input into the negotiation process was at the June IGE meeting, by which time, in line with Chasek and Rajamani's observations, it seemed to one of its delegates too late to bring anything new to the table, 'when we hadn't had a voice *a priori*' (interview with SA_23). As only cosmetic changes were made at the 2005 General Conference, when the Declaration was adopted, those states that did not attend the IGE meetings can have had little input into the UDBHR beyond the final vote.

Developing countries may have been disproportionately few in number at negotiations, but the UDBHR represents a significant effort to address their needs and concerns. As with the UDHGHR (1997), this had been the intention from the outset. The IBC, in its initial report on the possibility of a bioethics declaration, suggested the priorities of such an instrument should be meeting vital needs and increasing access to drugs (UNESCO 2003h: 4). Then the drafting group, at its first meeting, decided that the UDBHR should 'above all respond to the concerns of developing countries' (UNESCO 2004f: 3). By forming common regional fronts on some issues, these countries were able to voice their concerns relatively loudly, echoing Chasek and Rajamani's observations on the power of coalitions. This represented a compromise on states' individual views on certain points, in order to strengthen their negotiating positions overall. Describing the difficulties in balancing the national interest with broader concerns, the Kenya National Commission for UNESCO representative said, 'It's a challenge, because you as a country may be having certain inclinations, but we are also bound by what they call the "African Unity"' (interview with K_16). The South African delegate to the June IGE meeting also noted that people from the same region would speak with a common voice. They remarked that, on issues such as women and vulnerable communities, the Latin American countries, together with India, were the most vocal: 'So it seemed as if the world dynamics are still based on the developed and the developing worlds and it's the fact of life' (interview with SA_23).

The issue for which the regional groupings were most visible was social responsibility and health. This was initially introduced by the Latin American states and later also backed by the Asian and African Groups (interview with F_01). Carter Snead (2009: 213–4) writes, 'Most obviously, there was a very strong "development agenda" supported by the Group of 77 (G-77), the largest coalition of developing countries in the UN, who agreed to vote together for purposes of this negotiation.' A second written consultation, this time targeting IGOs, NGOs, national bioethics committees and independent experts as well as member states, had been launched in October 2004, to which only 31 member states and permanent observers responded (UNESCO 2005q). It was during this

consultation and a series of regional meetings towards the end of 2004 that the issue of social responsibility gained real prominence. Brazil and Paraguay argued strongly for a greater emphasis on a 'social agenda'. The former wrote, 'The draft text . . . is too narrow in scope in relation to the development of aspects connected to economic, social and cultural rights, which represent the "social agenda" of the draft declaration' (UNESCO 2005j: 2). Paraguay's response was in a similar vein:

> The Declaration has left out or has yet to include themes closely tied to bioethics, such as access to health care and drugs and the right to a life of dignity and a healthy environment. . . . A declaration cannot be universal if it leaves out these and other problems which affect perhaps the majority of the world's population, who are faced with poverty, hunger, illness, social exclusion and, in many cases, violence.
>
> (ibid: 7)

In the light of such comments, the IBC drafting group added an article on social responsibility to the draft text, the concept having previously featured in the preamble only (2005j: 3).

The formulation of the article came in for much discussion at the January 2005 IBC and IGBC meetings, where it was described by Justice Kirby, Chair of the IBC's drafting group, as softer than the 'right to health', but innovative (personal observation). Several Latin American delegates emphasized the importance of the article and argued that it should go further. Other participants thought that developmental goals were outside the remit of the declaration. The dichotomous opinions did not represent a straightforward split between North and South; Chile expressed the view that issues such as poverty and illiteracy were not bioethical issues, while Finland supported the inclusion of access to nutrition and water, seeing these as important in preventing ill-health (personal observations).

At the final IGE session in June 2005, developing countries are reported to have declared the article on social responsibility to be of 'paramount importance' (UNESCO 2005m: 6). It was approved by consensus by the meeting, a somewhat unexpected outcome given the previous opposition of some member states. Germany and the US, for example, had continually opposed the inclusion of articles dealing with social and economic development, not because they considered these issues unimportant, but rather as beyond the scope of bioethics and being dealt with in other fora (interviews with F_01 and F_02; UNESCO 2005k: 3–4 and 38). Moreover, the final article is more strongly worded than its original formulation, pronouncing 'the enjoyment of the highest attainable standard of health' a human right (UNESCO 2005s: article 14).

Snead sheds some light on this turn of events in his first-hand account of the negotiations, which had mirrored the split over cloning at the UN a few months before. The US found itself in a bind. With developing countries (most notably Costa Rica), it wished the UNESCO declaration to include a reference to respect for human life, which had been excised from earlier drafts. Its allies on the development issue opposed the reinstatement of this reference, for fear that it would

proscribe research on embryos. As a compromise, the US suggested a change of wording to the article on social responsibility, borrowing language from the WHO's constitution. The delegation explained that it had come to realize that the proposed declaration was not 'an academic or scholarly treatise on bioethics', but rather 'a more comprehensive document that was meant to express and acknowledge matters of human concern that arose at the nexus of science, medicine, and technology'. The suggestion proved acceptable to all (as did the re-insertion of the principle of respect for human life, in the interests of consensus) (Snead 2009: 210–18). This aspect of the declaration may help to dispel the belief, highlighted in Chapter 2, that 'universal' bioethics is in fact simply Western bioethics (interview with F_01; comment by Justice Kirby, IGBC meeting, January 2005 [personal observation]). Faunce and Nasu (2009: 316–17) have compared the social responsibility article, together with those on benefit sharing and transnational research (14, 15 and 21 respectively), with cosmopolitan norms.

While the Latin American countries were successful in keeping social responsibility on the agenda during the drafting of the UDBHR, this was not the case for every issue. Members of the Executive Board from Group III (Latin American and Caribbean states) had wanted the declaration to cover reproductive human cloning, sex selection, pharmacogenetics, germ-line interventions and beginning and end of life, but these were deemed too controversial (UNESCO 2004c: 4; UNESCO 2004e: 2). Developing countries as a whole were very concerned with intellectual property rights, but agreement on this subject was also considered impossible (interview with UK_01). (One participant at the IGE meetings commented that it was left out because it would 'bring a lot of politics', although the explanation given in the report of the June meeting was that it falls within the competence of other IGOs [interview with K_01; UNESCO 2005m: 3]). Overall, however, the declaration is seen to cover several themes particularly pertinent to developing countries. Indeed, those from Kenya involved in the drafting process declared themselves mostly satisfied with the final outcome (interviews with K_01 and K_16).

UNESCO considered the involvement of actors other than member states to be crucial to the drafting of the declaration. Its website read, 'only the participation of all the actors concerned could ensure that all the different perceptions of ethical and legal issues were taken into account' (UNESCO 2004o). As well as the invitation to make written comments on the third outline of the text in October 2004, there were comprehensive verbal consultations. Before even the first meeting of the drafting group, the IBC held an extraordinary session in order to gauge the opinions of 'the actors concerned' on the scope and structure of the proposed declaration (namely other IGOs, organizations such as the WMA and the Human Genome Organisation and national bioethics committees) (UNESCO 2004d: 1–6). At its eleventh session in August 2004, representatives of different 'religious and spiritual perspectives' gave presentations. This meeting also hosted a public discussion and was attended by more than 250 participants from 80 countries (UNESCO 2005b: 1). In 2005, national and regional expert consultations were held in several states, including Argentina, Mexico and Indonesia,

as part of an 'Ethics Around the World' project (UNESCO 2005h: 4; UNESCO 2005q). It was hoped that meetings would also be held in the African and Arab region, but this did not prove possible within the time available. Pharmaceutical companies were invited to make contributions at various sessions, but were 'quite quiet' (interview with F_01).

In terms of formal negotiations, other IGOs and non-state actors took part to a limited degree. Only 11 NGOs attended the two IGE meetings (UNESCO 2005e: 15; UNESCO 2005o: 17–18). The Provisional Rules of Procedure, published in February 2005, stated, 'All plenary sessions shall be held in public, unless the Meeting decides otherwise' (UNESCO 2005d: 3). The meetings were classified as category II, however, meaning that all observers had to be approved by the Executive Board. The Board approved the list of invitations in September 2004, fully five months before the rules of procedure were made public (personal e-mail, 16 March 2005). The only UN agencies other than UNESCO to attend the meetings were the World Trade Organization and the WHO, although IGOs had other opportunities to feed into the declaration, through the UN Inter-Agency Committee on Bioethics (UNESCO 2005e: 14; UNESCO 2005o: 16). At the Inter-Agency Committee's third meeting in June 2004, participants 'reiterated their full support for the drawing up of a declaration providing a universal ethical framework in the field of science and technology', but wished to clarify the scope of the declaration (UNESCO 2004g: 2). Their concerns on this front were carried through to the fourth meeting, in December 2004, when some committee members commented that the declaration 'should not go beyond the field of competence of UNESCO' (UNESCO 2005p: 1).

The low attendance of non-state actors at formal negotiations notwithstanding, the Director-General highlighted at the first IGE meeting in April 2005 the 'transparent and participatory nature of the elaboration process' (UNESCO 2005c: 1). Similarly, at the 2005 UNESCO General Conference, member states expressed satisfaction that the drafting process had been an open one, involving a wide range of actors (UNESCO 2005a: 2). The Director-General attributed this transparency partly to the availability of relevant documents on the UNESCO website, which he said made the drafting process open to 'the greatest possible number' (UNESCO 2005h: 1 and 7). At the January 2005 IBC meeting, the Chair of the drafting group, Justice Kirby, had declared that all documentation concerning the draft declaration would be put on the website, under a principle of transparency (personal observation). For ten Have (2005: 747), then Head of the Division of the Ethics of Science and Technology, this meant that people from 'the four corners of the world' were able to participate in the elaboration process, thereby 'nourishing intercultural dialogue'.

Those who had not been involved did not share these insider views on transparency. Even among those with ready internet access in Kenya and South Africa, several potential stakeholders had simply not thought, or had not had time, to look at the UNESCO website in connection with bioethics and genetics (interviews with SA_03 and SA_27 and informal conversations with geneticists in Kenya). One South African ethicist (SA_25) commented:

> You don't just want a faceless committee designing this. Maybe some of them do have experience, but why not make it an open process? What would be the problem with that? Why have they not involved individuals with expertise and wide recognition or standing in the international bioethics community?

Another (SA_19) said that the initial draft of a document such as the declaration should be drawn up by experienced committees, but then made open for public scrutiny 'in such a way that people know about it and it's readily accessible'. These sentiments are reflected in the bioethics literature. John Williams, then Director of Ethics at the WMA, in a September 2005 special issue of *Developing World Bioethics* devoted to the draft UDBHR, was critical of the fact that the version of the declaration approved by the June IGE meeting had not been through the same broad consultation procedures as earlier drafts (Williams 2005: 211). Macpherson (2007: 588) accuses UNESCO of having limited its consultations to its affiliates, thereby sidelining 'mainstream bioethicists' and the broader public. She found the documentation on the website hard to find and would have liked details on the deliberations behind the drafts, as well as the texts themselves. Snead (2009: 209) similarly laments that 'the substance of the deliberations was a jealously guarded secret'.

Whereas ten Have (2005: 746) has stated that 'the transparency and the active participation of all the actors concerned . . . has already largely contributed to the visibility and general acceptance of the text', Macpherson (2007: 589–90) feels that the declaration's credibility and impact have been damaged by UNESCO's failure to seek out or respond to peer review. Aside from the website's limitations, her main evidence for this failure is UNESCO's apparent ignorance of the September 2005 special issue of *Developing World Bioethics*. She also bemoans the lack of engagement with marginalized groups (ibid: 589). This echoes almost exactly the concerns of some of the Kenyan and South African interviewees in 2005-6 (K_07, SA_17 and SA_25). One (SA_17) commented:

> The declarations have made decisions for the international public, but which international public? I mean, for me, the research participants in South Africa are the rural research participants on the ground. How much have they had a say in terms of the declaration? Have we had our tribal leaders being involved in these discussions?

Howard Wolinsky (2006: 355) describes the negotiations as 'a dance between government and bioethics groups'. Although the texts of all three declarations were drawn up by the IBC, the body of independent experts, decisions on content of final drafts and whether they should be adopted ultimately lay with member states. (Similarly, it was states that determined whether the declarations should be drafted in the first place. When the IBC presented its report on the possibility of elaborating an instrument on bioethics to the IGBC, the latter was reminded that this was merely a 'feasibility study' and that it was for states to decide, at the General

Conference, whether the elaboration should go ahead [UNESCO 2003i: 8].) This was not without its problems. For the UDBHR (2005), some countries sent civil servants or embassy representatives (that is, members of the Permanent Delegations to UNESCO based in Paris) to the IGE meetings that finalized the draft, rather than bioethicists. Describing the relationship between experts and states as 'always a tension', a member of the Bioethics Programme said this meant that what had been put together logically and rationally by a body of non-state experts was then overridden in a political process by inexpert state representatives (interview with F_01). Attendees at the April and June IGE meetings corroborated this tension, with one observing that, although there were several non-state actors present, they had fewer opportunities to speak than the state representatives, even though they perhaps knew more about the subject matter (interviews with UK_01 and UK_02).

Another illustration of the tension is provided by the debate at the January 2005 joint IBC and IGBC meetings over whether the UDBHR (2005) and implementation guidelines for the IDHGD (2003) were to include reporting mechanisms, under which states would have to periodically inform UNESCO about measures taken to realize the declarations. A member of the IBC remarked informally that the committee would try to include more concrete obligations than in the past, but that this was a 'shot in the dark', as these would probably get watered down by states. Describing the room as having a metaphorical Red Sea down its middle that the meeting would have to try to bridge, Justice Kirby (Chair of the UDBHR drafting group) told those assembled that there would be some issues, such as the reporting mechanism, on which the two committees would take different views. The IBC members were independents, while the IGBC representatives were not, he said; each should fulfil their function, but it would be the states that would make the final decisions on such matters, through the political processes of UNESCO. The states duly decided at the June IGE meeting that it would be inappropriate to include any such mechanism in the UDBHR (UNESCO 2005m: 7–8).

Members of the two committees have diametrically opposed views on which was the more qualified to finalize the UDBHR. Justice Kirby (2010: 796) bewails the changes the IGBC made to the IBC's final draft: 'In part, some obfuscation must be laid at the door of the IGBC, and of the governmental representatives and so-called governmental "experts" who played with the IBC text, after it had been concluded.' He cites their changes to the text on informed consent as an example, which moved from broad principle to highly specific contexts, against the grain of trends in bioethics. By contrast, Snead (2009: 220), an IBC member from 2008–11 but the lead US representative at the joint IBC–IGBC meeting in January 2005 and the May and June IGE meetings, writes, 'It is worth noting that many of the flaws in the process of elaboration resulting from the work of the IBC drafting committee were (painstakingly) corrected by the subsequent negotiation and drafting sessions of the Government Experts.' ten Have (2006: 336) recognizes that having two bioethics committees is a challenge as well as a strength:

> Policy development and political decision making regarding bioethics need to be informed by expert scientific advice, and bioethical expertise, if it

wishes to be translated into policies and legislation, needs to be associated with politics. The unique link between IBC and IGBC also brings to light some of the difficulties with the connection between ethics and policymaking.

The human cloning debate

UNESCO's pattern of consultation on the governance of human cloning has been different from that on the three declarations. The debate has not been over the content of a legal instrument, the necessity of which is already recognized, but on whether there is even a call for such an instrument. There have been several opportunities for discussion since the debate launched in 2008, mainly at the regular meetings of the IBC and IGBC in September/October each year. The first opportunity came when the IBC's Working Group on Human Cloning and International Governance, consisting of members from Estonia, Israel, China and Egypt, met for three days from 30 June to 1 July 2008. One day was devoted to public hearings, to which experts and member states were invited, allowing 'transparency and clarity as per the work of the Committee' (UNESCO 2008d: 1). Twenty-six states plus the Holy See attended the hearings, the majority from developing countries, including eight Latin American and Caribbean states (Group III) and six African states (Group Va). All representatives were members of their country's Permanent Delegation to UNESCO in Paris (or Brussels in Malawi's case) (UNESCO 2008d, Annex II: 3–6). There were no outside observers, although one of the experts asked to give a presentation was from the WHO.

More states engaged in the IBC and joint IBC–IGBC sessions in October 2008, which discussed the Working Group's interim report (published in September) and heard further presentations by experts and stakeholders. Alongside the 35 (of 36) IGBC member states that attended, 38 non-IGBC states had representatives at the meetings (as observers), about half of which were developing countries. There were also several representatives of intergovernmental and non-state actors, such as the WHO, the European Commission and the International Council of Women (UNESCO 2008c; UNESCO 2008f). The IBC meeting included further public hearings on cloning, with presentations from members of the national bioethics committees of Indonesia, Madagascar and Brazil and the International Society for Stem Cell Research (UNESCO 2009d: 4). Claiming once again UNESCO's unique position in the field of bioethics, the report of the IBC meeting reads, 'Only through the multidimensional, multidisciplinary and multicultural reflection facilitated by IBC can sustainable solutions be devised for the complex ethical issues concerning cloning of human beings' (ibid: 1).

In its interim report of 2008, the Working Group had found that a new, binding instrument to ban human reproductive cloning was indeed justified, given developments in the field such as induced pluripotent stem cells (iPSCs), increasing commercial interest in the technology, growing public awareness, updated national regulations and ongoing concerns for the health of women and foetuses (UNESCO 2008h: 3–4). Participants at the October IBC meeting differed on whether there was likely to be a strong enough consensus on the need for a ban to

avoid a repeat of what had happened at the UN in 2005 and on whether recent scientific advances (especially iPSCs) were significant enough to warrant a new instrument (UNESCO 2009d: 5–6). Those at the joint IBC–IGBC meeting, which followed immediately, were similarly concerned to avoid a repeat of the UN debacle, but some emphasized how useful a binding international agreement would be to those developing countries which had not yet adopted national legislation on cloning and asked the committees not to shy away from ways to realize effective international governance (UNESCO 2010i: 12–13).

The Working Group erred on the side of caution in its final report of June 2009, concluding that a fresh international normative instrument would be premature, despite the potential benefit to those developing countries still lacking specific cloning regulations. Instead, it argued that increased and focused global dialogue, to include developing countries particularly, was 'crucially needed' (UNESCO 2009e: 7–8). This was endorsed by the IGBC at its sixth session a month later, where several participants noted that, because many developing countries lack 'a well developed national bioethics infrastructure', they benefit from international level discussions such as those at IBC and IGBC meetings. Nevertheless, some IGBC members asked that a disclaimer be added to the IBC report, to the effect that it expressed the views of the IBC rather than the official position of member states or UNESCO as an organization (UNESCO 2009f: 4).

On the advice of the IGBC, the IBC mandated an expanded Working Group to continue its work on cloning in 2010–11, focusing on three issues: (a) terminology, (b) dissemination and (c) options for regulation (UNESCO 2010g: 1). (The IGBC sixth session report states that the committee invited the IBC to 'further explore and elaborate different modalities and tools of soft regulation and governance' [UNESCO 2009f: 4]. In the official conclusions of the meeting this became a suggestion that the IBC review 'other possible options for its regulation' [UNESCO 2009b: 2]. The IBC moved back towards hard law, asking the Working Group to examine 'different options for legal regulation of human reproductive cloning (including the possibility of a moratorium)', after discussions at its sixteenth session in November 2009 [UNESCO 2010g: 1; UNESCO 2010j: 10].)

The Working Group presented a draft report at the IBC and joint IBC–IGBC meetings in October 2010. The Chair of the Working Group, Toivo Maimets, emphasized that it was indeed a draft and asked for a lot of input from the two committees. It was at a 'living document stage right now', he said (personal observation). The report put forward new terms and definitions for reproductive and therapeutic cloning, which it was hoped would be taken up by the scientific community. This was partly because existing definitions tended to refer to cloning by somatic cell nuclear transfer (SCNT) only and thus did not account for current and future developments in the field, such as iPSCs. Echoing those who have argued that reproductive cloning will not produce identical human beings (only people with the same nuclear DNA), the Working Group found definitions based on this premise to be 'scientifically incorrect'. It suggested keeping the term, given its widespread use in national and international law and guidelines, but

reformulating the definition based on intention, to 'using the linear DNA nucleotide sequence of an existing human being to create an embryo, which is implanted into womb with the purpose to produce human baby' [sic]. Somewhat inconsistently, it found the terms 'therapeutic cloning' and 'research cloning' misleading and therefore to be avoided, precisely because they are based on intention. As an alternative, the Working Group recommended terminology describing the process of obtaining pluripotent stem cells: 'derivation of pluripotent cells'. It stated, 'This terminology has an advantage of being descriptive, technically accurate, simple, easily understandable, and capable of incorporating any future scientific and technological developments' (UNESCO 2010g: 3–4).

Unfortunately, the IBC did not agree. It commended the Working Group for its work, but felt that terminology should encompass technology, procedures and intention (UNESCO 2011i: 6). One member suggested that the ethical issues cannot be dealt with holistically, but should be elaborated for each new technique developed. Others felt that if a certain process were allowed, it would be hard to regulate intentions for its use (one making the comparison with a nation's stated intent for nuclear power), while another said that to define one type of cloning according to process and another according to purpose was 'apples and pears' (personal observations, IBC meeting, October 2010). At the joint IBC–IGBC meeting there was general agreement that a clearer distinction between reproductive cloning and therapeutic cloning is needed, as current definitions are ambiguous and unsatisfactory, bringing confusion to decision-making. Germany and Syria drew a connection between terminology and regulation, thus linking two of the Working Group's areas of study. They argued that clear definitions are needed before international legislation can be developed (personal observations, IBC–IGBC meeting, October 2010).

The Working Group's 2010 draft report also pressed again for a binding instrument on human reproductive cloning (a convention or moratorium), citing sufficient consensus among governments to enable this. UNESCO would provide the best international platform to enact such an instrument, the report claimed, because of its standing in the field. This would sit alongside activities to encourage global discussion and debate (UNESCO 2010g: 6–7), but the IGBC showed no appetite for the former. Reporting on the joint IBC–IGBC session, the UNESCO website (2010d) states:

> IBC members were unequivocal in expressing concern that the recent scientific developments have raised a need for a binding international legal instrument. However, feedback by Member States of IGBC was indicative that the political hurdles that have prevented the realization of such instrument [sic] in the past are still in place.

The official report of the IBC meeting that took place earlier in the week (and which several IGBC members attended as observers) states that IBC members considered it 'imperative' to draw up a new legal instrument to ban human reproductive cloning as a matter of urgency, due to the speed of scientific

developments in the field juxtaposed with the time it would take to draft such an instrument. They also noted the need to thoroughly investigate the feasibility of such an enterprise (UNESCO 2011i: 6). At both meetings, several IBC members argued strongly for a convention specifically on human reproductive cloning, to be adopted as soon as possible, but members were not unanimous. Donald Evans, then IBC Chair, said at the beginning of the IBC discussion that it was time to 'get the boxing gloves out' and urged participants not to just be polite and say 'what we're supposed to say'. His opinion was that a convention or moratorium would require a very careful definition of the term 'reproductive cloning', specifying that the ban concerned the *bringing to birth* of a cloned embryo. In terms of the furore over other applications, he said, the ethical dilemmas cannot simply be defined away. He and Stefano Semplici, his successor as IBC Chair, were pessimistic about the chances of getting political agreement on a ban (personal observations, IBC and joint IBC–IGBC meetings, October 2010).

At the joint meeting, the US delegation (the first to comment) expressed puzzlement that the possibility of a convention was 'back on the table', thinking that this idea had been laid to rest in the 2009 report. They reiterated that such an initiative would be premature and advocated continued dialogue instead, coupled with support for states in developing regulations and policies. Germany and Brazil agreed, endorsing the *status quo*. Germany argued that existing regulations should be preserved and reinforced, not watered down, while Brazil described the current situation internationally as 'very comfortable', as it bans reproductive cloning but allows therapeutic cloning; UNESCO should instead focus on awareness-raising about the risks of cloning. This triumvirate prompted one of the IBC members to question why they considered a ban premature in 2010, but not in 2001 when the idea was first mooted at the UN (personal observations, IBC–IGBC meeting, October 2010).

Côte d'Ivoire disagreed that a convention would be premature, but was concerned about the possibility of a moratorium, as this would only postpone progress; a normative instrument giving shape to cloning and allowing it to develop would be welcome. Madagascar's representative made a similar plea. They questioned the Working Group's conclusion that there was international consensus that human reproductive cloning should not happen and insisted that the science should be allowed to develop. Scientific discovery is not about 'playing God', they said, but about understanding him better so that we can love him more. God knows this and knows when to put limits on human activity; scientists also know where to stop. Lebanon agreed that barriers cannot be put on scientific and human progress, as this is how mankind evolves, but considered this a reason for UNESCO to be vigilant, rather than employ a 'wait and see approach' to whether ethical values are respected in how research is applied (personal observations, IBC–IGBC meeting, October 2010).

Other states took a more pragmatic approach to the debate. Nigeria recognized that cloning already takes place with animals and plants and might have some use in medical applications, such as the replacement of diseased tissues and organs. The delegation described its position as in line with the Council of Europe and the

WHO, in that the country does not subscribe to human reproductive cloning. It had decided that the issue was to be placed 'on the front banner', through a consultation involving all stakeholders, to encompass the totality of views of Nigerians. Kenya took the middle ground. It recognized that previous attempts at international governance have failed, but highlighted UNESCO's role as a standard setter; as several developing countries still lack regulations on cloning, UNESCO should disseminate information that will help states to develop legislation where appropriate. Switzerland also made links to dissemination, the third strand of the Working Group's mandate for 2010–11. It proposed an international conference as a good way of defining the kinds of actions that need to be taken. This would also afford the opportunity for a deeper international dialogue to rebuild the international governance framework. Switzerland itself would not find a convention problematic, subject to a discussion of what form it would take. The delegation also underlined the risks associated with conventions, in that they are only binding on those states that ratify them (personal observations, IBC–IGBC meeting, October 2010).

The Working Group was to finalize its report for the eighteenth IBC session in May 2012, but instead presented a draft 'final statement' repeating the recommendations of the 2010 preliminary report and adding that 'technical manipulations of human embryo, either for research or therapeutic purposes' [sic] (that is, what is commonly understood as therapeutic or research cloning) should continue to be regulated at national rather than international level, according to social, historical and religious contexts (UNESCO 2011d: 3). The IBC chose not to adopt the statement because of the 'divergent positions' of its members on both the ethics and governance of human cloning (UNESCO 2011f: 4). By this point several IBC members appeared to be tiring of the topic. They felt that, as political consensus on a ban remained elusive, the committee could not go any further in its deliberations. One said that if they left the debate open, they could still be debating the same points in ten years' time (personal observations, IBC meeting, May–June 2011).

Some in the IBC would have liked to adopt the final statement as the culmination of its work in this area, including Maimets, the Chair of the Working Group. He was not overly optimistic that an international ban or moratorium could be achieved after the UN fiasco in 2005, but pointed out that it was for governments rather than the IBC to decide whether to take this forward. What the committee could say, as a body of independent experts, was that it does not support human reproductive cloning. Others opposed this. For the first time, ethics entered the debate (which the Working Group had been asked to steer clear of in its original mandate). Some members questioned the hitherto uncritical acceptance that reproductive cloning was undesirable and hence that the only barriers to a ban were political. Citing reproductive freedom, they felt that the philosophical arguments against cloning based on genetic determinism and the impact on the cloned child were not strong enough to justify a ban. These issues were not addressed in the draft statement, but one member argued that, as an ethical rather than political body, the IBC should be prepared to give at least a brief explanation of the ethical rationale for a ban (personal observations). This ethical turn was

alluded to by Semplici, the incoming IBC Chair, in his progress report to the IGBC at its seventh session in September 2011. He commented that the IBC had been unable to endorse the draft final statement because this would require a strong ethical argument against the use of SCNT for the purposes of producing a child, which the IBC considered a very challenging undertaking, without any promise of agreement (personal observation).

As the IBC always operates by consensus but could not agree on whether or not to adopt the draft statement, it was dropped by default. Evans, as outgoing Chair, explained to the IGBC in September 2011 that there had been some pressure at the IBC's meeting earlier in the year to go to a vote, but that he had resisted this. He also stated that he believed there would never be consensus on a ban, because the issue was a philosophical rather than scientific one, concerning the legal status of the early embryo. The IBC had not 'come up with the wisdom of Solomon' on this point (personal observation, IGBC meeting, September 2011). The IGBC largely agreed. The Danish representative thought it better to have a thorough report (from 2009) and leave it at that than to try in vain to reach a consensus. The US and Austrian delegates echoed these comments, saying that a tremendous amount of work had been done already and further headway might prove difficult. Lebanon felt that UNESCO should slow down rather than give up the issue completely as, despite its complexity, the academic community may be able to reach conclusions based on consensus in the longer term. Japan also felt that UNESCO should 'keep in touch' with cloning (personal observations, IGBC meeting, September 2011). The official conclusions of the meeting note the importance of the topic, but also the lack of consensus among both states and IBC members. Thus the IGBC merely 'encourages UNESCO, with the assistance of IBC as appropriate, to continue to follow the developments in this field in order to anticipate emerging ethical challenges' (UNESCO 2011c: 2–3). Consequently, the 2012–13 IBC Work Programme relegates cloning to monitoring by one or two IBC members, who are to report any significant developments in the field to the committee and thereby the Director-General (UNESCO 2012m).

Perspectives on cloning from sub-Saharan Africa

The Permanent Delegations (PDs) and National Commissions (NCs) which answered questionnaires in 2012 echoed several of the opinions on cloning voiced in the IBC and IGBC meetings. Most commissions supported the idea of a convention to ban human reproductive cloning. One West African NC wrote that, because African countries see science as key to development, without such conventions 'ethical ills would continue to be on the rise'. A Southern African NC believed a convention would help countries to adopt regulations on human cloning, even though it is not yet an issue in their region, due to lack of human cloning technology. Another Southern African NC thought that a convention would be useful as, in developing countries, it is only scientists who are interested in such issues, which makes it difficult to monitor and enact laws to prevent or regulate such practices. A third confirmed that conventions are useful in setting

normative parameters that can be domesticated at national level, as did its PD, which favoured a convention over dialogue. Only one country, from West Africa, did not support a convention. Both its NC and its PD felt that international dialogue should come first, which should be 'based on full understanding of all issues involved, including the usefulness of such a convention to the developing countries'. Other respondents supported dialogue alongside a convention, as 'both are equally important as they are interdependent' and dialogue 'keeps states on their toes', enabling education and sensitization, sharing of perspectives and experiences, consensus building and (echoing the Lebanese delegate) eventual agreement on international standards. An East African PD added, 'In this interconnected world, no issue may be dealt with in isolation. Countries have to fully cooperate for tangible results.'

Opinions also differed on the ethics and usefulness of cloning. Like at the IGBC meetings, respondents were not unanimous in rejecting reproductive cloning. Illustrating the remoteness of the issue for some developing countries, as noted by Arsanjani, two NCs, from East Africa and Southern Africa, did not know the issue was being debated at UNESCO and did not feel qualified to give an informed opinion. A West African NC respondent gave their personal view that cloning is not ethically right and so should not be promoted in the guise of development. A second Southern African NC, focusing on reproductive cloning, did not think cloning technologies would make an important contribution to development, because 'for African countries we already have high birth rates which increases the probability of getting all the relevant skills which may be required'. A West African PD made a similar point, but with a more negative spin: 'Not as it pertains to duplication of human beings in an already overpopulated world in a highly degraded environment.' Its counterpart NC simply said, 'Developing countries are yet to buy into cloning.' Likewise, a third Southern African NC commented, 'The positive results are not yet clear to developing countries.' Its PD gave a different view, believing that cloning technologies could make an important contribution to development, if accessible and affordable. It warned, 'In the contemporary world, many technologies exist that could address many development needs in many countries but their contribution is minimal due to high costs and restricted access.' The fourth Southern African NC also saw promise in cloning technologies, if applied appropriately: 'they must be regulated and used in a manner that respects human rights, peace and security'.

Within UNESCO's Bioethics Programme, relations between North and South and between state and non-state actors are ostensibly equal – or at least balanced – at international level. The organization has put in place rules and procedures to ensure that all states, along with experts and stakeholders in bioethics and genetics, have the opportunity to be heard. Nevertheless, representation from developing countries has been disproportionately low at intergovernmental meetings and the ultimate power held by states has created something of a two tier system of

decision-making between them and non-state experts. This was particularly apparent during the negotiations on the *Universal Declaration on Bioethics and Human Rights* in 2004–5, but has also been a feature of the discussions on human cloning. The need to heed all voices and yet achieve consensus has had a substantive impact on the content and nature of UNESCO's bioethics instruments (existing and potential), as explored in the next chapter.

5 Implementing bioethics

UNESCO's efforts to realize and enforce the declarations

The three declarations – the *Universal Declaration on the Human Genome and Human Rights* (1997), the *International Declaration on Human Genetic Data* (2003) and the *Universal Declaration on Bioethics and Human Rights* (2005) – are by nature non-binding. They are, nevertheless, the product of an intergovernmental body and thus qualitatively different (some would claim) to the bioethics guidelines and codes of conduct devised by professional organizations. This has implications for what UNESCO can demand of its member states and, conversely, what member states can expect of UNESCO. Focusing especially on dissemination and capacity-building activities, this chapter examines the content and strength of the UNESCO norms and the organization's efforts to ensure they are realized. It also assesses the degree to which these efforts overlap with those of the WHO and the potential long-term repercussions of UNESCO's failure to agree on a binding convention on human cloning.

The nature and content of the declarations

UNESCO gave very similar reasons for the choice of a declaratory rather than conventional (binding) format for all three declarations: first, declarations are generally adopted more quickly than conventions; second, states would be more likely to agree to non-binding norms; and third, greater flexibility might be beneficial in the rapidly changing fields of bioethics and genetics. For the UDHGHR (1997), the IBC decided:

> An instrument not requiring ratification, accession or acceptance, is likely to be adopted more quickly than a formal agreement, whereas the binding nature of a convention could well discourage certain States from committing themselves in so complex and changeable an area.
>
> (UNESCO 1999a: 79)

For the IDHGD (2003), it was thought that a declaratory instrument would not only facilitate consensus during the negotiation period, but also 'allow for adaptations in a domain where the variety of situations covered, and the complexity of the subject, is constantly evolving with new scientific discoveries' (UNESCO

2003k). For the UDBHR (2005), the IBC again argued that a declaration would have the greatest impact, because it 'would be better adapted to a constantly changing environment and would enable a broader consensus among Member States to be achieved rapidly' (UNESCO 2003i: 7–8). The views of a Kenyan official at the Ministry of Foreign Affairs chimed with this reasoning. They corroborated that states are more likely to agree to declarations than conventions. As Kenya would not be legally bound by a declaration, they said, it would not be too worried if not all its requirements were met during negotiations (interview with K_30).

Declaratory instruments were also considered appropriate because states would be able to interpret them as they saw fit within their national contexts. UNESCO's aim has been to elaborate universal norms that take account of the different traditions of its member states. Accordingly, the UDHGHR (1997) is intended to 'transcend different cultural, political and religious sensitivities' (UNESCO 1999a: 28). Lenoir (1998–9: 546) has claimed that the UDHGHR is 'on another plane' to European directives on genetics, as it 'does not seek to govern specific practices; rather, it spells out universally-accepted ethical principles'. (During the drafting of the declaration, by contrast, Alastair Iles [1996: 43] had predicted that the declaration would be 'constrained in its vision and transformative potential' because of the need to accommodate 'vast cultural and political diversity'.) For the IDHGD (2003), 'the declaratory form of the instrument was chosen for its appropriateness in the elaboration of principles that States can interpret taking into account their legal systems and different cultural, economic and social circumstances' (UNESCO 2003c: 3). The General Conference commissioned a similarly balanced approach to the drafting of the UDBHR (2005), judging that universal standards were needed in bioethics, but that these should be set 'in the spirit of cultural pluralism inherent in bioethics' (UNESCO 2004p: 47).

In order that these mandates be fulfilled, the declarations contain only general principles, to which all states were able to agree without conceding their cultural and political particularities. Andorno (2007: 150), a member of the IBC during the drafting of the UDBHR, writes of the declaration, 'Regardless of the weaknesses inherent to this kind of instrument, the very fact that virtually all states reached an agreement in this sensitive area is in itself a major achievement.' This resonates more with Young's observations about the messy process of regime negotiation than with Victor *et al.*'s on non-binding agreements encapsulating less compromised standards than binding ones. Articles in the declarations are more or less specific, depending on the issue concerned. Some appear reasonably detailed. All three declarations, for example, lay out guidelines for authorization for research with persons without the capacity to consent and the IDHGD (2003) and UDBHR (2005) offer concrete suggestions on what benefit sharing might actually entail, such as provision of new diagnostics and drugs or capacity building in data collection and research. Even so, these are minimal in comparison with the equivalent sections of the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002) of the Council for International Organizations of Medical Sciences (CIOMS), which run to several paragraphs.

A significant feature of the UDHGHR (1997) is that it says of the human genome, 'In a symbolic sense, it is the heritage of humanity' (article 1). Although UNESCO considered this conceptually innovative, the stronger formulation 'common heritage of humanity' was used in earlier drafts, a recognized term in international law (as applied to the sea and outer space, for example) and the one adopted by the Human Genome Organisation. Lenoir (1996), as president of the IBC, described the application of this legal term to the human species as 'the main originality' of the draft declaration. Member states made the change, concerned that the idea of 'common heritage' could be misconstrued to justify the appropriation of human genetic sequences for commercial purposes (Andorno 2003: 107). Relatedly, they added article 4 on commercialization just before the declaration was adopted: 'The human genome in its natural state shall not give rise to financial gains' (UNESCO 1997; Knoppers 1999: 24). This was in response to developing countries wishing to protect their genetic resources (Lenoir 1998–9: 553). While the article would appear to guard against gene patenting, the phrase 'in its natural state' renders it ambiguous in Andorno's eyes: 'Given that the ethical and legal problem is raised precisely by the patenting of human DNA sequences in something other than its natural form, . . . the Declaration gives the impression of having eluded the real problem' (Andorno 2003: 111). Kluge (2003: 124) makes a similar criticism, arguing that the article could be interpreted to justify gene patenting on the grounds that this concerns only parts of the human genome, which if separated from 'their contextual DNA' would not be in their natural state.

Several commentators have criticized the declarations for being vague and indeterminate (Taylor 1999: 510; Abbing 2004: 93; D. Benatar 2005: 221; Harmon 2005: 33; Landman and Schüklenk 2005: iv; Williams 2005: 213). IBC members, by contrast, have framed the declarations' generality more positively, as a necessary step in reaching an international consensus, from which states can draw in making more firm regulations (Andorno 2002: 960; Butler 2004: 369). Loretta Kopelman (2009: 262–70) takes the middle ground. The UDBHR (2005) fails in philosophical terms, she says, because it does not justify, rank, clarify or specify its principles, but its very vagueness may help to stimulate high quality public discourse among people of different backgrounds, of the kind Slaughter endorses. William Sweet and Joseph Masciulli (2011: 13) similarly defend UNESCO's use of the term 'human dignity', without definition, in all three declarations. They believe this is key to the 'global moral response' needed to advances in biotechnology, as it conveys the sense that human beings can never be used merely as means and are fundamentally equal. Andorno (2009: 228) also credits the UDBHR with making a 'significant contribution' to our understanding of the concept of dignity, as follows:

> The promotion of respect for human dignity constitutes not only the main purpose of the document (Article 2.c) but also the first principle that should govern biomedical issues (Article 3), the rationale for the prohibition of discrimination and stigmatization of individuals or groups of individuals

> (Article 11), the framework within which cultural diversity is to be respected (Article 12), and the interpretative principle for a correct understanding of all the Declaration's provisions (Article 28).
>
> (ibid: 234)

UNESCO puts great store by the fact that the declarations have been a dopted by consensus, believing this to confer on them normative legitimacy. Lenoir (1998–9: 558) wrote of the UDHGHR (1997) soon after its adoption:

> The active involvement of the states in the process of preparing the Human Genome Declaration is undoubtedly the best guarantee of its future effectiveness. The discussions were heated at times, and, naturally, the balance offered by the text remains fragile. Paradoxically, this fragility and controversy make the Human Genome Declaration's unanimous acceptance even more significant.

ten Have (2006: 341–2) has made a similar claim of the UDBHR (2005): 'The unanimous adoption by the member states is not merely symbolic but gives the declaration moral authority and creates a moral commitment.' This was echoed by the Bioethics Programme leader at the IBC's meeting of 31 May to 2 June 2011, who said that it had been a big achievement to get agreement among diverse countries and that it was particularly significant that a declaration on such a sensitive issue as bioethics had been adopted by acclamation, as this was not common practice (personal observation).

Yet the emphasis on decision-making by consensus can also be seen as a weakness. A number of issues arose during the drafting of the UDBHR (2005) that proved difficult or impossible to resolve. Group I (Western European and North American) and Group IV (Asian) states were at odds over whether the declaration should extend to the biosphere or be limited to humans and a definition of the term 'bioethics' had to be dropped because consensus on wording and scope could not be reached (UNESCO 2005m: 2–3). Of most relevance to research ethics was the furore over an article on risk assessment. States were unable to agree whether or not it should incorporate the precautionary principle (that is, that practices that have not been proved to be safe should be avoided). The eventual resolution at the June 2005 IGE session epitomizes many regime negotiations. The official records of the meeting state, 'The meeting decided to retain the article by amending it in such a way as to formulate a general principle without going into detail' (UNESCO 2005m: 7). Hence the article's rather nebulous wording:

> Appropriate assessment and adequate management of risk related to medicine, life sciences and associated technologies should be promoted
>
> (UNESCO 2005s: article 20)

as compared with draft formulations, for example:

> When scientific evidence of serious or irreversible damage to public health or human welfare or the environment is not sufficient, provisional, adequate and proportionate measures shall be taken in a timely manner. Such measures shall be based on the best scientific knowledge available and on procedures that are specially designed for evaluating the ethical issues at stake. These measures should be carried out in accordance with the principles set out in this Declaration and with respect to human rights and fundamental freedoms.
> (UNESCO 2004b: 8)

Despite the non-binding nature of the declaration, then, the 'lowest common denominator' effect could not be avoided in this case. This was affirmed by a member of the Bioethics Programme secretariat, who said:

> We had an article on risk management, which was in fact arguing the precautionary principle without mentioning it. And then some of the delegations, they took the whole text out and they changed it for a very general text, which has been accepted. So now the text there is an open door, it's just a generality.
> (interview with F_01)

How controversial issues in bioethics might be included in the text also proved irresolvable (Macpherson 2007: 589; Snead 2009: 210). Thus no mention is made of gene therapy or stem cell research, for instance. Instead, general and procedural principles are intended to provide a basis for 'the search for common positions' on issues for which no such position could be found in specific terms (UNESCO 2004k: 1 [quoted]; Snead 2009: 221). The IBC tried to make provision for these issues to figure in future revisions to the declaration, with the following clauses:

> 31 (c) Five years after its adoption and thereafter on a periodical basis, UNESCO shall take appropriate measures to examine the Declaration in the light of scientific and technological development and, if necessary, to ensure its revision, in accordance with UNESCO's statutory procedures

and

> 31 (d) With respect to the principles set forth herein, this Declaration could be further developed through international instruments adopted by the General Conference of UNESCO, in accordance with UNESCO's statutory procedures.
> (UNESCO 2004b: 10)

The governmental representatives removed the clauses at their June 2005 IGE meeting, however, considering them inappropriate (UNESCO 2005i: 7–8). Thus it appears that the declaration will be less flexible in a 'constantly changing environment' than the IBC initially hoped (UNESCO 2003i: 7–8).

The normative power of the declarations

Although the declarations, by definition, cannot be binding on member states, what states might seemingly be obligated to do was still of concern during negotiations. There was substantial debate during the drafting of both the IDHGD (2003) and the UDBHR (2005) over whether states 'shall' or 'should' implement their principles. At the IDHGD IGE meeting, the experts representing their governments 'agreed that insofar as possible the word "shall" would be replaced by "should" or by "may" in the text of the preliminary draft'. Only in relation to the IBC and IGBC was 'shall' retained (UNESCO 2003c: 4). For the UDBHR, some states felt that 'shall' could be used as an indication of moral commitment, without compromising the non-binding nature of the text, while others, including the US, Canada and Germany, were adamant that only the conditional form was appropriate within a declaration, except in regard to actions prescribed for UNESCO (interview with UK_01; UNESCO 2005c: 3; UNESCO 2005j; Snead 2009: 210). A more specific example concerns the free flow and sharing of scientific and technological knowledge. An article in the draft UDBHR asserting that states should 'make every effort to guarantee' these was softened so that they should merely 'encourage' them, after several member states of the IGBC (namely Canada, Germany, Saudi Arabia, Latvia and the US) objected to the stronger formulation at the IBC–IGBC meetings in January 2005 (UNESCO 2004b: 9; personal observations).

UNESCO places a high value on the commitment of states to the implementation of the declarations that each of the texts articulates. Jan Helge Solbakk (2007), chief of the Bioethics Programme from 2007 to 2008, remarked in a presentation on the UDBHR that this commitment made the declaration 'harder than soft law', in that it differed from a document like the *Declaration of Helsinki* of the World Medical Association (WMA), which can have only moral weight. Macklin (2005: 244) agrees, seeing the UDBHR's 'greatest strength' in its 'stature as an international declaration issued by a United Nations Organization'. Andorno (2009: 225–6) similarly places emphasis on the declarations' intergovernmental origins. He refutes the idea that their non-binding nature reduces them to 'purely ethical or rhetorical recommendations deprived of any legal effect'. Echoing Goodin (p. 39), he sees the declarations as 'potentially binding', as states gradually take them on board. ten Have (2005: 746) goes further, claiming that the value and strength of the UDBHR 'are in no way diminished' by its non-binding nature. 'For the first time in the history of bioethics,' he writes, 'all States in the international community are solemnly committed to respect and to implement the basic principles of bioethics, set forth within a single text.'

The three declarations vary slightly in what is expected of member states in terms of compliance. While several articles of the UDHGHR (1997) allude to national law in relation to research ethics, confidentiality and reparation for damage, the section on promotion of its principles requires states to do this 'through education and relevant means' and 'all appropriate measures' (whatever those might be), rather than through codification *per se* (UNESCO 1997: articles

20 and 22). In her paper published soon after the adoption of the declaration, Lenoir (1998–9: 546 and 548) stated that its primary purpose is to enable states to enact legislation. Yet she went on,

> Their [states] commitment is, above all, political and moral. It is also motivated by the advantage that states and the scientific community saw in introducing stability into a field which is strongly affected by the vagaries of the public response to new discoveries. States saw a need to establish points of reference which could serve as guidelines for researchers, practitioners, and policy-makers.
>
> (Lenoir 1998–9: 553)

In the IDHGD (2003) and the UDBHR (2005) the legislative push is stronger: states are to 'take all appropriate measures, whether of a legislative, administrative or other character', to give effect to the declarations' principles (UNESCO 2003b: article 23; UNESCO 2005s: article 22). This stipulation is reinforced in the UDBHR, one of its stated aims being to provide a universal framework to guide states in formulating legislation, policies or other instruments on bioethics (article 2(a)).

In several of its reports concerning the declarations, UNESCO refers to the practice within the UN of first adopting a declaration and then following up with a binding instrument at a later date (as was the case with the Universal Declaration of Human Rights and the subsequent covenants on civil, political, social, economic and cultural rights). Lenoir (1998–9: 549–50) noted that the UDHGHR (1997) was intended as a precursor to a convention, although there was 'no guarantee' this evolution would happen. Federico Mayor, former Director-General of UNESCO, wrote in the preface to UNESCO's 1999 book on the history of the UDHGHR, 'Eventually, UNESCO should perhaps, on the basis of a searching evaluation of the measures taken and the prevailing situation, take the initiative once again so as to entrench the principles enshrined in the Declaration more firmly in law' (UNESCO 1999a: III). Mayor's use of the word 'eventually' is telling. A member of the Bioethics Programme, when interviewed in 2005, thought it might be possible to combine the 1997 and 2003 genetics declarations to form a convention in the future, to include a prohibition on cloning, but said that this would depend on the global political climate; for conventions, they observed, 'the politics is much heavier' (interview with F_01). Another member of the Programme, interviewed in 2011, did not believe this development would unfold, as it would entail several difficulties and disagreements (interview with F2_03).

Implementation and enforcement

In his book on environmental politics, *The Global Commons*, Vogler (1995: 152) states, 'The question of effectiveness should be at the heart of any discussion of regimes.' Andreas Hasenclever *et al.* (1996: 178) explain how this effectiveness is measured: 'First, a regime is effective to the extent that its members abide by its

norms and rules. Second, a regime is effective to the extent that it achieves the objectives or purposes for which it was intended.' The real key to whether UNESCO's declarations can be successful as instruments of governance lies in the extent to which they are taken up by states and other actors; having formalized norms is only a first step. Koïchiro Matsuura made this point in his speech as Director-General of UNESCO at the first meeting of the IBC after the General Conference had approved the UDBHR in 2005. He said, 'Its adoption is just the beginning. To give full life to the Declaration and render it effective, the most important part of the work remains to be done' (UNESCO 2005a: 3). This section examines UNESCO's attempts to ensure its member states take up the bioethics and genetics declarations. 'Harder than soft law' they may be, but UNESCO's implementation activities tend to take a management approach, aimed at encouragement and facilitation.

UNESCO's capacity-building activities

Dissemination

One of UNESCO's foremost activities in promoting the declarations is dissemination, in order that they reach as wide an audience as possible. Within two years of its adoption, the UDHGHR (1997) had been distributed to IGOs and other international institutions, UNESCO National Commissions, Permanent Delegations and field offices, ethics committees, universities, NGOs, the media and various specialists, through brochures (120,000 copies), posters, journals and conferences (UNESCO 1998b: 29 and 53–4; UNESCO 1999b: 2–3). By October 2001, half a million copies of the declaration had been published, in 20 languages, more than 80 articles on the declaration had been written worldwide and over 40 television and radio interviews had been given. The International Society of Bioethics awarded its 2002 Prize to UNESCO, for its work on the UDHGHR and in bioethics in general (UNESCO 2001a: 6–7). The second declaration, the IDHGD (2003), is perhaps less well-known. Almost two years after its adoption, many countries were 'not even aware that there is such a declaration', said a member of the Bioethics Programme in September 2005. Portugal, Israel and Turkey were exceptions, where IBC members had liaised with their National Commissions to provide local translations (interview with F_01).

Since 2005 the Bioethics Programme has focused particularly on dissemination of the UDBHR. By 2007 the declaration had been translated into 24 languages (none African) on top of UNESCO's six official ones (Arabic, Chinese, English, French, Russian and Spanish), in cooperation with National Commissions (UNESCO 2007e). At the joint IBC–IGBC meeting in October 2010, Evans stressed that dissemination was UNESCO's most important activity. As the declarations and other publications are costly to produce (in terms of airfares, for example), it is imperative that they do not just gather dust, but rather take root in the lives of people around the world. The declarations must actually make a difference to how states view their citizens with regard to science and technology,

he said. They should also have an impact on institutions, as they are not addressed exclusively to states. But, at a world conference of universities he had recently attended, only one of 1,000 delegates had heard of the UDBHR (personal observations).

At the same meeting, IBC and IGBC members suggested several ways to raise the profile of the declarations. Some said that members of both committees had a responsibility in this regard and should try to ensure that local and regional UNESCO offices publicize the declarations to schools, universities, the general public and, in the case of IGBC members, governments. Two IBC members pointed out that, as independent experts, they have no official mandate to work under UNESCO's umbrella, leaving a question mark over their role that hinders such efforts. Echoing Held's observations about chains of delegation, the need for better communications between (a) the Bioethics Programme secretariat and National Commissions, (b) the secretariat and national bioethics committees (NBCs) and (c) National Commissions and ethics bodies within their countries was also highlighted. This would give national level institutions a bigger role in distributing the declarations and, crucially, adapting information to the local context. As one Latin American IBC member explained, documents may be on the internet, but access is not always easy or part of a society's culture (personal observations, IBC–IGBC meeting, October 2010).

In answer to the comments about NBCs, the Bioethics Programme chief responded that some are still very young and thus need to be built up further before they can fully engage with the public, although awareness-raising events always form part of their training (see below). An African IBC member sounded another note of caution in this regard. NBCs can function as hubs for exchanges of experiences and capacity building, they said, but goodwill is insufficient: networking requires resources. Sometimes NBCs are ignored by authorities or exist on paper but have no premises, so UNESCO also needs to work more with decision-makers (personal observations, IBC–IGBC meeting, October 2010).

The Bioethics Programme secretariat, despite having a small staff, makes a plethora of information on its activities freely available on the UNESCO website. But when it comes to actively distributing materials to member states, there can be problems. Members of the Programme interviewed in 2005 (F_01) and 2011 (F2_03) explained that they cannot be sure whether information is always getting to the most appropriate government departments, because UNESCO deals primarily with ministries of education (where National Commissions often sit), even though these might not be the most natural ports of call with regard to bioethics and genetics. This can also be the reason behind communication problems between National Commissions and existing NBCs, several of which have been developed through ministries of science and technology or health (interview with F2_03). This issue was discussed informally by attendees at the IBC's eighteenth session in May–June 2011. It would be natural for a health ministry to hold an event on bioethics, they said, but if organized through a National Commission the official host would most likely be the ministry of education. Persuading an education ministry of the importance of bioethics might

not be easy, but it would be diplomatically awkward for a ministry of health to take the lead.

Several committee members also raised the issue of language at the 2010 joint IBC–IGBC meeting, saying that more translations of UNESCO documents are needed if they are to reach the widest audience possible. One IBC member from an Arab state used the ironic example of a 2008 report on bioethics in Arab countries being available in French and English but not Arabic. The Kenyan IGBC representative appealed for the UDBHR (2005) to be translated into Kiswahili, which is widely spoken in sub-Saharan Africa and one of the official languages of the African Union. Members also felt that more could be done to engage the public through the mass media (although another Arab state IBC member warned that messages have to put together carefully, since some people in developing countries are not entirely trustful of international organizations, seeing them as a new form of colonialism). The IGBC Chair wanted to see bioethics on YouTube and Facebook, to reach young people. The following year, at the IGBC's September meeting, he asked how UNESCO could particularly target the main stakeholders. The head of the Bioethics Programme replied that in 2012–13 they would be focusing on the media, parliamentarians and judges, as well as civil society. The Programme is trying to reach out to both decision-makers and the general public in new ways, such as television and the internet, in collaboration with UNESCO's information and communications and external relations sectors (personal observations, IBC–IGBC meeting, October 2010 and IGBC meeting, September 2011).

As well as the declarations themselves, UNESCO disseminates reports by the IBC, which give guidance on particular articles. Lenoir (1998–9: 575) has described this role of the IBC, mandated in articles 24 of the UDHGHR (1997) and 25 of the UDBHR (2005), as unique, because it is an independent body. Héctor Gros Espiel made a similar point in his 1998 report to the IBC on the implementation of the 1997 declaration:

> The Universal Declaration on the Human Genome and Human Rights is innovative in that it entrusts the IBC with a role in the monitoring of its implementation. It is, indeed, the first document of a declarative nature that stipulates the existence of a system of follow-up and implementation.
>
> (UNESCO 1998b: 28)

Since member states sometimes arrive at a formulation for an article that is 'open to multiple interpretations', one of the IBC's duties is to work out how to go from 'the very general level of the principle to much more practical guidelines, how to do it in different countries and cultures' (interview with F_01). The aim is to produce usable, practicable documents that will guide states, institutions and individuals in operationalizing the declarations, rather than academic treatises (comments by Donald Evans, IGBC meeting, September 2011 [personal observation]). To this end, a new series of reports was launched in 2008, on the principles of the UDBHR (2005). The report on informed consent provides

explanations of the relevant principles in the UDBHR and gives examples of how they might be applied in certain contexts (UNESCO 2008g), while the report on social responsibility and health outlines 'possible concrete strategies and courses of action' for translating the principles of article 14 into specific policies (UNESCO 2010h: 5).

In the biennium 2008–9, the IBC began to explore issues around article 8 of the UDBHR, on human vulnerability and personal integrity. It continued this work in 2010–11. The topic garnered considerable discussion and disagreement at meetings, demonstrating some of the difficulties of operating by consensus. The final report contains no definition:

> Attempts to define vulnerability in general risk drawing the concept too widely or too narrowly, thereby triggering disputes rather than resolving them. In most cases, however, it is relatively easy to recognise vulnerability when it arises: something fundamental is indeed at stake.
>
> (UNESCO 2011g: 2)

This was because neither the assigned working group, nor the IBC more broadly, could agree on one (echoing the debate over the definition of 'bioethics' during the UDBHR negotiations). At the IBC and IBC–IGBC meetings in October 2010, some IBC members were concerned that it would look weak to write a report but not be able to say what it was about, but others applauded the working group's decision not to get bogged down with a complex philosophical discussion, which might have alienated prospective readers. IGBC members were similarly split (personal observations). Nevertheless, the final report was welcomed by states at the IGBC meeting in September 2011, with the representative of the Dominican Republic commenting that it would be an extremely useful tool in developing countries lacking services and legislation, where people have been exploited in clinical trials and stem cell research (personal observations).

The IBC also publishes reports on contemporary bioethical issues, such as gene therapy (1994), embryonic stem cells (2001) and pre-implantation diagnosis (2003). Alongside its work on cloning and vulnerability, in 2010–11 it decided to examine the ethical implications of traditional medicine. 'Traditional medicine' has proved as difficult to define as vulnerability, in terms of the scope of the report, as what is 'alternative' or 'complementary' in one country may be 'mainstream' in another. The use of the contrastive term 'Western medicine' was objected to at meetings by some IBC and IGBC members, as well as invited speakers, as being indicative of the arrogance of the developed world rather than an accurate description of the provenance and use of allopathic medicine ('modern medicine' was preferred). Despite these obstacles, the topic was considered important enough to warrant another year's work. At the IGBC's September 2011 meeting, for example, the Ghanaian representative, backed up by Kenya's, described it as a 'hot metal' issue, but pleaded that it should stay on the agenda, particularly as it ties in with UNESCO's two global priorities, 'Africa' and 'gender equality' (personal observations).

The September 2011 IGBC session also debated other possible topics for the biennium 2012–13. Suggestions at the IBC meeting earlier in the year had included biobanking, regenerative medicine, neuroscience, benefit sharing, genetic testing and organ transplantation. Of these, biobanking proved to be the most popular with IGBC members (personal observations). This has become an increasingly important issue for developing countries, with several NBCs requesting that it be addressed in their training (see below; interview with F2_03). As one African IBC member explained at the May–June 2011 meeting, scientists based in the global South are tired of being treated as little more than a 'post office box' for biological samples (personal observation). There was a push from UNESCO's Director-General, via Pilar Álvarez-Laso, the Assistant Director-General for Social and Human Sciences, for the IBC to concentrate on articles in the UDBHR, namely those on non-discrimination and non-stigmatization (article 11) and benefit sharing (article 15) (personal observations, IBC meeting, May–June 2011 and IGBC meeting, September 2011). The Work Programme for 2012–13 duly uses article 11 as a catch-all:

> The Committee will focus on the principle of non-discrimination and non-stigmatization as set forth in article 11 of the Declaration, by using this principle as a "conceptual umbrella" under which the new risks and responsibilities arising from progress in different sensitive areas of medicine, life sciences and associated technology (including but not limited to biobanks; access to drug [sic]; organs, tissues and cells transplantation and trafficking; neuroscience; HIV/AIDS, and nanotechnologies) could be transversally analyzed.
>
> (UNESCO 2012m)

A third information source provided by UNESCO is the Global Ethics Observatory (GEObs), launched in December 2005 at the IBC's twelfth session in Japan (UNESCO 2006c: 9). GEObs can be accessed via UNESCO's website (www.unesco.org/shs/ethics/geobs) and is available in all of the organization's official languages. Hosting six web-based databases – comprising ethics experts, institutions (including NBCs), teaching programmes, legislation or guidelines, codes of conduct and ethics resources – GEObs covers the ethics of science and technology and the environment as well as bioethics. UNESCO sees GEObs as a 'crucial platform' for supporting member states in their ethics activities, providing models for legislation or policy (UNESCO 2006c: 9; UNESCO: 2007c; Ang *et al.* 2008: 740). It is also intended to have a broader reach (ten Have and Ang 2007: 16; UNESCO 2010c: 15). People designing new ethics courses might use the education section to seek the advice of those with previous experience, for example. 'It's a kind of facilitator of contacts among different people', said a Bioethics Programme representative a few months before its official launch. In particular, they hoped that GEObs would enable people in developing countries to access resources such as reports and guidelines from other regions quickly, to which they did not previously have access (interview with F_01).

Tee Wee Ang *et al.* (2008: 740) write of GEObs, 'it could also inform the discourse and work of the scientific community, civil society and the private sector, with the potential for cross-fertilisation of ideas on bioethics regulations across countries and regions'. Thus it has the capacity to become a Slaughter-like information network, but to fulfil this potential people must know about it and consider it worthwhile (hence, perhaps, ten Have's several publications on the initiative in prominent ethics journals). The efforts are starting to bear fruit. An evaluation of UNESCO's ethics activities in 2008–9 by its Internal Oversight Office (IOS) surveyed 375 GEObs users, 75 per cent of whom were very satisfied or satisfied with the resource. The evaluation also noted that member states were more willing to supply information to UNESCO than to databases compiled by NGOs or universities, although there were still information gaps (UNESCO 2010c: 5–6). The head of the Bioethics Programme reported at the IGBC meeting in September 2011 that GEObs is used increasingly in Asia and Latin America and has now been linked with the European project ETHICSWEB, to boost visibility (personal observation).

Usage increased steadily year on year up to 2012, which saw a slight drop (see Table 5.1). The amount of data in GEObs has also multiplied impressively over the last five years, despite constraints on human and financial resources (the IOS evaluation found that 'the amount of data that needs processing and inputting into the GEObs databases exceeds the resources that have been assigned to the task' [UNESCO 2010c: 2]). The data are gathered and inputted by the Bioethics Programme secretariat, which ensures quality control. As Table 5.2 shows, the legislation and resources databases continue to grow significantly, with the former gaining a lot of users (interview with F2_03). Specific sections of legal documents are cross-referenced with articles in UNESCO's 2003 and 2005 declarations, for policy-makers to draw upon should they wish to codify the declarations within their own domestic law (Ang *et al.* 2008: 740).

Table 5.1 Use of GEObs, 2005 to 2012

Year	*Number of unique users*
2005[a]	165
2006	2,298
2007	2,707
2008	3,323
2009	3,595
2010	3,623
2011	4,029
2012	3,796
Total	23,536

Source: UNESCO (2013).

[a] from launch on 8 December.

Table 5.2 Number of entries in GEObs, 2007 to 2012

		2007	*December 2009*	*June 2012*
Database 1:	Experts	851	1,405	1,515
Database 2:	Institutions	200	437	527
Database 3:	Teaching programmes	162	232	2,355
Database 4:	Legislation	58 (4 countries)	468 (22 countries)	738 (34 countries)
Database 5:	Codes of conduct	141	151	151
Database 6:	Ethics resources	N/A	211	416

Sources: UNESCO (2007e; 2010c: 14; 2011m); GEObs (accessed 29 June 2012).

Capacity-building programmes

Alongside information dissemination, UNESCO has more active programmes aimed at facilitating uptake of the three declarations. Under the auspices of the Bioethics Programme, it supports the establishment of NBCs where they do not already exist. When the UDBHR was adopted in 2005, only about a quarter of member states had a NBC (Wolinsky 2006: 355). UNESCO (2010b: 1) states, 'Providing technical assistance in the process of establishment of National Bioethics Committees (NBCs), as well as the subsequent capacity-building for ensuring their viability and sustainability, are essential elements of UNESCO's *capacity-building action* in the field of bioethics.' These committees can provide a clear point of contact for the Bioethics Programme secretariat and are seen as intermediary steps towards the long-term goal of state level legislation (ibid; interview with F_01). Without such bodies of experts to advise policy-makers, say ten Have *et al.* (2011: 380), it is unlikely that states will make efforts to effect the declarations. According to a report from 2001, UNESCO was then helping seven countries to set up national committees, including South Africa (although this was not mentioned by a single participant during fieldwork). The other countries were Algeria, Côte d'Ivoire, Jamaica, Morocco, Nepal and Senegal (UNESCO 2001a: 6). More recently, this work has continued under an initiative entitled Assisting Bioethics Committees (ABC). It has focused mainly on Africa, where there has until recently been a lack of ethics infrastructure (sub-Saharan Africa is the only region not mentioned in a 2005 report to the German National Ethics Council on NBCs, for example) (Fuchs 2005: 7).

In 2008–9, ABC activities were held in 14 African countries (out of 30 in total), costing USD 170,000 (53 per cent of the total ABC budget) (UNESCO 2010c: 25). As well as this direct support, the Bioethics Programme distributes guidebooks on how to set up, run and educate bioethics committees, with further volumes on public policies and public debate forthcoming. Like GEObs, the guidebooks are available in all six official languages of UNESCO (UNESCO 2011m). The IOS 2008–9 evaluation surveyed the chairs of nine newly established NBCs. Of the

five who responded, four had used the guide *Establishing Bioethics Committees*, three had used *Bioethics Committees at Work* and two had used *Educating Bioethics Committees* and had found them useful. The evaluation spins these numbers positively, although it might have been expected that all the committees would have used all the guides, given that they had been established under the ABC programme (UNESCO 2010c: 5 and 18–19).

The ABC initiative derives from article 19 of the UDBHR (2005), which commits states to instituting ethics committees at different levels. As medical and research ethics committees are already in place or are being set up by states themselves or other organizations, UNESCO decided to focus on helping states to establish NBCs (Bioethics Programme progress report, IBC meeting, May–June 2011). Under UNESCO's definition, NBCs' mandates go beyond ethical review, to include policy promotion and dialogue. Echoing IBC members at the 2010 meetings, ten Have *et al.* (2011: 380) outline this expanded role thus: 'As a forum for intercultural exchange, a national (bio)ethics committee can provide a platform to engage citizens and society as a whole in dialogue about (bio)ethical issues on a regular basis.' The ABC programme has a particular methodology for building the capacity of NBCs in this and other respects, devised by a committee of experts in 2006 (ibid: 383). Yet there is also considerable flexibility, to ensure that training is tailored to the needs of the country (UNESCO 2010b: 2; Bioethics Programme progress report, IBC meeting, May–June 2011).

The process is usually instigated by a member state, which will request assistance from UNESCO. The first step is a 'diagnosis' of what ethics capacity exists in the country already. Next comes an exploratory mission, to ascertain what the 'optimum modalities' of the NBC will be and the practicalities of setting it up (UNESCO 2010b: 3). The programme conducted 14 such missions in 2007–9, all in Africa and Latin America (ten Have *et al.* 2011: 383–4). The launch of the committee is usually combined with an awareness-raising event and a formal signing of a Memorandum of Understanding (MoU) with UNESCO, concerning the three-year period of technical support to follow (UNESCO 2010b: 3). Ideally, a government minister (of health, education or science) should conduct the inauguration, to signify its significance (UNESCO no date b). Of the 14 countries that hosted exploratory missions, nine had established NBCs and six had signed MoUs by November 2011, with the rest still considering their options. Some countries with already established NBCs, such as Côte d'Ivoire and Kenya, also signed MoUs, to avail themselves of the ABC training programme (ten Have *et al.* 2011: 384; UNESCO 2011b).

The technical support aims to ensure sustainability of the committees. A series of intensive two or three day sessions (one per year) largely follow the pattern of the guidebooks, training the nascent NBCs in, *inter alia*, working methods, building up documentation, establishing a secretariat, principles and practices, public engagement and legislation, as well as issues considered particularly relevant to the national context (UNESCO 2010f). Members of the Bioethics Programme secretariat lead the sessions, with support from teams of experts from countries with long-established NBCs (ten Have 2006: 346). This transferral of

experience and expertise is considered a very valuable aspect of the ABC programme by UNESCO (UNESCO 2010b: 2). Teams have thus far been English, French or Spanish speaking, but at the IGBC meeting in September 2011 the delegate from Portugal said that their country would be willing to participate in the programme to develop NBCs in lusophone African countries. As Cape Verde was, at the time, still considering establishing a committee after the exploratory mission of 2008, this was a timely offer (ten Have *et al.* 2011: 384; personal observation, IGBC meeting, September 2011). Beyond the scheduled trainings, the ABC methodology includes six-week internships for NBC secretariats and longer-term partnerships with experienced committees. These partnerships are a means to promote North–South and, at some stage, South–South collaboration. The Swiss and Belgian NBCs are working with their Togolese and Guinean counterparts respectively, for example (ten Have *et al.* 2011: 387; Bioethics Programme progress report, IGBC meeting, September 2011).

Although the technical support stage is aimed at sustainability, there are doubts about the viability of NBCs in resource-poor countries in the long term. ten Have *et al.* (2011: 387) note, 'Experiences in the ABC project show that sustainability is a serious challenge.' At the IBC–IGBC meeting in October 2010, an IBC member expressed their concerns about the make-up of committees, asking whether they are genuinely pluralist and independent (personal observation). The IOS 2008–9 evaluation also raised these issues, linking independence with financial sustainability (UNESCO 2010c: 19–20). Political considerations may also have an impact. Whether a NBC gets up and running even is dependent on the will of the government. UNESCO can only explain why a committee is needed and offer expertise: 'The actual decision is up to them' (ten Have *et al.* 2011: 384). Internal power struggles can delay procedures. ten Have *et al.* (ibid) give the example of Mauritius, where there was a dispute about whether the process should be led by the university or the Academy of Sciences. This was eventually resolved at parliamentary level, through a bill to create a NBC.

Ongoing governmental backing is crucial. The IOS 2008–9 evaluation warned that, while the ABC programme was instrumental in establishing NBCs, the committees would only survive if they enjoyed the commitment of national stakeholders (UNESCO 2010c: 2). The limited resources of the programme itself are another challenge, as more states look to establish NBCs. One option being explored is online modules (to be delivered through e-learning, teleconferencing and webcasting, to the journalists, parliamentarians and judges who are to be the focus of efforts in the 2012–13 biennium). A study commissioned from The Open University in the UK found that this would enable a broader, more efficient reach, but that the face-to-face nature of the existing methodology plays a key role in its success (Bioethics Programme progress reports, IBC meeting, May–June 2011 and IGBC meeting, September 2011; UNESCO 2011b). Furthermore, as ten Have *et al.* (2011: 387) point out, the internet is not always easily accessible in developing countries. When interviewed in September 2011, a member of the Bioethics Programme secretariat (F2_03) wondered what the results of a future evaluation would reveal about the quality of the committees that have been set up,

as some may not be able to conduct their work due to funding constraints. Overall, however, they were positive about the ABC programme, seeing the partnerships with peer bodies as a means of supporting and strengthening the newer committees.

UNESCO's second capacity-building activity is the Ethics Education Programme (EEP), which helps states to fulfil their obligations under the various articles in the three declarations on ethics education and training (UDHGHR, articles 20, 21 and 23; IDHGD, articles 6(a), 23(a) and 24; and UDBHR, articles 18(2/3), 19(d), 22(1) and 23(1)). UNESCO launched the EEP in 2004, in the wake of a report by the World Commission on the Ethics of Scientific Knowledge and Technology (COMEST, a UNESCO body) from the previous year on the teaching of ethics. The report recommended that, *inter alia*, UNESCO develop ethics courses, support ethics teaching in developing countries, establish fellowships and chairs in ethics and appoint a board of ethics experts to focus specifically on ethics teaching (ten Have 2008: 57–8). UNESCO hopes the EEP (together with the education section of GEObs) will ensure that 'future generations of scientists and professionals' learn the principles in the declarations, whether or not states develop legislation (interview with F_01).

Whereas UNESCO's reputation as primarily an educational institution may have hindered its efforts to liaise with ministries of health or science and technology in some countries, it has been a boon in relation to the EEP. ten Have (2008: 59) writes, 'In many countries, even if there is the motivation to introduce ethics teaching, problems will be encountered in the implementation, because of a lack of adequate resources. . . . Unesco, with its experience in education, is in a position to remedy this situation.' Similarly, Nouzha Guessous-Idrissi (2010: 98), a member of the IBC from 2000 to 2007 and of UNESCO's Advisory Expert Committee for the Teaching of Ethics (see below), has commented that it is 'absolutely logical' for UNESCO to encourage its member states to promote ethics education and training, as education is 'the foundation on which it is built'. At the IBC–IGBC meeting in October 2010, two IBC members called for National Commissions to use their connections with education ministries to suggest curricula for primary and secondary schools on the UDBHR, to aid dissemination (personal observation).

There are four main aspects to the EEP, all of which closely align with the COMEST recommendations. Alongside the database of teaching programmes in GEObs, UNESCO has written a Core Curriculum in bioethics, appointed Chairs in Bioethics and developed a training course for ethics teachers. The curriculum is based on the UDBHR (2005). Thus it has a global reach, given that the UDBHR was agreed by international consensus. Nevertheless, it is designed to be sufficiently flexible that it can be moulded to suit the requirements of different regions. Intended primarily for use in medical and science schools, it can also be deployed much more widely (Bioethics Programme progress reports, IBC–IGBC meeting, October 2010 and IBC meeting, May–June 2011). The curriculum was developed by the *ad hoc* Advisory Expert Committee for the Teaching of Ethics, appointed to assist the Bioethics Programme secretariat with the EEP. The committee consisted of four IBC members and representatives of the Third World

Academy of Sciences, the WMA and COMEST (UNESCO 2008b: i). (Ironically, the member from WMA was its former Director of Ethics, John Williams, who had been critical of the UDBHR during its drafting, as we saw in the previous chapter [Williams 2005].) After several committee meetings and a consultation with 24 further experts, mostly from developing countries, the curriculum was finalized and published in early 2008 (UNESCO no date c). Study materials and casebooks on *Human Dignity and Human Rights* and *Benefit and Harm* followed in 2011 (UNESCO no date f).

Details on the instigation of the Core Curriculum in universities are somewhat hazy. There were plans to pilot it in Kenya, Israel and the Philippines in 2008, but no documentary record of the outcome appears to exist (UNESCO 2007e). At the IBC–IGBC meeting in October 2010, the chief of the Bioethics Programme reported that several universities were willing to act as potential test sites. MoUs had been signed with five institutions in Asia and the Pacific, four in Europe and North America and one in Latin America and the Caribbean, with several others from these regions showing an interest, as well as three in Africa and two in the Arab world. Moreover, the curriculum had already been largely adopted by the Standing Committee of European Doctors, received the backing of the British Medical Association and the UK's General Medical Council and contributed to the Master in Bioethics of Saudi Arabia's National Guard Health Affairs. There would be a probable global deployment in 2011. In September the following year, however, in the update to the IGBC on the Bioethics Programme's activities, the test sites were not mentioned, although it was reported that the study materials had been requested widely. The global deployment appears to have been delayed a year, as the Advisory Committee was to meet again in November 2011, to assess feedback from the pilot phase and prepare for a global rollout (no information on this meeting is available) (UNESCO 2010f; Bioethics Programme progress reports, IBC–IGBC meeting, October 2010 and IGBC meeting, September 2011). The course materials are freely available on the UNESCO website.

One handicap to the rollout of the Core Curriculum may be the lack of faculty qualified to teach bioethics. This is something the EEP's Ethics Teachers' Training Course (ETTC) – developed in cooperation with the UNESCO Chair in Bioethics of Haifa, Israel – aims to address (ten Have 2008: 59). The ETTC is targeted at early career educators, introducing them to methods and resources for ethics teaching and giving feedback on their technique (UNESCO 2011m). It has proved particularly popular in the former Eastern Europe, where courses have been held in Romania (2006), Slovakia (2007), Belarus (2008), Serbia (2011), Croatia (2010, 2011 and 2012), Lithuania (2012) and Azerbaijan (2012). Courses were also held in Saudi Arabia and Kenya in 2007 and Namibia in 2012 (UNESCO no date d).

The 2008–9 IOS evaluation, which focused on the five courses held up to and including 2008, raised serious doubts about the efficacy and worth of the ETTC programme: 'The teacher training courses involved a small number of individuals, some of whom are no longer teaching in ethics, which raises the question of whether UNESCO needs to continue with this type of training' (UNESCO

2010c: 3). Feedback from the participants themselves proved positive. Of the 38 (of 68 in total) who responded to the IOS survey, 86 per cent had found the training useful, 78 per cent used the skills they had acquired once a month or more, 65 per cent were members of regional ethics networks and 59 per cent had taken part in national debates on ethics. Of concern to the IOS was the rate of attrition, with only 79 per cent still teaching ethics, despite the short space of time since they had been on the course (ibid: 5, 22 and 24).

The UNESCO Chairs in Bioethics also received mixed praise in the IOS evaluation. There are 12 chairs in all, in Israel, Slovakia, Argentina, Peru, Brazil, Mexico, Kenya, Côte d'Ivoire, the US, Spain, Portugal and Italy (UNESCO 2011m). The evaluation found that the contribution of the chairs (then nine in number, with two appointed only in 2009) had been 'uneven', with those from Spain, Israel, Kenya and Brazil proving more active than the others (UNESCO 2010c: 23). The Bioethics Programme is trying to address this by working with both the Chairs in Bioethics and those in related disciplines to bolster bioethics programmes at university level. There was a Symposium of UNESCO Chairs in Bioethics, Peace, Human Rights, Democracy and Tolerance in Italy in March 2011, for example (Bioethics Programme progress reports, IBC meeting, May–June 2011 and IGBC meeting, September 2011). At the IGBC meeting in September 2011, the Kenya representative supported these efforts and lobbied for the chairs to get more involved on the ground, to aid sustainability of programmes. They also hoped to see the sharing of best practice between the chairs (personal observation). The former Kenyan Chair in Bioethics would also like to see networking among chairs, to stimulate cross-fertilization of ideas (interview with K2_01).

In addition to its EEP activities, UNESCO is supporting the International Association for Ethics in Education (IAEE), created in 2011. Although an independent body, the IAEE was founded by ten Have (now at Duquesne University in Pittsburgh in the US, where the IAEE secretariat is based) and aims to provide a global platform for exchanging information and experiences in ethics teaching (broadly framed), so there are close connections with UNESCO in both personnel and mandate (UNESCO no date e; Duquesne University 2012). Thus far, the Association has held its inaugural conference, which was attended by more than 200 delegates from 29 countries, including India, Kenya, the Dominican Republic, Tunisia and Romania. Further conferences are planned for 2014 in Turkey and 2015 in Brazil. Until then, the IAEE will work on creating a website to enable ongoing knowledge exchange, through which users will be able to link to GEObs and the Core Curriculum (UNESCO 2012g). The IAEE mirrors in structure Reinicke's Global Public Policy Networks (see p. 32). As the Association is still young, it is perhaps too early to tell how well it will sit alongside UNESCO's activities, or whether its semi-independence will be a help or hindrance in its becoming respected and valued by the (bio)ethics community.

The final activity of the Bioethics Programme is awareness-raising about ethics among the general public, with a view to ensuring that civil society engages with policy-makers and experts in ethical debate around science and technology. From 2004 to 2007 this was done primarily through the Ethics Around the World

conferences, organized by the Division of the Ethics of Science and Technology in conjunction with UNESCO National Commissions and field offices, as well as academic and research institutions. The conferences had the specific purpose of stimulating debate at national and regional levels and thus focused on topics of relevance to the host country. There were 15 in total, with at least one in every region. Conferences and seminars have since been organized on a more *ad hoc* basis and have targeted the ethics community more than civil society generally. Three have taken place at the initiative of the Chairs in Bioethics, in Kenya (2008), Israel (2009) and Brazil (2009) (ten Have 2006: 347; UNESCO 2007e). Another, the Joint Action for Capacity Building in Bioethics (JACOB) between the European Commission and UNESCO (funded by the EU's Seventh Framework Programme), followed the IBC's sixteenth session in Mexico in 2009 (UNESCO 2010e: 9).

There is little independent evaluation of UNESCO's capacity-building endeavours. The large majority of academic papers reviewing its activities have been written by people either currently or previously associated with the Bioethics Programme, as members of the IBC or the secretariat. The 2008–9 IOS evaluation was independent of the Programme, but still fell under the auspices of UNESCO. One of its recommendations was that the Programme should strengthen its monitoring frameworks. Another was that it should consolidate its efforts where it has most impact, to make the most of its limited human and financial resources (UNESCO 2010c: 2–3). In line with Young's estimation of IGO resources, the Bioethics Programme's ambitions for encouraging implementation of the declarations may be curtailed by funding limitations. For the secretariat to engage in more follow-up activities, more money and staff would be needed (interview with F2_03).

During the biennial period 2004–5, out of UNESCO's USD 610 million budget for its regular programme, the amount devoted to 'ethics of science and technology, with emphasis on bioethics' was a shade over USD 3.25 million (just over 0.5 per cent). As the 'principal priority' of the Social and Human Sciences Major Programme, this represented 26 per cent of the amount dedicated to activities (excluding cross-cutting projects), compared to 15.3 per cent in the previous biennium (UNESCO 2004a: 13–14 and 147). For 2006–7 funding for both the Major Programme and the ethics section was slightly reduced, although ethics remained the principal priority and its percentage share rose to 30 per cent (UNESCO 2006a: xiii–xiv and 123–4). The ethics budget more than doubled in 2008–9, to just over USD 7.2 million, representing 2.6 per cent of UNESCO's total budget for programme activities (UNESCO 2008a: xi and 270). 2010–11 saw another slight increase, to just under USD 7.4 million, followed by a drop in 2012–13 to just over USD 6.5 million (1 per cent of the total budget of USD 653 million) (UNESCO 2010a: 270; UNESCO 2012a: 324 and 340). To put these figures into context, in a 2004 document seeking to attract funding partnerships for various projects, the foundation and running costs of GEObs over three years were projected at nearly USD 3.4 million (UNESCO 2004m: 53).

Duplication of activities

Chapter 3 described how, in an *ad hoc* international system, the mandates and programmes of IGOs have a tendency to overlap. This tendency has been mitigated to some extent in bioethics through the formation of the United Nations Inter-Agency Committee on Bioethics. The committee was initiated by UNESCO, expressly to avoid duplication and promote collaboration and information exchange among its membership. According to then Director-General Koïchiro Matsuura, this action confirmed the organization's role as a 'catalyst for international cooperation' in the field of bioethics (UNESCO 2005i: 39). The Committee is made up of mainly UN agencies, but also other relevant regional and international IGOs, at UNESCO's suggestion (interviews with F_01 and F2_03; UNESCO 2003i: 9–10). UNESCO provides the permanent secretariat, although members take turns to host meetings. The UN members are the Office of the High Commissioner for Human Rights, the International Labour Organization, the Food and Agriculture Organization, the World Intellectual Property Organization, the United Nations University and WHO; the non-UN associate members are the European Commission, the Council of Europe, the Organization for Economic Cooperation and Development, the African Union, the Arab League Educational Cultural and Scientific Organization, the International Centre for Genetic Engineering and Biotechnology and the World Trade Organization (UNESCO 2011m; UNESCO no date a). Henriette Abbing (1998: 155) recommended this kind of coordination in an article on the UDHGHR (1997) and similar texts:

> From a point of view of effectiveness, efficiency and transparency it would be more fruitful if international discussions could be centered around a particular subject, rather than being framed according to the statutory mandate of an international organization. Bringing together the various international organizations involved to discuss on equal footing a topical issue avoids a shattering of the debate, and guarantees an integrated approach of all aspects involved through the input of the particular focus of each single organization involved.

The first task of the Inter-Agency Committee was to contribute to the drafting of the UDBHR (2005). Since then it has met periodically to tackle issues of common interest. Although the ethics of genetics has taken something of a 'back-seat' compared with the UDBHR within the Bioethics Programme's capacity-building activities, this is not the case at inter-agency level. In 2008 the UN's Economic and Social Council (ECOSOC) requested that UNESCO investigate the possibility of an inter-agency coordination mechanism on genetic privacy and non-discrimination (ECOSOC Decision 2008/233). As per ECOSOC instructions, UNESCO consulted with UN agencies and member states, as well as other relevant international organizations and the Inter-Agency Committee. Via questionnaires (which, like those on the draft UDBHR, remitted low response rates), it found that, in several cases, both states and IGOs had legislation and/or

programmes in place to protect genetic data. As during the cloning debate, some states pressed for international initiatives to help build national capacities, on genetic privacy and non-discrimination (ECOSOC 2011: 4–8; Bioethics Programme progress report, IGBC meeting, September 2011).

In 2010, ECOSOC requested that UNESCO defer its report for another year, to enable further consultation with member states and analysis by the Inter-Agency Committee (ECOSOC Decision 2010/259). At its tenth meeting, in May 2011, the committee discussed UNESCO's findings and heard from a variety of experts, who suggested that genetic data should not be treated in isolation, but as part of a broader concern with privacy and non-discrimination in health settings more generally. Both UNESCO and the committee concluded that there is a call for information exchange and collaboration in this area, but that a specific coordinating mechanism is not needed, as the Inter-Agency Committee is well placed to fulfil this mandate (ECOSOC 2011: 9–10). At the July 2012 ECOSOC meeting, in line with UNESCO's recommendations, the Council passed a resolution inviting the Inter-Agency Committee to continue to consider genetic privacy and non-discrimination and to promote international cooperation in this area, with the issue to be removed from the Council's agenda (ECOSOC 2012). A remarkably similar outcome, then, to the culmination of UNESCO's four years of work on the governance of human cloning.

The 2008–9 IOS evaluation of UNESCO's ethics activities found that UNESCO was the 'lead agency' internationally on bioethics, having established 'comparative advantages' in the field (UNESCO 2010c: 2). In reality, there is as much cooperation as there is competition between organizations. UNESCO has worked with its inter-agency partners and others on several initiatives. On the back of the JACOB conference in Mexico in 2009, the European Commission supported the publication of UNESCO's *NBCs in Action* in 2010 (UNESCO 2010e: 9; UNESCO 2011m). In 2010–11 UNESCO contributed to a WMA expert conference on the ethics of placebos, a CIOMS-hosted panel on how to integrate research and treatment and (alongside WMA and CIOMS) a meeting of the US Presidential Commission for the Study of Bioethical Issues, on human subjects protection (Bioethics Programme progress report, IGBC meeting, September 2011; PCSBI 2011).

Perhaps the UN agency with which UNESCO's bioethics and genetics activities might be seen to overlap the most is the World Health Organization. The WHO's 2002 report *Genomics and World Health*, published after the adoption of UNESCO's UDHGHR in 1997 and during negotiations on the IDHGD of 2003, described the WHO as 'in a position to adopt a crucial leadership role in bioethics'. This would enable it to 'exercise its normative function for setting standards and guidelines and harmonization of procedures', partly through helping member states to regulate genomics (WHO 2002: 8 and 10–11). The WHO has indeed been active in bioethics, through its Ethics and Health Initiative, launched in October 2002. It produced the *Research Ethics Committees: basic concepts for capacity-building* manual in 2009 and *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants* in 2011. It also hosts the Opinions submitted by National Ethics Committees (ONEC) online

database, which contains details of both committees and their opinions (available at http://apps.who.int/ethics/nationalcommittees/). As of May 2012, there were 107 committees listed (WHO 2012b).

ONEC was developed after the eighth Global Summit of National Bioethics Advisory Bodies in 2010. The Ethics and Health team provides the permanent secretariat to the Summit, which meets biennially (WHO 2012c). Perhaps ironically, considering the nascent IAEE, ten Have *et al.* (2011: 387) have questioned the usefulness of such international gatherings, claiming that they do little to build NBC operational capacity or stimulate knowledge exchange between meetings. The WHO has also recently established a Global Network of WHO Collaborating Centres for Bioethics. There are six centres so far, all in developed countries (the Joint Center for Bioethics in Toronto is one of them), but the WHO is encouraging partnerships between centres in high- and low-income countries (WHO 2012a).

While all these activities appear to duplicate UNESCO's, the two organizations often work in partnership. It is the Ethics and Health Initiative that represents WHO on the Inter-Agency Committee. UNESCO, the WHO and the Council of Europe contributed to meetings on bioethics and research ethics in Cyprus and Lithuania in May 2004 and a regional meeting of NBCs in Cairo in 2007 was a joint WHO–UNESCO initiative (WHO 2005–6: 1–6; ten Have *et al.* 2011: 382). More recently, UNESCO's input into the *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants* was considered by the WHO to be 'especially valuable' (WHO 2011: viii). This belies the claims of the 2005 *Developing World Bioethics* special issue on the UDBHR that, in promulgating the declaration, UNESCO was encroaching on the mandate of the WHO (see Landman and Schüklenk 2005: iii and Williams 2005: 212). In fact, ten Have responded in a *SciDevNet* article that the contributors were perhaps not *au fait* with how UN agencies work (Shetty 2005). Andorno also directly answered the *Developing World Bioethics* criticisms, claiming that the work of the two organizations can 'perfectly coexist', as UNESCO tends to elaborate general norms, whereas the WHO produces more technically focused guidance (Andorno 2007: 151–2).

Since Andorno made these comments, UNESCO has clearly expanded its remit to include provision of technical support. But the fact that UNESCO has produced guidebooks primarily aimed at NBCs, whereas the WHO's guidance is targeted at institutional RECs, is indicative of what should be a clear-cut division of labour between the two organizations. It is the WHO's work with NBCs, through the Global Summit, that muddies the waters. Another potential clash concerns the specialisms of each agency. At the discussion of future topics for IBC reports at the IGBC meeting in September 2011, a representative of the WHO's Ethics and Health Initiative outlined how several of the suggested areas were already being covered by the WHO or other bodies, namely traditional medicine, biobanks and organ transplantation and trafficking (personal observation). Since these topics, as well as activities with NBCs and RECs, were to be discussed at the Inter-Agency Committee meeting in May 2012, perhaps the overlap issue is being resolved (UNESCO no date e).

In September 2011 the IGBC Chair had encouraged the two agencies to systematically work out their responsibilities, not only to avoid duplication within the UN, but also for the sake of end-users in hard-pressed ethics committees, who find it tiresome to answer similar enquiries from different bodies. Álvarez-Laso, Assistant Director-General for Social and Human Sciences, responded that the division of labour is clear, having been approved by the governing bodies of UNESCO and the WHO (personal observation). In contrast, a member of the Bioethics Programme secretariat felt that there needed to be further clarification on which type of ethics bodies each organization works with, which could only come from a higher level. The matter was becoming urgent, having been raised by both the IGBC and member states more generally (interview with F2_03). If these uncertainties can be addressed, the organizations' programmes will be mutually reinforcing, as per Young's observations on international institutions.

Enforcement

UNESCO pursues its programme of encouragement through capacity-building activities in part because it does not have the power to compel its member states to adopt the declarations. Lenoir's words on the draft UDHGHR (1997) illustrate the limitations: 'The idea of the IBC is to propose a Declaration which could serve as a reference, a pattern or a source of inspiration to the States *willing* to adopt legislation on bioethics' (Lenoir 1996; italics added). A Bioethics Programme member (F_01), interviewed in 2005, lamented that the organization is blamed by some for the lack of implementation of the declarations, when in fact it 'cannot do much more than what the member states allow us to do'. Another member, speaking in 2011, similarly felt that states could do more to keep up with their own commitments. The secretariat can help, but it is states' responsibility to implement the declaration (interview with F2_03). There has been a reluctance among states to even self-report to UNESCO on their bioethics and genetics activities. Allyn Taylor argued in 1999 that the lack of a formal supervisory mechanism for the UDHGHR (1997) was of 'significant concern'. She recommended that self-reporting by states on their implementation of the declaration be combined with fact-finding and review by an independent body, to promote a 'truly constructive dialogue' and predicted that the 'growing sense of urgency' on the need for international cooperation on genetics might serve to 'soften national opposition to substantial organizational supervision under a voluntary auditing process' (Taylor 1999: 480, 513, 527, 531 and 535–6). The negotiations for the UDBHR (2005) would suggest otherwise.

Early in the formulation of the UDHGHR (1997), it was decided that if the declaration was to have a 'real impact' a follow-up mechanism would be needed (that is, a system of implementation review or SIR) (UNESCO 1999a: 38). Implementation guidelines, endorsed by the General Conference in November 1999, thus stipulated that an evaluation should be carried out five years after the adoption of the declaration (UNESCO 2000b: 9–10). The IDHGD (2003) similarly suggests that states should submit reports to the IBC and IGBC on their

implementation of the declaration (article 25) and the IBC's early recommendations on what became the UDBHR (2005) were that it should include such a proviso (UNESCO 2003h: 12). Whereas the 2002 evaluation of the UDHGHR duly took place in the form of a questionnaire, the proposals for the two later declarations met with resistance from member states (contrary to the trend identified by Victor *et al.*, that states are becoming more favourably disposed to SIRs). At the January 2005 IBC and IGBC meetings (which discussed possible implementation guidelines for the IDHGD as well as the text of the draft UDBHR), several government representatives felt that reporting mechanisms were inappropriate to non-binding instruments, as did those attending the IGE meeting in June 2005. The states most vocal in their opposition to periodic reporting were the US, Canada, Germany and India (personal observations; UNESCO 2004i; UNESCO 2005m: 8).

According to a member of the Bioethics Programme, the reaction of member states to the IBC's initial suggestion that the UDBHR require biennial reports by states was, 'Well, that's out of the question' (interview with F_01). This attitude was picked up on several years later, at the October 2010 IBC–IGBC meeting. An IBC member noted that dissemination seemed to be the main concern, even five years after the UDBHR had been adopted. They attributed this sluggishness to the one-way communications between the secretariat and field offices and harked back to the early drafts of the declaration, which had called for reports from member states. They suggested that, in lieu of an official reporting mechanism, the secretariat should ask states for unofficial reports, which could go on the website as a form of information exchange. The IGBC representative from Romania proposed a special department in UNESCO to disseminate documents and collect information from all member states (personal observations). The issue was raised again at the IGBC meeting in September the following year. The IGBC Chair asked whether it was possible to have some kind of feedback system, to ensure UNESCO's work is of benefit. When the head of the Bioethics Programme replied that systematizing feedback when resources are limited is a big challenge, but that IGBC members could play an important role by providing information on their countries, the Chair put forward the idea of an electronic template (personal observations). The official conclusions of the session include this suggestion:

> [The IGBC] recognizes the significant role Member States can play in assessing the impact of UNESCO's action at regional and national level, and towards this end encourages the Secretariat to offer means to the Member States for providing feedback on a range of bioethics activities within their borders, including the promotion and dissemination of the Declaration, through a standardized and user-friendly template.
>
> (UNESCO 2011c: 2)

This lack of a reporting mechanism for both the IDHGD (2003) and UDBHR (2005) would seem to render them weaker instruments than their predecessor. In reality, however, it makes little difference, because the 2002 evaluation exercise

on the UDHGHR (1997), like many SIRs, was something of a failure (despite being deemed an 'essential ingredient' of UNESCO's bioethics work by the then Director-General [UNESCO 2002b: 2]). Around 2,500 questionnaires were sent to states, IGOs, NGOs, national ethics committees, universities and academic institutions, the private sector and prominent individuals. Since only 100 or so questionnaires were returned, with very few from states, the results were of limited significance, as the Assistant Director-General for Social and Human Sciences acknowledged when reporting the results to the IGBC. He appealed to members to consider new evaluation methods that would engage stakeholders (UNESCO 2003i: 8–9). The official report of the evaluation to the General Conference was not so candid, concluding that the survey provided a 'rich variety' of information on the impact of the declaration, which had clearly become 'an authority in bioethics' (UNESCO 2003f: 7).

The Bioethics Programme representative (F_01) interviewed in 2005, agreeing with the Assistant Director-General, felt that the evaluation process was too time-consuming, given the poor response rate. They described how as a secretariat they were in something of a no-win situation: 'They [member states] don't want to be compelled to report on what they do. At the same time they're always asking us, "How is the declaration impacting the member states?"' They hoped that GEObs would enable the gathering of information on the implementation of the declaration independently of political processes and thus in a way that is non-threatening to member states. The member of the secretariat interviewed in 2011 (F2_03) confirmed that GEObs was working as intended, in terms of data collection. They did not see it as an alternative to self-reporting, however, as the information is collected by the secretariat rather than submitted by governments (interview with F2_03).

Adoption by member states

All three UNESCO declarations require states to take 'all appropriate measures' to instigate their principles at national level. If they are not to 'remain paperwork', as non-binding instruments they must be effected by states (ten Have 2006: 343). Precisely because they are non-binding, however, there is no obligation on states to do so. That declarations can only persuade rather than compel states to modify their laws was reiterated by an official at the Kenyan Ministry of Foreign Affairs. A South African ethicist likewise said that as 'merely declarations' the UNESCO instruments serve to 'remind governments of their responsibility' (interviews with K_30 and SA_27). Lenoir (1998–9: 575) drives home this point in relation to the UDHGHR (1997):

> The implementation of the Human Genome Declaration depends, first and foremost, on the will of states. For instance, it may be hoped that some states will publish the Human Genome Declaration in their official gazettes or journals. It is for states to incorporate the principles of the Human Genome Declaration into their legislation, where appropriate. It is for them to set up

> ethics committees which can refer to the Human Genome Declaration. Finally, it is chiefly for states to develop curricula on bioethics. The first aim of the text is to encourage the states deprived of any legislation on bioethics (including most developing and Eastern European countries) to legislate in the field in accordance with the principles of the Human Genome Declaration.

The UDHGHR (1997), as the oldest of the three declarations, might be expected to have been enacted to the greatest degree. In this regard, at a Round Table at the 2001 UNESCO General Conference, 53 ministers of science (or their equivalents) made the following statement:

> In conclusion, we, the participating and represented ministers of science: (i) undertake to participate actively in the promotion of the principles set out in the Universal Declaration on the Human Genome and Human Rights and in its implementation, in particular by drawing inspiration from it in the formulation of our legislation or regulations, and by considering possible extensions to the Declaration when it is evaluated in 2002–2003.
>
> (UNESCO 2003a: 12)

Since very few countries responded to the 2002 evaluation, it is difficult to measure whether they have fulfilled this undertaking (the claim of the 2003 IDHGD's preamble notwithstanding, that its predecessor had received 'firm support' internationally and had been adopted by member states within their legislation, regulations or ethical codes [UNESCO 2003b]). The IBC's 2001 paper on solidarity between developed and developing countries reported a paucity of efforts to fulfil articles 17 to 19 of the declaration, on disease research, knowledge sharing and capacity building: 'States rapidly recognized the implications of the new scientific advances, but they have not always been so prompt in undertaking projects of solidarity and international co-operation as set out in the Universal Declaration on the Human Genome and Human Rights' (UNESCO 2001b: 14).

It is worth noting that the UDHGHR (1997) and the IDHGD (2003) do not appear on the agendas of IBC sessions after 2003. From that point, with regard to standard setting at least, all the attention appears to have fallen on the drafting and follow-up of the UDBHR (2005). A member of the Bioethics Programme explained that, although the two earlier declarations are not being very actively promoted, they have not been abandoned. They are always referred to in trainings and so on, but there is less of a focus on them because they cover a more restricted area than the UDBHR. The Programme can accomplish more through the broader bioethics declaration, which can then act as a stepping stone towards more specific legislation on genetics. Some NBCs are indeed working on this, according to their countries' needs (interview with F2_03).

Lack of information from member states is not the only obstacle in assessing how far the declarations are being implemented at national level. Even when states enact legislation, it is difficult to measure how far this is a direct response to the declarations. The IOS 2008–9 evaluation found, 'There is evidence that

national legislation (post-2005) in numerous countries reflects the principles of the UDBHR. There is, however, insufficient evidence to attribute this to the work of UNESCO' (UNESCO 2010c: 1). The member of the Bioethics Programme interviewed in 2005 (F_01) averred that it is whether the declarations are being adhered to that is important, not whether this is being done deliberately or not: 'Even if we don't know if it's *post-* or *propter-* the declarations, it is just what we want, because UNESCO is making the declarations to have more policies in the area of genetics, whether or not it's our initiation of the whole process.'

If it is not the declarations that are inspiring regulatory innovations, it can be questioned whether they are really filling a gap, as UNESCO claims. A review of the legislation and guidelines database of GEObs reveals that, of the 54 domestic laws or guidelines from 19 countries cross-referenced with the IDHGD (2003) by July 2012, 45 had been developed before 2003, but only nine after. Of the 638 instruments from 34 countries (134 from Australia alone) cross-referenced with the UDBHR (2005), only 57 had been developed after 2005 (GEObs, accessed 6 July 2012). Some of the connections drawn are rather tenuous. Kenya's 2008 Water Act is cross-referenced with article 16 of the UDBHR on protecting future generations, for example. While this is a valid acknowledgement of UNESCO's broad understanding of bioethics, it seems very unlikely that the Act will have been inspired by the declaration rather than other international instruments more directly addressing environmental issues. Perhaps tellingly, when states have taken the opportunity at IGBC meetings to report on their ethics activities, they have listed workshops, university programmes, translations, media engagement and NBCs, but not legislation (personal observations, IGBC meetings, October 2010 and September 2011). The IBC meetings held in Kenya (2007) and Azerbaijan (2011) were different. In each case, the day of presentations devoted to informing the committee of activities to implement the declarations in the region (another means of finding out what is happening in states) touched on recent or needed legislative initiatives (UNESCO 2008e; UNESCO 2011p; interview with F2_03).

No documents in GEObs had been cross-referenced with the UDHGHR (1997) by July 2012 but an earlier initiative had conducted a similar exercise. General Conference resolution 29 C/17 (1997) had asked the Director-General to prepare a 'global report on the situation worldwide in the fields relevant to the Declaration, on the basis of information supplied by the Member States and of other demonstrably trustworthy information gathered by whatever methods he may deem appropriate' (UNESCO 1998d: 46). The Director-General duly wrote to all member states requesting information on legislation or regulations on bioethics, adopted or pending, with a particular emphasis on genetics and biotechnology (UNESCO 1998b: 58). The information provided and collected afforded a review of 41 states across all regions (UNESCO 1999b: 4). Arguably, then, this precursor to GEObs was a more fruitful enterprise than the 2002 evaluation.

Some states may be taking up the declarations' principles selectively, or putting their own interpretations on them. Such adaptability could be seen as a weakness or a strength. Shawn Harmon (2005: 37) writes of the UDHGHR (1997), 'By its frequent deference to domestic lawmakers, it fails to provide a universal response

that will guard against piecemeal legislation and a "race to the bottom".' Andorno (2002: 962), by contrast, believes that to impose a comprehensive legal framework on countries with differing sociocultural backgrounds would be both impossible and unfair. Echoing Victor *et al.*, Christian Byk (1998: 237) sees the UDHGHR's non-binding flexibility in a positive light: 'it facilitates adhesion to the Declaration by those states which have difficulty satisfying the implementation of the principles, but which intend to go further that way'. UNESCO, for its part, endorses national contextualization. In a 2006 paper outlining all UNESCO's bioethics activities, ten Have wrote: 'As principles they are universally adopted, but in practice their application must be tailored in multiple ways to accommodate different types of research and health care, categories of patients and problems, and cultural settings and traditions' (ten Have 2006: 342–3).

The lack of universal norms on cloning

In its June 2010 report, the IBC Working Group on Human Cloning and International Governance gave a list of tenets that it would like to see in a convention or moratorium on human reproductive cloning. These included: rendering reproductive cloning (defined as per the Working Group's revised terminology) a crime, with the practice to be tried before the International Criminal Court and under the domestic law of ratifying states; penalties and denials of funding for offending corporations and institutions; 'trade cross-retaliation' and embargoes on research cooperation against offending states; a trade prohibition on cloned embryos (but not cloned tissues or cells for research); and disputes between states to be heard by the International Court of Justice. The instrument would also outline the ethical and human rights responsibilities of states, corporations and individual researchers (with particular reference to the vulnerability of embryos, foetuses and children) and, in similar fashion to the *UN Declaration on Human Cloning*, juxtapose the cloning issue with immediate challenges such as inequalities of health.

The report gave three reasons why the Working Group considered a robust instrument necessary. First, the norms in existing international instruments (such as the UN declaration and the Council of Europe protocol) are vague and inconsistent. Second, none are enforceable at global level. Third, they may impede beneficial medical research while unintentionally sanctioning unethical practice (UNESCO 2010g: 11–12). The Group's draft final statement of 2011 added, 'the current non-binding international regulations cannot be considered sufficient in addressing the challenges posed by the contemporary scientific developments and to safeguard the interests of the developing countries that still lack specific regulations in this area' (UNESCO 2011d: 3).

If this is the case, UNESCO's inability to meet the need it has identified is problematic, as Maimets, Chair of the Working Group, recognizes. At the IBC and IBC–IGBC meetings in October 2010, he implored the assembled delegates to consider what the two committees will say when (not if) cloning happens, as key global bioethics bodies. The representative of the Russian Federation made a similar point, asking how the IGBC will react when, in the near future, a human

clone is created in a jurisdiction without a moratorium (personal observations). Camporesi and Bortolotti (2008: e15) also highlight the urgency of the matter, in the *Journal of Medical Ethics*: 'To conclude, we propose that in the time left before human reproductive cloning is attempted successfully, progress on the ethical debates should be made and good regulatory measures adopted as a result.'

The Working Group's 2010 report declared that any international instrument on cloning would best be elaborated by UNESCO:

> As an international organization that has a solid track record in standard-setting and capacity building in bioethics, UNESCO provides the best global platform to initiate the processes towards a moratorium or a prohibition on human reproductive cloning under international law.
>
> (UNESCO 2010g: 6)

The organization has failed to fulfil this self-stated role on two counts. As neither the 2010 report nor the 2011 draft final statement were formally adopted by the IBC, the final official verdict of the Working Group dates back to 2009. This means that all the Group's work in the biennium 2010–11, including the revised terminology, has essentially come to nothing. Furthermore, this work does not appear to have hit the radar of the scientific and ethical communities, as neither the proposed definitions nor the initiative more broadly have been discussed in the relevant journals.[1]

With regard to therapeutic cloning, the Working Group's draft final statement suggested that this should continue to be dealt with at national level, because of countries' different attitudes towards the status of embryos (UNESCO 2011d: 3). This could be seen as a cop-out, as was noted by one member of the IBC at its May–June 2011 meeting, where the statement was presented (personal observation). Isasi and Bartha Knoppers (2006) demonstrated the plethora of national approaches to embryonic and stem cell research in their review of policies in 50 countries. This diversity poses a challenge to international harmonization, but also makes it difficult for transnational research consortia to operate. In its 2008 interim report, the Working Group had sought to address this issue, recommending the development of guidelines at international level for states where human embryonic and stem cell research is legal, based on existing formulations by professional associations (UNESCO 2008h: 5). This idea did not survive in the later reports. The problem was that these plans, combined with a convention or moratorium specifically addressing human reproductive cloning, would have taken UNESCO very close to the initial proposals for the UN instrument, which proved abortive. Mindful of what had happened at the UN only a few years previously, member states chose the safe option, politically speaking. What this means is that the 'black hole' in international legislation on cloning that UNESCO has identified remains to be filled.

Member states of UNESCO have, arguably, shown more interest in the drafting of the three bioethics and genetics declarations than in their implementation, reflecting the compromise attached to non-binding international instruments. Despite UNESCO's considerable efforts to promote the declarations among policy-makers, experts and the general public, direct uptake by member states (as far as this can be measured) has been rather poor. This is partly because the declarations carry no legal obligations for sovereign states. It is also because, in some instances, states already have adequate policies in place. For those states that have not yet established bioethics systems, the declarations may galvanize them into doing so, or at least this is what the UNESCO Bioethics Programme hopes. Indeed, its capacity-building projects have engendered fledgling national bioethics committees and ethics education programmes in several countries, particularly in the global South. Thus it may be that the 'added value' of the declarations lies more in the initiatives they have spawned than in the documents themselves.

6 Contextualizing bioethics

The declarations in Kenya and South Africa

In the preface to UNESCO's volume on how the UDHGHR (1997) came into being, then Director-General of UNESCO Federico Mayor wrote, 'It is now the responsibility of States to breathe life into the Declaration, *inter alia*, by reflecting it in their domestic legislation' (UNESCO 1999a: III). Seven years on from the adoption of the third declaration, the UDBHR (2005), this chapter outlines how far all three are reflected in the laws, regulations and policies of two states in particular: Kenya and South Africa. First, though, we look again at the negotiation process for the 2005 bioethics declaration.[1] The analysis takes a step back from the negotiations themselves, to see what, if anything, first happened at national level to enable each country to work out its negotiating position. This is followed by a review of how stakeholders (geneticists, ethicists and so on) in Kenya and South Africa perceive the declarations and whether they see the governance of human cloning as an important issue.

Negotiations at national level

The Director-General of UNESCO reported in 2002, 'Despite the ever greater importance of bioethics worldwide, this discipline is still too often the preserve of a handful of specialists' (UNESCO 2002b: 5). Reflecting this, the UDBHR was drafted as a 'practical application' document rather than an academic one (UNESCO 2005c: 3–4). At the June 2005 IGE session charged with finalising the declaration, the Director-General thanked member states for sending 'strong, quality delegations' (UNESCO 2005m: Annex II, 1). (Williams [2005], by contrast, sardonically refers to those who attended this meeting as 'experts'.) The chief Kenyan delegate, a scientist, was selected as the country's then UNESCO Chair in Bioethics (who later became Chair of the IGBC). They were accompanied to the June meeting by the Kenyan Deputy Permanent Delegate to UNESCO (based in Paris) and to the previous session in April by a member of Kenya's National Council for Science and Technology. The chief South African delegate, a geneticist, was appointed by the Minister of Education and attended only the June meeting, although the South African Deputy Permanent Delegate to UNESCO was at both sessions. The Kenyan IGBC representatives at the January 2005 meetings were both from the National Commission for UNESCO (interviews with K_01 and SA_23; UNESCO 2005e: 1 and 9; UNESCO 2005f: 5; UNESCO 2005o: 1 and 10).

Although the majority of people from Kenya and South Africa interviewed in 2005–6 were unfamiliar with the declarations, several had strong opinions about who should be representing them at international negotiations more generally. A Kenyan civil society actor (K_14) could find no consistency from one meeting to the next: 'The people who represent the government – today it's this person, another month it's somebody completely different from another ministry.' A university researcher (K_26) also saw the appointment process as a capricious one, resulting in ill-informed government officials attending international meetings at short notice, with little time to absorb the relevant facts and statistics. They asked, 'Who is representing my views as a geneticist?' South African participants were also of the opinion that representatives at international negotiations need to have a certain level of expertise, although they differed on where the requisite expertise lay. Some of those who conduct genetic research involving human subjects felt that experience 'at the coalface' was important. This would furnish an understanding of the intricacies of obtaining informed consent, for example (interviews with SA_12, SA_20 and SA_21). One (SA_21) commented, 'I think it's very dangerous to have a group of academics putting it [the UDBHR] together when they don't understand what the issues are on the ground, because they can dream up things that are wonderfully ethically sound, but are totally impractical.' A long-standing member of a research ethics committee also thought that practical experience was important, but in terms of ethical review rather than research. Having seen some registers of those involved in UNESCO's bioethics activities, they expressed concern that very few of the people listed had sat on an ethics committee, remarking, 'I found one South African representative that I know has no bioethics research experience on any committee in this country, but is regarded as an expert – and that worries me' (interview with SA_19). Others thought that those with a background in the philosophy of bioethics had a vital role to play, because they have been trained in the logical construction of arguments. One said of the UDBHR, 'I can't see that there were bioethicists involved in the drafting of that thing. . . . I think it's unusable' (interviews with SA_08 and SA_16 [quoted]).

The tensions between these different positions were articulated by a prominent actor in South African bioethics:

> So what does it mean to be 'a bioethicist'? Should everybody who calls him or herself a bioethicist be consulted? Bioethics is a contentious field populated by scholars, professionals and others from many disciplines, not all of whom have had an adequate training or experience. So whose voices should be heard?
>
> (interview with SA_09)

Their words mirror what ten Have (2010: 14) has said in the context of the UNESCO Bioethics Programme:

> It is not clear who are experts. As an established discipline, bioethics has a body of knowledge, validated experiences, textbooks, journals, and best

practices. In this sense, there is distinctive bioethics expertise. At the same time, as a public and policy-making discourse, bioethics is also a more general approach to particular issues, expressing, for example, political views on moral issues.

On being asked who should have put the declarations together, most participants thought a range of people essential, including scientists, ethics committee members and philosophically trained bioethicists, but also government representatives, legal experts, civil society actors and those with previous experience of international negotiations (interviews with SA_05,08,10,14,21,22,24,30,31, 32,33). One government official (SA_31) who had attended many such negotiations commented, 'The people who are prepared to explore the art of the possible are the people we should have in the room' – the 'art of the possible' signifying compromise. To include at intergovernmental meetings a diverse range of stakeholders from each member state might prove impractical, but governments could seek the advice and opinions of such actors in deciding what views their delegations should take to the negotiating table. For one interviewee, whether there had been wide consultation on the draft UDBHR (2005) was more important than who actually made the final decisions: 'I think the process is key, rather than just the people' (interview with SA_22).

Kenya's role in the negotiation of the declaration was coordinated by the National Commission for UNESCO. In formulating its position, the Commission garnered opinions from various people it considered experts, namely members of its own Natural Sciences and Social and Human Sciences Committees and officials from the Ministry of Justice and Constitutional Affairs, the Kenya Medical Research Institute and the National Council for Science and Technology (interviews with K_02, K_13 and K_16). These expert views were sometimes overruled by the permanent delegates to UNESCO in Paris, who work with their counterparts from other African delegations to form positions on issues as a consolidated African Group (interviews with K_16 and K_30). Nevertheless, the chief Kenyan representative at the IGE meetings in April and June 2005 carried out a similar consultation process to the National Commission, in order to be able to present a 'Kenyan position' (interviews with K_02 and K_16).

The tension between experts and states identified at international level by IBC and IGBC members seems, therefore, to have been mirrored at national level. Two members of the National Council for Science and Technology (NCST) later explained that, because the Permanent Delegation to Paris had only recently been established at the time of the UDBHR negotiations, its connections to other bodies were uncertain. By 2012 the lines of communication with the National Commission were far better established, with Kenya's IGBC representative able to get information to the Delegation quickly and easily if unable to attend a meeting in Paris themselves. Furthermore, the Paris office has proved very useful in strengthening relations (and therefore consensus) with other countries in the African Group, not least because, being on site, they are privy to corridor conversations (interviews

with K2_16 and K2_21; informal conversation with African delegates at the IGBC meeting, September 2011).

In both Kenya and South Africa, input into the negotiating positions for the UDBHR (2005) on the part of government officials appears to have been curtailed by lack of communication within and between departments. At the time of fieldwork in 2005, both the Kenya National Commission for UNESCO and NCST fell under the Ministry for Education, Science and Technology. A member of the Commission described those at NCST as 'very close partners' and, indeed, an NCST representative attended the April IGE meeting (interview with K_16). Nevertheless, two members of NCST, who dealt with biotechnology and bioethics respectively, did not know of the declarations. The former (K_20) said that the connection with UNESCO had never been clear, the latter (K_21) that they had never heard of UNESCO engaging in any kind of bioethics activities. (K_21 did know about a proposed regional bioethics centre at a Kenyan university, but had not realized it was a UNESCO initiative.) Equally, the chief delegate to the IGE meetings (K_01) appeared unaware of ethical guidelines NCST had recently produced. It seems, then, that key information was not shared within and between the National Commission for UNESCO and NCST.

South Africa faced a similar problem, but between government units rather than within them, as it has separate departments for education and for science and technology. In 2005 UNESCO headquarters dealt directly with the Department of Education (where the South African National Commission for UNESCO was housed, now the Department of Basic Education), which did not consult with the Department of Science and Technology with regard to the UDBHR. A member of the latter (SA_26) complained, 'Different government departments are not interacting enough, so that there is kind of an information gap between the different ones and not enough collaboration.' The lack of coherence between government departments working on cross-cutting issues was also noted at an expert meeting on biotechnology held in South Africa in 2008 (NBAC 2008: 2).

Some South African government officials working on biotechnology policy in 2006 were unaware of the declarations before being asked for an interview (SA_28 and SA_31). One of them, from South Africa's Department of Science and Technology, corroborated the difficulty highlighted by IBC and IGBC members at their 2010 meeting in ensuring information gets to the right ministries:

> Basically we don't track the UNESCO processes directly from the department, which is something that made me think that we should do more, because the UNESCO relationship is owned by our Department of Education and they hadn't briefed us or asked us for assistance in this particular declaration.
>
> (interview with SA_31)

They deemed the three declarations, as a suite, to be good documents (having read them in preparation for the interview) and judged there was still time for them to contribute to the 'enabling legislative framework' called for in South Africa's

2001 National Biotechnology Strategy, where there were still gaps in legislation or regulations (DACST 2001: 50). The gaps they referred to, however, were with regard to stem cell research and the use of embryonic tissue, to which there are no references in the UNESCO declarations and, moreover, were to be covered in forthcoming national regulation. Another member of the Department of Science and Technology (SA_26) thought that it was perhaps already too late for the declarations to have much impact on South African biotechnology policy:

> Bioethics is obviously a key issue in growing a biotechnology sector, so it's very important. It probably would have been useful if, at an early stage, we could have grappled with these things and taken them on board. Not that we haven't, but we've now developed our own thinking . . . well, almost in the absence of the UNESCO documents.
>
> (interview with SA_26)

There was little or no broader dialogue with scientists, civil society groups or the general public on what they thought should be in the declaration in either Kenya or South Africa. On this point, the chief Kenyan representative at the IGE meetings said:

> No, there is not such a thing. Actually that's an issue which myself and another colleague who also attended the April meeting raised when we came back, in our report: that before any of those meetings take place, there must be meetings to agree on our stand and formulate our agenda. And that one has not taken place.
>
> (interview with K_01)

Echoing Chasek and Rajamani, they explained that internet access was slow and costly in Kenya, which may have put people off looking at the UNESCO documentation. They surmised, 'So many people are not even interested to know – if you are not directly involved, why should you read about UNESCO?' (Others interviewed in 2005 hoped new communications technologies would facilitate the country's greater involvement in bioethics and genetics. A member of the National Commission [K_16] believed email would enable Kenya to assert itself more strongly on the IGBC, while in regard to capacity development in science and technology, a scientific advisor to the Commission and the Kenyan government [K_13] averred, 'We don't need to build new buildings, we can communicate through the internet.' NCST is cautious in this regard, noting the digital divide as one of the challenges to harnessing the full potential of science and technology for development in its Strategic Plan 2009–13 [NCST 2010c: 19].)

In South Africa, the only input – albeit of a limited fashion – came from the South African Medical Association's Human Rights Law and Ethics Committee (interviews with SA_16 and SA_23). A quote from a senior member of a university bioethics department (SA_17) serves to illustrate the paucity of consultation: 'You know, UNESCO has never contacted me with anything, so it's basically

finding out from our bioethics circles as to what's happening in UNESCO and then looking up things on our own. But I have never been contacted by UNESCO.' Combined with the lack of governmental input, this left the chief delegate to the June IGE meeting with what Chasek and Rajamani would term a 'hollow mandate' as to how they were to represent South Africa. They commented, 'In hindsight, I attended the meeting poorly equipped to voice the opinions of the country' (interview with SA_23).

The declaration will need a wider support base than was evident during its negotiation if it is to be implemented fully at national level. This was recognized by participants in the UDBHR (2005) IGE meetings from both countries. The chief Kenyan delegate (K_01) thought it necessary to share the declarations beyond those few who had attended the international negotiations. 'Otherwise,' they remarked, 'we go to those meetings, we keep quiet, that's the end of it.' When interviewed in 2005, they were planning to hold a meeting to raise awareness about the declaration and to discuss how it might be domesticated, to which they would invite 'the experts, the communities and interested parties'. This they duly did in 2008 (see below). Their South African counterpart (SA_23) likewise commented that the declaration's principles needed to be promoted among the general public:

> We all have a responsibility to ensure – not just as scientists, but as members of the general public – that this sort of best practice is part and parcel of the very core of our moral values. It doesn't matter that you only try to aspire to these when you're doing genetic research, it should be core principles and perhaps we should have some education around it.

To achieve this, they said, the relevant government departments – the Department of Science and Technology, the Department of Health and the Department of Education – would have to work in partnership. Communications between the three departments and the South African National Commission for UNESCO have improved of late. The Commission, based in the Department of Basic Education, has a unit that coordinates its work in relation to 10 different government departments, including Higher Education and Training, Science and Technology and International Relations and Cooperation. The Department of Health is not one of the 10, but liaises with the Department of Science and Technology on ethics matters (email from National Commission, 24 July 2012).

Perceptions of UNESCO in Kenya and South Africa

The declarations

In 2005–6, 53 interviewees in Kenya and South Africa unconnected with UNESCO were asked to what extent they knew the three bioethics and genetics declarations. Thirty had come across them, of whom 18 only peripherally. One geneticist suggested that UNESCO publish the declarations in scientific journals, to heighten

awareness among their community (interview with K_05). (Six interviewees did have UNESCO connections. Of these six, three were unaware of the declarations before being invited to become involved with UNESCO activities.) Once informed of the content and purpose of the declarations, interviewees had varying opinions on their potential usefulness. Two South African geneticists said the declarations would need action behind them to move them beyond being merely 'a nice statement' (SA_27) or 'nice platitudes' (SA_20). A Kenyan geneticist (K_29) similarly commented, 'Of course, the implementation is quite different from the declarations themselves.' On this point, speaking in 2011, the former Kenyan Chair in Bioethics regretted that the UDBHR was adopted as a declaration rather than a convention, as this has made implementation difficult. They would have liked states to have had to submit to monitoring and evaluation (interview with K2_01).

The translation to national and local levels was the key determinant for several people. One South African supporter of the declarations (SA_01) said, 'I think that this [the UDBHR] has been a helpful document and now it's just a matter of how it filters down to more of a grassroots level.' Less positively, a South African geneticist (SA_18) ruminated,

> They seem to take the way out always of talking of the regulations in the individual countries or the laws of the individual countries and so on. So it can only be an advisory sort of document and I think that's fine, but it would seem as though they don't have any teeth.

A scientist who advises both UNESCO and the Kenyan government (K_13) believed it would be 'dangerous' to adopt the declarations without translating them into 'what is happening locally'. Several others said that universal principles should not be embraced unthinkingly; working out their practical application in particular contexts is often the most challenging aspect of implementing international instruments (interviews with K_15,16 and SA_10,17,24,25). One long-standing ethics committee member (SA_19) went further, believing there to be too much variation between countries for universal norms to be useful. They asserted, 'I believe strongly that national, local ethics guidelines are the things to follow.'

Some valued the declarations as benchmarks that could be referred to in lobbying for the introduction of internationally agreed standards at national level (K_16 and SA_13,23,30), or, like UNESCO, saw additional guidelines as necessary in an era of new technologies and scientific developments (K_10,19,29 and SA_32). A member of two Kenyan research ethics committees (RECs) (K_25) was particularly interested in the genetics declarations, because they thought it likely their committees would have to assess a growing number of protocols for research in this area in the future. Writing soon after the adoption of the UDHGHR (1997), Abbing (1998: 157) saw it as having this potential:

> The Declaration, in providing a framework which is based on general consensus, certainly will support developments in those countries where

> human rights in relation to genetics are not yet sufficiently guaranteed by the law nor applied in practice. It can be called upon in case of practices not in line with the principles layed [sic] down in the declaration.

Several participants welcomed all three declarations as reinforcing and fleshing out important principles of social responsibility, benefit sharing and capacity building (K_17,19 and SA_01,12,24,33). One (SA_11) said that the declarations are important as a 'global signpost', but that people must be given the opportunity to recognize this. A 2012 questionnaire respondent, who had come to know of the declarations through UNESCO's dissemination activities, corroborated this view. They believe the UDBHR (2005) provides important support for the human rights espoused in the South African constitution and being realized in society.

Most 2005–6 participants with an involvement in bioethics did not see the declarations' intergovernmental origins as distinguishing them significantly from other ethics documents. They (and their institutions) referred mainly to the WMA's *Declaration of Helsinki* and the CIOMS guidelines for international level guidance (K_06,07,08,09,17,19 and SA_04,05,10,14,19,24,30). Particularly with regard to the UDBHR (2005), several people saw what to them was simply another international bioethics declaration as unnecessary, or thought that people might become confused as to which guidelines (and the norms contained therein) to follow (interviews with K_07,09,17,28 and SA_04,05,08,10,14,20,22,25,27, 33). One (K_06) lamented, 'There is a plethora of different guidelines that people are trying hard to get to grips with.' Another (SA_17), who sits on several RECs, was of the opinion that there are too many 'talk-shops' coming up with declarations, to the detriment of implementation 'on the ground'. One person (SA_32) opined that, although the declarations might be useful as a reference point, by and large RECs in South Africa were already aware of the principles enshrined in the declarations' articles. Others thought the declarations complementary to pre-existing instruments or that it was useful to be able to draw on different perspectives (interviews with SA_06,24,26,30,31). Researchers at the Kilifi KEMRI-Wellcome Trust Collaborative Programme in Kenya and the South African National Bioinformatics Institute, for example, when faced with a particular ethical problem, would look to synthesize all the relevant resources in order to reach the most appropriate solution (interviews with K_07 and SA_02).

The concern about overlap was still present in 2011–12. Although not dismissive of the declarations, a member of KEMRI (K2_17) did not see them as automatically becoming the main reference documents on ethics: 'UNESCO, for many of us, is a new kid on the block . . . for myself it would just be like any other thing I might be interested in.' A representative of the Regional Documentation Centre at Egerton University (see Chapter 7) recognized that it would be some time before knowledge about the declarations spread beyond those who attend UNESCO-sponsored conferences and workshops (interview with K2_32). Among the small number of people who returned follow-up questionnaires in 2012 (11 from South Africa, four from Kenya, with an even split between scientists and ethicists from both countries), only two used the declarations in their work, with the chief

international reference points remaining the *Declaration of Helsinki* (used by 11 people), the CIOMS guidelines (nine) and the US' Belmont Report (seven). One person added, 'It is to some extent a time issue' and suggested that the declarations could be posted on the website of the Southern African Society for Human Genetics, to make them more easily accessible. More encouragingly, although opinions on the significance of (a) the declarations having been agreed by states and (b) the UDBHR addressing bioethics in a broad sense (rather than just research ethics) ranged from 'not at all significant' to 'very significant', there was a positive leaning on both counts, 10 people apiece opting for 'quite significant' or 'very significant'. One person elaborated on their apparently contradictory responses, explaining that, although their institution did not currently use the declarations, they believed them to be potentially important documents. Another will refer to the declarations on an upcoming project establishing a biobank for Africa. (Note that the questionnaire was not sent to members of the Kenyan National Bioethics Committee, as the aim was to see what influence the declarations had had beyond those involved in the ABC programme – see below.)

Human cloning

Views on the governance of human cloning in Kenya and South Africa reflect those of IBC and IGBC members and sub-Saharan National Commissions and Permanent Delegations, in content and diversity. Kenya does not as yet have an official position on whether or not human reproductive cloning should be banned (interview with K2_21). One NCST member (K2_21), interviewed in 2011, felt that the issue is presently only of peripheral importance to Kenya and other developing countries, but as the technology is likely to be developed soon it is important to be ready, as cloning legislation could have a big impact. Another (K2_16) felt that a meeting with politicians was necessary to educate them on the issue, so that they would not take misinformed positions, as some had done on genetically modified organisms (GMOs). A Kenyan scientist and public policy activist (K2_31) was concerned that research would move faster than legislation, leaving responsible researchers without guidance and resources and rogue scientists to do as they please. They thus supported an international convention to regulate cloning. Echoing the comments of Maimets and the Russian Federation delegate about how UNESCO's silence on the issue might be perceived, they went on:

> You know, unless the same international bodies become bold enough and have a convention, based upon which countries can draw their policies and legislations, then you will potentially be leaving very delicate and important research and development, especially in the area of human genetics and reproductive cloning, to decisions by individuals. . . . So a convention would be a good start. What I'm just wondering is, who are the lead opponents of not having a convention? I mean, why wouldn't we have a convention to regulate activities in reproductive cloning? . . . they don't have to wait for – what I should say – rogue research, or research that does not intend to be

> beneficial but commercial. They don't have to wait for certain negative outcomes before they decide that a convention is necessary. I think it would just be good to have a measure in place that researchers in various countries can use to regulate themselves.

Among questionnaire respondents, only four supported an outright ban of human reproductive cloning, while nine thought that research in this area should be carefully regulated (two did not answer the question). A Kenyan scientist (K2_32), interviewed in 2011, displayed a similarly cautious optimism:

> All these technologies have benefits, but they also have risks. . . . So what I would say is to just take a precautionary approach. We cannot say a complete no, but we can also not say an open yes. It's just a matter of learning from what's going on elsewhere, but also taking precaution.

Thirteen and ten questionnaire respondents respectively thought that therapeutic and reproductive cloning were important issues, warranting UNESCO's attention. They were less sure that cloning technologies have the potential to make an important contribution to addressing development needs, several finding themselves perplexed by this notion. Most supported international dialogue as a means to improve the international governance of human cloning. One geneticist elaborated that this would help to create essential awareness about the difference between therapeutic and reproductive cloning (and thought that cloning could contribute to development 'when used correctly and in a scientifically safe and ethically sound environment'). Another, like the IGBC delegate from Switzerland, reasoned that intense dialogue would raise awareness and thus lead to better regulation and monitoring. Fewer respondents favoured a convention, mirroring the IBC's preference for dialogue.

Adoption of the UNESCO declarations in Kenya and South Africa

Both Kenya and South Africa are upholding the UNESCO declarations to a greater or lesser extent, through their regulatory frameworks for bioethics and genetics. The ethics systems in both countries have developed substantially over the last decade. Both adopted national guidelines on bioethics in 2004: *Guidelines for Ethical Conduct of Biomedical Research Involving Human Subjects in Kenya* and *Ethics in Health Research: Principles, structures and processes* (South Africa). Both countries also have more specific guidelines, on HIV/AIDS vaccines and clinical trials: the *Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines* (2005), the *Guidelines on Ethics for Medical Research: HIV preventive vaccine research* (produced by the Medical Research Council of South Africa in 2003 and adopted as national guidelines) and the *Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa* (second edition, 2006). As might be expected, these documents articulate

well-established bioethical principles such as informed consent, autonomy, privacy and confidentiality and the need for risk/benefit analyses. They also deal to some degree with several of the issues discussed in Chapter 2 around the ethical dilemmas generated by genetics and research in developing country contexts. In this they draw on the *Declaration of Helsinki*, the CIOMS guidelines and other international ethics documents, but not the UNESCO declarations existing at the time of their publication.

Kenya in 2005

Under the 1977 Science and Technology Act, the National Council for Science and Technology was established to advise the government on 'all matters relating to the scientific and technological activities' (NCST 2012b). It was given ultimate control over what research takes place in Kenya and the power to ensure it is conducted ethically. Some of these powers were devolved to institutional ethics committees, such as the Ethical Review Committee of the Kenya Medical Research Institute (KEMRI). The 2004 ethical guidelines (produced by NCST) described this system as 'weak with many loopholes' (NCST 2004: 2). Certainly, the regulatory framework was far from clear in 2005, when the first period of fieldwork in Kenya was conducted. A member of the Council explained that ethics were not a major concern when the Science and Technology Act was promulgated and thus do not feature prominently within it. NCST had been pushing for many years for the Act to be updated to include current ethics issues, but as several acts were awaiting amendment this was likely to take some time (interview with K_21). The KEMRI ethics committee had gone one step further and recommended a 'stand alone' act for biomedical research involving humans, seeing the Science and Technology Act as too generalized (interview with K_19). The KEMRI-Wellcome Trust Collaborative Programme at Kilifi was using the NCST guidelines, but was assuming these were still in draft, having not heard otherwise (interviews with K_06, K_07 and K_09). On being asked whether the guidelines were legally binding, one member (K_06) commented that this 'would be quite a useful thing to know'. A member of NCST (K_21) confirmed that they could not be binding, by their very nature as guidelines.

Fieldwork revealed some ambiguity as to the status and purpose of certain ethics committees in Kenya. The Science and Technology Act (1977) made provision for a medical sciences committee. This became the Health Sciences Specialist Committee in 1983 and took on responsibility for research ethics policy, regulating institutional committees (such as the KEMRI committee) and reviewing proposals from foreign researchers (interview with K_21; NCST 2010a: iii). Several interviewees in 2005 agreed that, in practice, the KEMRI committee functioned as a national ethics committee, as it is mandated to review protocols from researchers based outside KEMRI (K_07,15,19,21,22,25). Indeed, the KEMRI website reads, as it has done for several years, 'The Committee is accepted by the Ministry of Health as a National Ethical Review Committee' (KEMRI 2012). It seems strange, then, that the Ministry decided to set up its own

ethics committee. In January 2001, following recommendations in the National Health Sector Strategic Plan, it established a Health Standards and Regulatory Services Department to, among other things, 'provide the priority medical research agenda' and 'review medical research protocols in Kenya' (Ministry of Health, Republic of Kenya 2001: 1–2 [quoted]; interview with K_27).

As noted by Daniel arap Moi, then president of Kenya, the new department's mandate included the launch of a national ethics committee (Ministry of Health, Republic of Kenya 2001: 6). The National Medical Research, Ethics and Traditional Medicine Committee was duly created in 2002, ostensibly including KEMRI and NCST among its membership (Ministry of Health 2003). On the relationship between this new committee and KEMRI, a member of the latter (K_17) said in 2005:

> The Ministry of Health wanted to start their own. It would be a year ago, we all met together, the Director of Medical Services and some visitors from the Walter Reed [a US-based institute] and they said that they wanted to start their own. But, notwithstanding, we decided we would not wait for them. If they started their own, that's fine and they'd tell us how we would relate to them. But we consider ourselves the National Ethical Review Committee.

They also explained that, as a consequence of the proliferation of committees, it was possible that some research went unapproved, because people could plead, 'I got confused, I didn't know where to go, so I decided not to go anywhere.' A Ministry of Health report (2003) similarly acknowledged that stakeholders needed to be educated on the relationships between KEMRI, NCST and its new committee.

Despite the profusion of committees described above, in 2005 the National Commission for UNESCO, with the then Bioethics Chair, was looking to form a National Bioethics Committee (interviews with K_01 and K_16). Their rationale was the same as that behind UNESCO's Assisting Bioethics Committees initiative: they would start with a committee and perhaps push for a bill 'later on' (K_01). (Interestingly, however, the Chair was unaware at the time of UNESCO's guidelines on how to set up just such a committee.) A member of the Commission did not think the new committee would overlap with Kenya's pre-existing ones because it would engage primarily in sensitizing people about bioethics and the three UNESCO declarations in particular, rather than ethical review. They said, 'I don't think there's any other committee that is doing that.' Furthermore, it would include among its membership representatives from the relevant government bodies (interview with K_16). Not everyone was convinced. A member of NCST (K_21) welcomed the idea of working with UNESCO to promote knowledge sharing and capacity building, but thought that a new committee was unnecessary.

As for the declaration being adopted into Kenyan law, those connected with UNESCO explained why it might be a long time before this happened. A member of the National Commission (K_16) outlined the difficulties of first raising the

necessary political will: 'How are you going to sell it to your country? How do you advise? Do you wait until there's a problem, then you say, "Okay, let's refer to . . ."? Or do you need to sensitize people in advance?' Even if this were to be achieved, the legislative process is a slow one, involving negotiations between several ministries. It can also be somewhat capricious. A scientist who was advisor to both UNESCO and the government (K_13) warned that if the desk officer assigned the portfolio for adoption of a declaration was a 'middle of the roader', nothing might happen for several years. The National Commission representative lamented the slow rate of legislation in Kenya, which meant the system was clogged with pending bills. Also, they pointed out, if the government changes, sensitization of ministers has to begin all over again. In spite of such difficulties, they believed the sensitization of policy-makers worth pursuing, to gain backing for the financial support of the Commission's programmes. If policy-makers believe an issue to be important, they said, they will provide the resources to recognize this importance (interview with K_16). A long-standing member of a Kenyan REC (K_19) described what could be achieved by engaging with government: 'Our policy-makers here are fairly open, yes, they are quite open to new ideas. But as I say, you just need to empower them with the information, they need to know what you are talking about.'

Kenya in 2011

There have been significant changes in the research ethics regulatory framework in Kenya since 2005. A National Bioethics Committee (NBC) has indeed been formed, but through NCST rather than the National Commission, replacing the Health Sciences Specialist Committee (HSSC). The Ministry of Health's ethics committee, created in 2002, has also become part of the new NBC. NCST realized that its ethics provision was no longer adequate, as there are several more research institutions in Kenya now than when it was established in 1977. Thus in 2009 the HSSC took on the task of 'transforming itself' into the National Bioethics Committee of Kenya, broadening its mandate in light of the UDBHR of 2005 (UNESCO 2009a: 1; NCST 2010a: iii and 1 [quoted]; interviews with K2_21 and K2_25). Here the declaration's intergovernmental origins played a part; it was felt that, because it sits closer to law than WHO and CIOMS guidelines, it would be easier to domesticate and use in legal activities (interview with K2_21). The committee's new mandate includes advising the government on ethical issues, such as traditional medicine and use of technology; providing a forum for consultation and public debate; ensuring the highest ethical standards in research; training and accrediting institutional ethics committees; publishing guidelines (on materials transfer, for example); and liaising with corresponding bodies in other countries (NCST 2010a: 1–4; interview with K2_21).

The committee has 17 members and is multidisciplinary (in line with article 19 of the UDBHR), to save procedures 'from being mere rhetorical gambits' (NCST 2010a: 1 [quoted]; interview with K2_21; NCST 2012a). By November 2011, when the second period of fieldwork was conducted, it had met six times and its

members believed it had achieved a lot in a short period (interviews with K2_21 and K2_25). It had also gone through UNESCO's ABC programme, becoming the first committee to complete all three stages of the training. Like the founding of the new committee, the training was organized through NCST, which had established a direct connection to the UNESCO Bioethics Programme secretariat in Paris. The Memorandum of Understanding was signed with what had become the Ministry of Higher Education, Science and Technology, NCST's parent ministry (separate from the Ministry of Education, the parent ministry of the National Commission) (UNESCO 2009a: 1; ten Have *et al.* 2011: 385; interview with K2_21).

The first training, held in November 2009, was attended by members of the HSSC, as well as representatives of Kenyatta National Hospital, KEMRI and other universities and research institutions, some of whom were destined to sit on the new committee. As well as discussing ethical issues of particular concern in Kenya (including regulation of traditional healers, use of genetic samples and review of multi-centre research), participants drafted the mission, role, mandate and rules of procedure of the new NBC (UNESCO 2009a: 2–4). As per the ABC model, the third training session in November 2011 dealt with issues of particular relevance to the country, including accreditation of institutional RECs and materials transfer agreements (conversations with participants, November 2011). Over the year 2011–12, the NBC would also be deciding whether ethics committees are needed at provincial level (interview with K2_21).

The NBC has devised a comprehensive system for the accreditation of institutional RECs. The relationship between NCST and these committees was unclear in the past, but has improved (interview with K2_25). As the inaugural edition of *Bioethics Info-Net*, a newsletter produced by the Kenyatta National Hospital-University of Nairobi REC, notes:

> In the past the NCST could only note the existence of committees and several did not inform the NCST of their existence. . . . Accreditation will reinvigorate ethics review in the country and ensure sustainability as the national research system continues to grow.
>
> (KNH-UoN REC 2011: 4)

The accreditation application form (NCST 2011) asks for information on the genders, qualifications and specializations of committee members and whether they have had ethics training. It also asks for a copy of a committee's standard operating procedures. To pass, a committee must have at least seven members, a variety of expertise, at least one member from outside the institution, a lay member and a gender ratio of no more than 2:1 either way. Accreditation lasts for three years and committees must send in annual reports, to include details of research protocols reviewed and any training, monitoring or difficulties encountered (NCST/NBC 2011: 4–5).

All institutions with RECs were required to apply for accreditation by October 2011, including 'those that have been in existence for a long time' (NCST no

date). As of July 2012, 12 RECs had been accredited, from both public and private institutions, out of 15 applications and an estimated 30 to 35 committees in the country in total (NCST 2012a; interview with K2_21). At present there is no absolute legal obligation for committees to apply, but they would have to under a revised law. A member of NCST (K2_21) was confident that more RECs would come forward once the structure was wholly in place, as most have already gained the US Federal Wide Assurance, which is required of any institution receiving research funding from the US federal government. Under the new system, research protocols can be submitted to any accredited committee. It was hoped this would lighten the KEMRI committee's burden, but this effect is yet to materialize. Both national and international applicants have so far stuck with KEMRI, as they are familiar with its processes (interview with K2_17).

Another task the NBC is undertaking is a review of the 2004 ethical research guidelines. This is necessary, states the NCST website, because 'research activities have grown in quantity and the global arena has shifted towards favoring the conduct of research in countries that have weak research infrastructure' (NCST 2012a). (Note also that the guidelines do not specifically cover genetic research.) The review sits alongside the broader effort to revise the Science and Technology Act, which finally progressed, after much 'forwards and backwards', after the adoption of the new constitution of 2010 (interview with K2_21). Several acts are being revisited to ensure they comply with the constitution, particularly with regard to human rights, as well as a more regionalized form of government. The draft of the new science and technology act was formulated by a taskforce and adjusted in light of public comment and debate, before being put before Parliament. NCST members hoped that the new act would be in place by 2013, but once a piece of legislation reaches the political level it is out of their hands. Given the number of acts being deliberated, in function of the new constitution, it may take some time (interviews with K2_16 and K2_21).

There are also plans for an act specifically on ethics and committees, as the current provisions are not well grounded in legal terms. This will draw on the UNESCO declarations (interviews with K2_16, K2_21 and K2_32). They are useful in countries where the requisite ethical structures do not exist, a member of NCST (K2_21) explained, unlike in Europe and the US, where ethics systems have been developing since the Second World War. The UDBHR (2005) is especially pertinent, said their colleague (K2_16), because Kenya participated in its drafting. Even though it is rather weak, as a non-binding instrument, that active involvement has an impact on a nation. Again, the timeframe is uncertain, but the NBC was to use 2012 to lay the groundwork by talking to the government about how the UDBHR should be understood.

What has seemingly changed little since 2005 is the relationship between NCST and the National Commission for UNESCO. One member of NCST viewed the relationship positively, seeing the work of the two bodies as complementary. For one thing, NCST provides advisors for the Commission's specialist science committees. They explained:

> So you can see the Council and the Commission have no choice other than to work together, because one is a national institution – competent institution – for science issues. KNATCOM, or National Commission, has mandate over those science areas that are handled by UNESCO. . . . So any committees of KNATCOM, then the Council sits in, depending on the area. So the Council sits on that to provide the advice. Now, when we have issues that cut across a couple of ministries and it's not necessarily a UNESCO issue on its own, then we take it up as a Council.
>
> (interview with K2_16)

Yet this does not appear to be how the relationship works when it comes to bioethics. Another member of NCST (K2_21) said that all three ABC trainings had already taken place and the National Commission had not been involved: 'I think that tells you everything you need to know.' They saw the Commission as a primarily diplomatic rather than 'hands-on' body that focuses mainly on basic education and did not think the imminent reintegration of the education and science and technology ministries would make a difference to the relationship. The former Bioethics Chair (K2_01), who had been peripherally involved with the formation of the NBC and had attended the second ABC training at the invitation of the Bioethics Programme secretariat in Paris, was more hopeful in this regard, but was irked that the Commission had not been invited to join the NBC or attend the training. In his view, the National Commission, as a UNESCO body and therefore broad-ranging, was better placed to deal with cross-cutting bioethics issues than NCST, which falls under a particular ministry. They also felt that the Commission needed a new paradigm of operation that would see it being more proactive as a link between the government and the people.

Given the lack of communication between NCST and the National Commission, it is perhaps not surprising that Kenya's progress report to the 2011 UNESCO General Conference, delivered by the Minister of Education, did not mention the setting up and training of the NBC (Republic of Kenya 2011). But despite their reservations about the Commission, the NCST representative would be happy to work with the Bioethics Chair and Regional Documentation Centre at Egerton University (see Chapter 7) to run training courses for institutional REC members (interview with K2_21). What has improved since 2005 is Kenya's participation in the IGBC, which has become more structured. Whereas before 'consultation was quite narrow and to a few individuals who are in the know', the IGBC representative (a member of NCST) will now be able to refer issues to the NBC. Some issues may also be referred, where relevant, to the new National Biosafety Authority, which is independent but was 'a baby of the Council' (interview with K2_16).

The National Biosafety Authority is an outcome of the National Biosafety Act of 2009. At the time of fieldwork in 2005, Kenya was awaiting the adoption of a Biosafety Bill, which was first promulgated in 2003. Interviewees could see neither the Bill being expanded to cover human genetics, nor a separate bill on the human side being drawn up in the near future (K_01,13,18,21). In 2006 the

National Biotechnology Development Policy was published: 'The Government will initiate appropriate steps to nurture platform biotechnologies for the benefit of Kenyans and, ensure that Kenya becomes a key stakeholder in the international biotechnology enterprise within a decade' [sic] (Republic of Kenya 2006: 5). The policy specifies six priority areas, including medical biotechnology (to include molecular diagnostics, but expressly not human cloning or the unethical use of stem cells) (ISAAA 2009).

It is agricultural biotechnology which has received the most attention, both from policy-makers and the public, with the National Biosafety Act being adopted after more than a decade of wrangling about GMOs (Karembu *et al.* 2010). The National Biosafety Authority oversees the handling and use of GMOs, thus implementing the Cartagena Protocol on Biosafety (National Biosafety Authority 2012). Kenya has also been devising a Biosciences Framework, which was due to be finalized by June 2012. The framework will deal with non-human research, promoting biosecurity, biosafety and the bioeconomy; that is, the safe, sustainable, developmental and fair use of biological materials (NCST 2012c; conversation at NCST, November 2011). Broader still is Vision 2030 ('A Globally Competitive and Prosperous Kenya'), launched in 2007, which seeks to transform Kenya into a middle income country by 2030. 'Science, Technology and Innovation' is one of six foundations of the policy, as reflected in the government's significantly increased funding of research in recent years (Republic of Kenya 2007: i–ii; NCST 2010b: 30; NCST 2010c: 33; interview with K2_31).

South Africa in 2006

The South African bioethics framework was somewhat more coordinated than the Kenyan one in 2005–6. The South African Constitution of 1996 entrenches the rights and dignity of all, including the right 'not to be subjected to medical or scientific experiments without their informed consent' (Cleaton-Jones and Wassenaar 2010: 710; Dhai and McQuoid-Mason 2010: 2). According to the National Health Act of 2003, implemented by the Department of Health, a National Health Research Ethics Council is to carry out a variety of tasks, including writing guidelines for RECs and setting norms and standards for research with humans; disciplining those found to be in violation of these guidelines or norms; registering and auditing RECs and adjudicating complaints about them; and advising the national and provincial departments of health on issues in research ethics (Clause 72 (6)) (Republic of South Africa 2004: 74). The 2004 ethical guidelines, *Ethics in Health Research: principles, structures and processes*, were written by an interim committee, which subsequently disbanded. At the time of fieldwork in early 2006, the permanent council had not yet been appointed (an invitation for nominations had been issued) (Republic of South Africa 2006).

In terms of implementation of the UNESCO declarations, the chief South African IGE delegate (SA_23) acknowledged, 'The translation post the declaration [UDBHR] has been absolutely pathetic and somebody needs to drive it in a

forceful sort of way. And I don't believe that the infrastructure is there for that to happen.' On returning from the IGE meeting in June 2005, they recommended in their report to the South African National Commission that the country should have a central committee to deal with ethics. This committee would engage with the various RECs around the country, to bring them under one 'umbrella' within a virtual structure. National guidelines would 'serve as a framing document that's a "one-stop shop" for anyone wanting to apply to ethics committees to conduct research', thus ensuring that people would be following the same rules, whether they were based within a university, an NGO or any other institution. These proposed functions are in fact very similar to those set out in the National Health Act for the planned National Health Research Ethics Council.

South Africa in 2012

The permanent National Health Research Ethics Council (NHREC) was established in October 2006 and met for the first time in January 2007. Its mandate, as set out above, is very similar to that of Kenya's National Bioethics Committee: standard setting, accrediting and monitoring RECs and advising the government. It can also take disciplinary action against anyone contravening the National Health Act (and any related norms, standards or guidelines) and draft or advise on amendments to relevant sections of the Act (namely Chapter 8 on human samples and Chapter 9 on research). The committee has 14 members, appointed by the Minister of Health (the Department of Health provides the committee secretariat). The members, with other appropriate persons, also form various working groups on pertinent topics, such as vulnerable populations and materials transfer (Department of Health 2010; NHREC 2010: 4; NHREC 2010–11: 8–9 and 13; NHREC 2012c).

The composition of the NHREC and its rules of procedure are regulated under the National Health Act. Section 72 specifies aspects such as the number of members (no more than 15) and the nomination process, but regulations published in September 2010 expand on these stipulations. (Draft regulations for public comment were published in February 2007, but appear to have been finalized only several years later, a few months after the committee's second term of office began in 2010 [Republic of South Africa 2007d and 2010a; NHREC 2010–11: 9]. The draft and final regulations for the National Health Research Committee, which decides on and coordinates health research by public bodies, identifies priority areas and advises the Minister on strategy, were published in the same months [Republic of South Africa 2004: 73, 2007c and 2010b].) Under the regulations, NHREC members must include a range of experts in ethics and law, as well as representatives of the community and the pharmaceutical industry. Nominations are to be sought via the Government Gazette and one or more newspapers, 'enjoying circulation in the entire Republic for appointment'. The committee must meet at least four times a year (Republic of South Africa 2010a: 4–5 and 7). Chapter 11 of the Act, 'Regulations', makes provision for the Minister of Health to constitute regulations relating to any aspect of the Act, after public

comment, with any on human subjects research to be made in consultation with the NHREC (Republic of South Africa 2004: 88–90).

The REC accreditation requirements are very similar to those in Kenya. Using language that mirrors strongly article 19 of the UDBHR, the 2004 ethical guidelines stipulate that RECs should be 'independent, multi-disciplinary, multi-sectoral and pluralistic'. They must have a minimum of nine members, including at least one lay person and neither gender is to have more than 70 per cent of seats. Accreditation will be re-assessed every three years (Department of Health 2004: 13 and 15). The application form (NHREC no date) requires details of stakeholders (organizations) which can submit applications to the REC, number of applications processed, terms of reference and working procedures. All RECs were to register with the NHREC by 30 April 2008, but an evaluation carried out in October 2009 (by which time 22 had registered) showed that the NHREC still had to identify and register some committees, primarily those recently established or in private organizations (NHREC 2008; NHREC 2009: 5 and 13). By July 2012 there were 33 RECs on NHREC's online register (NHREC 2012a). Where the process differs from Kenya's is that accreditation in South Africa is offered at two levels. Level 1 committees can only review research that is likely to be of minimal risk (that is, low budget research not involving drug testing or human tissue), whereas Level 2 committees can review all types of health research, including multi-centre studies involving collaboration within South Africa or beyond. Level 1 accreditation is considered a 'stepping stone' towards Level 2, hence committees are encouraged to build the capacity required for the higher level within five years of registration (Department of Health 2004: 12).

As in Kenya, the 2004 guidelines are under review. By 2010–11, the NHREC's Ethics in Health Research Working Group had examined the first four chapters of the guidelines and sent out revisions for wider stakeholder input. The NHREC 2010–11 report (p. 19) reads:

> The guidelines 'Ethics in Health Research: Principles, Structures and Processes' (blue book) was last updated in 2004. Since then numerous changes had occurred in NHREC and the National Health Act prompting a need to review and revise the ethical guidelines. It was also noted that NHREC played a national role in coordinating activities in research ethics and so had a responsibility to debate and deliberate important substantive issues in research ethics with a view to formulating a policy document on these issues. It is on this basis that this working group was constituted.

Section 71 of the National Health Act ('Research on or experimentation with human subjects') came into effect from 1 March 2012. This introduces some new requirements for health research, such as the categorical need for written consent. A statement posted on the NHREC website (NHREC 2012f) acknowledges that the 2004 guidelines are in conflict with these legal requirements and pledges that detailed regulations, including guidelines for RECs, will be issued in due course. In May 2012 the Department of Health issued a policy framework for health

research approval, consolidating the basic requirements of the South African Constitution, the Health Act, the 2004 ethics guidelines and the 2006 clinical trials guidelines (Department of Health 2012).

Brief regulations had already been released in 2009 with regard to 'research on human subjects', which contained several of the provisions on consent referred to in the NHREC's 2012 statement, including the need for ministerial consent for non-therapeutic research with minors. These do not appear to have been formally adopted, however, as they are no longer available in the South African Government's online document repository. Draft regulations (which remain in the repository) had first been released for public comment in February 2007 (Republic of South Africa 2007b and 2009). The NHREC's 2006–9 progress report notes the drafting of these regulations as one of the activities of the Human Subjects in Research Working Group. In 2008 the Group was awaiting ministerial approval and translation to the vernacular and in 2009 consolidated the final version in light of public comment (NHREC 2010: 6–7). In the NHREC's second term of office, the Group merged with the Vulnerable Persons Working Group, to form the Regulations Related to Protection of Vulnerable Human Research Participants Working Group. Activities in 2010–11 included 'development of draft amendments to s71 of the National Health Act, and submission to the Legal Unit in the DoH' and a meeting with said Legal Unit to debate the regulations on human subjects (NHREC 2010–11: 13–14). This appears to have been a separate process to the review of the 2004 guidelines. (No further update was available as of July 2012.)

Unlike Kenya's 2004 guidelines, South Africa's contain chapters on human genetic research and the use of human samples. These mirror many of the articles of the IDHGD (2003). The chapter on human genetic research recognizes that individuals share genes with relatives and other members of the population and may be subject to genetic discrimination or stigmatization. It stipulates, 'Researchers should consider the social and cultural significance of their research, especially in the areas of complex socially significant characteristics and the genetic characteristics of collectivities' (Department of Health 2004: 42–5). 'Collectivities' are defined as:

> Groups distinguished by: common beliefs, values, social structures and other features that identify them as a separate group; customary collective decision-making according to tradition and beliefs; the custom of leaders expressing a collective view; members of the collectivity being aware of common activities and common interests.
>
> (ibid: 28)

Despite these synergies, the UNESCO genetics declarations do not appear to have inspired this chapter, as they are not cited in the guidelines' list of key international texts. As the guidelines were published in 2004, it is possible that the chapter on genetic research had already been drafted when the IDHGD was adopted in October 2003.

The chapter of the 2004 guidelines on human samples simply repeats section 68 of the National Health Act ('Regulations relating to tissue, cells, organs, blood, blood products and gametes'), with the added provision that 'additional ethical issues that arise in genetic research using human tissue need to be addressed in conformity with human genetic research (Reproductive Biology and Genetic Research [MRC Book 2])' (Department of Health 2004: 38). This book forms part of the Medical Research Council of South Africa's *Guidelines on Ethics for Medical Research*. Echoing some of the philosophical objections to human reproductive cloning outlined in Chapter 2, the book states, 'The pre-embryo [the stage from fertilisation to 14 days] should be treated with the utmost respect because it is a genetically unique, viable human entity. . . . The production of excess embryos for the sole purpose of research should be discouraged' (MRC 2002: section 2.2). It also recommends that human reproductive cloning through somatic cell nuclear transfer (SCNT) be prohibited, on the grounds that the risks to the potential child outweigh the benefits (ibid: section 3.7.3). The National Health Act prohibits human reproductive cloning by any means (Republic of South Africa 2004: 63).

Since 2006 there has been a whole raft of regulations to further enact the National Health Act, particularly section 68. Some were presented as drafts for public comment in 2007, but never came to fruition. Instead, new drafts on the same section were produced in 2011, with the final versions coming into force on 2 March 2012, as outlined in Table 6.1. The delay in instituting these and other

Table 6.1 Promulgation of sections 68 and 71 of the National Health Act

Name	*Section of Act*	*Date of draft*	*Date came into force*
Regulations regarding the use of human DNA, RNA, cultured cells, stem cells, blastomeres, polar bodies, embryos, embryonic tissue and small tissue biopsies for diagnostic testing, health research and therapeutics	68	5 Jan 07	N/A
Regulations relating to research on human subjects	71	23 Feb 07	N/A
Regulations relating to human stem cells	68	4 May 07	N/A
Regulations relating to the use of human biological material	68	1 Apr 11	2 Mar 12
Regulations regarding the general control of human bodies, tissue, blood, blood products and gametes	68	1 Apr 11	2 Mar 12
Regulations relating to the import and export of human tissue, blood, blood products, cultured cells, stem cells, embryos, foetal tissue,[a] zygotes and gametes	68	1 Apr 11	2 Mar 12
Regulations relating to stem cell banks[b]	68	1 Apr 11	2 Mar 12
Regulations relating to tissue banks	68	1 Apr 11	2 Mar 12

[a] the words 'foetal tissue' did not appear in the title of the draft version of the regulations.
[b] the draft title was 'Regulations relating to stem cell institutions or organizations'.

parts of the Act was a cause of concern for scientists and legal experts alike in South Africa, who wrote in the country's medical and legal journals of their frustration at the lack of up-to-date legislation, the most relevant promulgated act being the Human Tissue Act of 1983 (Pepper 2009: 505; NBAC 2010: 2; Swanepoel 2010: 3; Sithole 2011: 56–7).

In January 2007 the South African government invited comment on proposed 'Regulations regarding the use of human DNA, RNA, cultured cells, stem cells, blastomeres, polar bodies, embryos, embryonic tissue and small tissue biopsies for diagnostic testing, health research and therapeutics', another adjunct to the National Health Act (Republic of South Africa 2007a). These gave comprehensive instructions on the collection, processing, storage and use of DNA, RNA and so on. The draft regulations relating to research on human subjects of 2007 also contained a chapter on genetic research, but this was dropped from the unadopted 2009 version (Republic of South Africa 2007b and 2009). The 2012 regulations on biological material cover the collection and use of material from living and dead persons, for genetic testing and research, sex selection (prohibited except for medical reasons) and stem cell research and therapy (allowed, including the use, but not creation, of embryonic stem cells), as well as storage and disclosure of genetic information (Republic of South Africa 2012d).

The other 2012 regulations (see Table 6.1) expand on those on biological material. Those on bodies, tissues and so on outline how and for what purposes these can be procured; those on import and export give detailed guidance on the circumstances under which permits will be issued; and those on stem cell and tissue banks deal with donation, handling, storage and record keeping (and, for tissue banks, registration and inspection). All five sets of regulations carry penalties of fines and/or imprisonment for contravention or non-compliance (Republic of South Africa 2012a, 2012b, 2012c, 2012d, 2012e). While all these regulations mean that the whole of Chapter 8 of the National Health Act has now been enacted, the legislation is not sufficient to deal with stem cell tourism or therapies being offered that have not been fully tested (Pepper 2012: 60). The influence of the UNESCO declarations on the formulation of these regulations, if any, is unclear. When interviewed in 2006, one member of the team that drafted the 2007 version (on DNA, RNA and so on) was unfamiliar with the UNESCO instruments, while another said that the 1997 and 2003 declarations had 'definitely assisted the writing of the regulations for the genetics that's going to come through soon' (interviews with SA_04 and SA_17 respectively).

As well as the regulations for genetic research that fall under the National Health Act, South Africa has a National Biotechnology Strategy (2001), administered by the Department of Science and Technology. (The strategy was published by the Department of Arts, Culture, Science and Technology, which split into the Department of Arts and Culture and the Department of Science and Technology in 2002.) The strategy includes a National Biotechnology Advisory Committee, which was in the final stages of composition at the time of fieldwork in May 2006. The proposed function of the committee was to advise the Minister of Science and Technology on the progress of biotechnology development in South Africa,

particularly in terms of innovation and commercialization, but also ethics and legislation. Initially a separate bioethics committee was also planned, but after consultation with the South African Medical Research Council, the Department of Health and experts in the field (including a member of the Interim National Health Research Ethics Committee), it was decided that this would only duplicate existing initiatives. Instead, the advisory committee was to include ethicists among its members, to keep it informed of relevant bioethics issues or developments (interviews with SA_28 and SA_31). Solomon Benatar was appointed (NBAC 2006).

The National Biotechnology Advisory Committee met for the first time in November 2006. Since then it has held four workshops, on South Africa's biotechnology sector (2008), the biotechnology policy environment (2009), the biotechnology pipeline (2010) and bioprospecting for the bioeconomy (2012). The Committee has also produced position statements bemoaning the lack of regulations on stem cells and 'genomic sovereignty' (that is, matters of access to and benefit sharing from human genetics, including import and export of materials). The statements are undated, but it seems reasonable to deduce that they played a part in bringing about the regulatory push of 2011–12. At the 2008 workshop, Benatar put forward the view that bioethics should not be seen as a 'handmaiden' to biotechnology, to be used as a convenient support for arguments for scientific advancement, but as an opportunity to ask important questions about what research should be done and why, in the context of addressing inequalities of health, poverty and human rights (NBAC 2008: 6–7).

Also under the auspices of the National Biotechnology Strategy, the Department of Science and Technology produced two sets of guidelines (legal and ethical) on biotechnology research in 2006, in partnership with the Health Professionals Council of South Africa (HPCSA). These are still referred to by some researchers, according to 2012 questionnaire respondents, yet are not available on the department's website, nor can they be found via an internet search. The HPCSA produced a series of booklets in 2008 on a plethora of ethical issues, one of which is on biotechnology research. It does not include the UNESCO declarations in the list of local and international documents used in compiling the guidelines (the *Declaration of Helsinki*, the CIOMS guidelines and the Belmont Report all feature), but article 2 of the UDHGHR (1997) is quoted, which states that everyone's rights and dignity must be respected, regardless of genetic characteristics. As the booklet was written with funding from LifeLab, one of the Biotechnology Regional Innovation Centres set up under the National Biotechnology Strategy, it appears it has subsumed the 2006 guidelines (HPCSA 2008a: 3). Both it and the one on health research ethics more generally (HPCSA 2008b) are posted on the NHREC website (NHREC 2012g). It seems likely that they will need to be updated in light of the 2012 research regulations.

Stakeholders in ethics and genetics in Kenya and South Africa had minimal input into the negotiation process for the UNESCO declarations, with the knock-on

effect that their acceptance of the declarations has been rather slow. Generally, they feel that translation to the national context will be the key test of the declarations' validity. Both countries have now adopted many of the provisions of the declarations; for instance, they each have a national bioethics committee that accredits RECs, which must be independent and pluralistic (see UDHGHR, article 16; IDHGD, article 6; and UDBHR, article 19). What is interesting is that Kenya has drawn explicitly on the UDBHR in developing its ethics systems, whereas South Africa's efforts have been independent of UNESCO. As might be expected, given that only a few of the questionnaire respondents from South Africa use them, the declarations do not appear on the webpage where the NHREC makes available copies of several ethics documents, including CIOMS, Helsinki and Belmont (NHREC 2012g). The difference in approach may be due to the fact that Kenya has played a far more prominent role in the UNESCO Bioethics Programme than South Africa. Kenya has held a seat on the IGBC since the committee's inception in 1999 (and chaired it from 2007 to 2009) and has championed bioethics at the General Conference (interviews with K2_01 and K2_16). Furthermore, a Kenyan medical researcher has been a member of the IBC since 2008. By contrast, no South African has sat on the IBC since 2003 and the country has never held a seat on the IGBC. Of late, the only involvement it has had with the two committees has been to send a Paris-based Permanent Delegate to some of their meetings as an observer.

7 Contextualizing bioethics

Mapping progress in Kenya and South Africa

In 2005–6 fieldwork participants identified certain interconnected issues, relevant to both genetic research and research with human subjects more broadly, which are particularly pertinent to Kenya and South Africa. These can be categorized as: protection of research subjects; health development, capacity building and benefit sharing; capacity for ethical review; and public understanding and engagement. This chapter assesses how effectively these issues are being dealt with by the two countries, through their reinvigorated ethical systems. It also considers the impact of UNESCO's capacity-building programmes in Kenya, particularly in the area of education and asks whether further activities in both Kenya and South Africa would be well received by the genetics and bioethics communities.

UNESCO bioethics activities in Kenya

As the previous chapter demonstrated, the UNESCO Bioethics Programme has had more of an influence on Kenya's ethics systems than South Africa's. This extends beyond the ABC programme. The 2008–9 evaluation of UNESCO's ethics activities by its Internal Oversight Office (IOS) showed that an active UNESCO chair can be the linchpin of a country's engagement with the Bioethics Programme. This has been the case in Kenya. In 2005 the Kenya National Commission for UNESCO laid plans for a regional bioethics centre at Egerton University, which holds the Bioethics Chair, having recognized that Kenya did not have the facilities to implement the articles in the declarations concerning ethics education (interviews with K_01, K_13 and K_16). The plans were approved at the 2005 General Conference (resolution 33 C/DR.53) and the Regional Centre for Documentation and Research on Bioethics was inaugurated in May 2007 by the Director-General of UNESCO himself (UNESCO 2005t: 193; UNESCO 2007d; interview with K2_01). The Centre's remit extends beyond research ethics, its ultimate aim being to increase understanding of what bioethics means among as many policy-makers, stakeholders and citizens as possible (interview with K_13).

In August 2008, the Centre hosted a conference on 'Bioethical Perspectives and Practices in Research, Medicine, Life Sciences and Related Technologies in sub-Saharan Africa'. Participants came mostly from Kenya (and the majority from

Egerton), but there were a few from elsewhere in Africa and further afield. Speakers gave papers on patient autonomy, HIV/AIDS, GMOs, traditional medicine and bioethics issues in Africa, among other subjects (UNESCO 2009c). In his opening speech, the Permanent Secretary of the Ministry of Education expressed the wish that Kenya would become the first country to initiate UNESCO's Core Curriculum in its public universities (ibid: vii).

Members of KEMRI and NCST had welcomed the plans for the Centre when interviewed in 2005, seeing it as a good opportunity for information sharing (interviews with K_17, K_19 and K_20). Yet it is currently under-used. An Egerton staff member interviewed in 2011 explained that borrowing of the Centre's resources had mainly been restricted to Egerton lecturers and students, because there is no inter-library loan system (interview with K2_32). This was a disappointment to the former UNESCO Bioethics Chair (who moved on from Egerton in 2011) and members of the National Commission, who considered the establishment of the Centre a very important moment in Kenyan bioethics (interview with K2_01 and National Commission members).

When interviewed in October 2005, the Bioethics Chair was unaware of UNESCO's Ethics Education Programme (EEP) (interview with K_01). Less than two years later, the EEP ran a pilot Ethics Teachers' Training Course (ETTC) at Egerton, the Centre having been launched a few months earlier (UNESCO 2007a). This was the second pilot of the course, after the first was held in Romania in 2006. The course was advertised via National Commissions, Permanent Delegations, GEObs and the UNESCO website. From 20 applications, 16 people were invited to participate and seven were able to do so. There was a preference for African participants and the seven included three from Kenya, one from Uganda and one from Tanzania (the other two were from Iran and Italy).

All the students found the course useful, not least because it afforded an opportunity to exchange ideas with colleagues from other countries. Participants had to pay travel costs only, but lack of resources to cover even these prevented several invited students from participating, so it was decided that future courses in developing countries would focus on recruitment from within the host country (UNESCO 2007b). Again bearing out the findings of the IOS evaluation, one of the participants, when interviewed in 2011, did not as yet teach bioethics at their institution, because there was no suitable course in their department (although the science department had asked them to give a lecture on the UDBHR as part of a new course on biotechnology). A second ETTC at Egerton was due to take place in January 2012, but has been postponed indefinitely (interview with K2_32).

Views on UNESCO's capacity-building activities

When interviewed in 2005–6, most participants in Kenya and South Africa knew as little of UNESCO's capacity-building activities in bioethics as they did of the declarations; as with the declarations, once apprised of the nature of these activities, levels of enthusiasm varied. The 2012 questionnaire respondents

demonstrated a slightly better knowledge of (and as wide a range of opinions on) the Bioethics Programme. Two 2005–6 interviewees (SA_10 and SA_24) welcomed the guidelines on establishing bioethics committees. One (SA_24), who taught on a regional research ethics training programme, described them as 'very, very useful', as for many students their first task on returning to their home countries was to form an ethics committee. Other interviewees were ambivalent, because they did not see 'a big gap in literature' (SA_01). They were concerned that the guidelines would duplicate national and international documents that deal specifically with RECs (interviews with K_21, SA_05 and SA_17).

These concerns were echoed by one questionnaire respondent in 2012, who believed UNESCO to be wasting limited resources by encroaching on the WHO's territory, given the latter's recently updated guidelines for RECs. They also saw the majority of the IBC reports as superfluous to requirements, as what is really needed is harmonization, above more guidance documents. Few respondents knew of the five ethics committee guidebooks or the IBC reports on ethics issues and even fewer had used them, but several indicated that they might refer to them in the future. One wrote, 'I think all ethics committees should be aware of these guides and understand how they can implement guidelines aligned with local cultural and legal frameworks.' Of the topics in the IBC's 2012–13 Work Programme, biobanks and HIV/AIDS proved the most popular, with nanotechnologies, regenerative medicine and neuroscience the least popular (although opinions were relatively scattered). This reflects the views of two South African interviewees of 2006, one a geneticist (SA_20) and one an ethicist (SA_14), who were unenthused by the IBC's reports on cutting edge technologies, the latter describing them as 'totally irrelevant to the vast majority of the world'.

The Bioethics Programme's other information source, the Global Ethics Observatory database (GEObs), was better received in 2005–6. Several South African participants welcomed the initiative, partly because it would provide data they did not have access to elsewhere (interviews with SA_01,05,08,10,24). One ethics lecturer (SA_14) asserted, 'It would be very useful, absolutely. I certainly don't know of anything like that.' A second (SA_16) thought the section on education would help people enrolling in ethics programmes to ensure that they were going to be taught by suitably qualified teachers (rather than 'fly-by-night' ethicists who 'waltz in and start teaching ethics without proper training') and might also highlight where courses were lacking and thus encourage more funding. One person (SA_09) who had been asked to provide information concerning their institution's interest in the GEObs programme was less keen, as this would require devoting considerable time to the 'bureaucratic organization' of research ethics, rather than more important scholarly aspects. In 2012, only one questionnaire respondent was aware of GEObs, whose experience was that it gets outdated rapidly. They compared it unfavourably with the MARC database of RECs (Mapping African Research Ethics Review Capacity), funded by the EU's European and Developing Countries Clinical Trials Partnership (EDCTP) and Pfizer, which allows entrants to update data themselves (see www.researchethicsweb.org and Ijsselmuiden *et al.* 2012). Of the other respondents, four-fifths thought it likely that

they would access GEObs in the future and half would consider making their details and/or details of their institution or teaching programme available to the database.

2005–6 interviewees were mixed in their reception of the EEP. A South African ethics teacher (SA_24) and the head of a research institute in Kenya (K_07) thought that, while there was clearly a need for more ethics training in some places, UNESCO would have to find a niche, because there were already several organizations working in this area. The teacher suggested that UNESCO involve Africans in designing a curriculum that included African philosophical perspectives, while the research institute head commented:

> One of the ironic things now is, I probably get more circulars for workshops for training in ethics than any other area. . . . Every organization seems to be organising capacity building in ethics, which you can't say is a bad thing, but I just wonder how much of it is duplicated, how high quality some of it is and how well coordinated everything is.

A South African research ethicist (SA_22) made a similar point with regard to ethics initiatives more generally:

> I think there are quite a lot of parallel activities going on globally – not maybe all as wide in scope as the UNESCO one, but, for example, working with UNAIDS and WHO and the EU – and there seem to be lots of parallel initiatives to set up guidelines, to create networks, to create inventories. And I suppose initially it's going to be a good thing, but ideally one day some of them should be collapsed, because it's obviously quite expensive. But I think the good thing is that ethical issues in research generally are suddenly being quite substantially funded and I think that's quite important and especially in developing country related stuff.

Perhaps UNESCO has found its niche with the ETTC, with its focus on training university ethics teachers (as SA_16 intimated was necessary) rather than REC members, at whom most ethics courses are aimed. Like with GEObs, most 2012 questionnaire respondents had not come across either the ETTC or the bioethics Core Curriculum previously, but were largely in favour of both. They also mostly agreed with the IBC and IGBC members who thought that bioethics should be taught at all education levels, although one cautioned that, while it is important to create awareness from an early age, there are already many pressing needs within the South African school system. Respondents cited existing ethics courses for researchers and ethics committee members, but felt there could still be a call for UNESCO's offerings, if these were to take account of the sub-Saharan African context and address the need for societal education on the social value of research, how participants are protected and ethical and moral values more broadly. A member of KEMRI (K2_17), interviewed in 2011, was also supportive, as their team was discussing a possible ethics curriculum at the time. They also welcomed

the ETTC initiative, saying, 'The curriculum is already there for trainers of trainers – why should we sit down and crack our heads when we can just look at it and say, "Okay, we can do this, we can do this, we'll take out this, we'll use this"? And, you know, we are good to go.'

Ongoing ethics issues

Protection of research participants

Both Kenya and South Africa decided that their national ethics guidelines of 2004 were needed in part to protect poor and marginalized people from being exploited by unscrupulous researchers. Both sets duly give specific instructions concerning vulnerable groups such as pregnant women and prisoners (Department of Health 2004: preamble and 24–30; NCST 2004: 2 and 10–14). When interviewed in 2005–6, several people saw such provisions as necessary to prevent vulnerable people being subjected to undue inducement to take part in research projects of no relevance to them (interviews with K_25 and SA_12,19,30,32). In a 2011 draft report on vulnerability, South Africa's National Health Research Ethics Council (NHREC) expressed concern that these protections are not afforded by South African law at present, as the only vulnerable group to which section 71 of the National Health Act makes special reference is children. The report mentions the 2007 draft regulations on research with human subjects, which are based on section 71, but not the phantom 2009 version that went unadopted (see p. 115). The 2009 regulations made provision for several vulnerable groups, including pregnant women, prisoners and users of indigenous medical systems. They did not, however, include those rendered vulnerable due to 'broader, rights-based factors (such as social marginalisation, or illiteracy)', an omission in the 2007 draft regulations of which the NHREC report is critical (Republic of South Africa 2009: 5–6; NHREC 2011: 13). The draft report also criticizes the Act's insistence on written consent, which it sees as restrictive (ibid: 14). Relatedly, Caroline Kithinji and Kass (2010: 15) have expressed concern at the lack of oversight of the readability of consent forms translated into Kiswahili in Kenya.

Ethics committees in both countries take particular care that projects which involve research into Africa's 'treasure store' of diseases or evolutionarily significant DNA are not exploitative (interviews with K_17 [quoted] and SA_04), although some Kenyan NGO representatives (K_10 and K_11) expressed concern about vulnerable people being asked to give blood samples without being adequately informed of their rights. There is also the problem of tradition being used as a justification for denial of human rights. In 2009 the Chair of the KEMRI ethics committee raised the issue of same-sex couples being ignored in HIV interventions because of widespread opposition to homosexuality in the country (Kaberia 2009). This issue was also raised at Kenya's first ABC training workshop, in terms of how RECs should handle situations whereby the personal beliefs of members about same-sex relationships make the review of research protocols

difficult (UNESCO 2009a: 2). With regard to marriage, the Kenyan guidelines aim to strike a balance between universal and local values:

> In most rural communities in Kenya due to sociocultural arrangements, women, particularly married ones, may not give their consent to participate in research without the express permission of their husbands. In such circumstances, while the husband may give his "consent", the woman should still be allowed to give her individual consent. If after the husband has given his consent but she decides not to participate in the research, her decision not to do so must be respected. Kenya has as many as 42 tribes, and there are bound to be unique sociocultural backgrounds for each tribe.
>
> (NCST 2004: 11)

While this provision may ensure that no woman will be induced to take part in a research project against her will, it does not indicate what should be done if a wife wishes to participate against her husband's wishes.

One means to guard against exploitation of vulnerable people is to engage with the communities within which it is hoped research will take place. Both the Kenyan and South African guidelines of 2004 call on researchers to be aware of and respect the cultural traditions of the communities in which they wish to conduct research and to liaise with and seek permission from their leaders where appropriate (Department of Health 2004: 25 and 28; NCST 2004: 11 and 14). As Danie du Toit, Chair of South Africa's NHREC, puts it, 'Informed consent that is based on the language, idiom and culture of the participant is empowering, not only to the subject but also to the investigator' (NHREC 2010: 2). Researchers, ethicists, policy-makers, NGO representatives and those with commercial interests alike, when interviewed in 2005–6, saw this type of interaction as tremendously important, partly because of the culture in many African societies that decisions should be 'ratified communally', often by chiefs (K_08 [quoted], K_01,02,04,05,06,09,19, 20,25 and SA_01,02,04,12,13,21,22,30,32). Almost as many expressed reservations about the ethos of community consent and engagement, because defining who or what 'the community' actually is and who should be representing it is very difficult.

A further danger is that insisting on community consent may reinforce repressive hierarchies, denying women and young people an equal voice (interviews with K_03,07,08,11,18 and SA_05,10,19,33). Said one participant (SA_16), 'I think it sounds very nice, but I don't know how one does it. Often it's lip service, because I mean the problem even before that is, what is the community, where do you find it?' Another (K_07) felt that the UDBHR (2005) would have to deal with these subtleties to be of any use. It simply states, however, that for a research project on a group or community, agreement from representatives may be sought, in addition to that of individual participants (article 6). The subsequent IBC report on consent (2008) expands on this, but still in rather generalized terms, summarized as follows:

> Seeking consent from an individual is indispensable even if his/her community is consulted, but the actual value of the consent of an individual, once the

> community has given its approval, may sometimes provoke questioning. Decision-making in the family unit might pose similar problems as well. However, it should be noted that although it is important to observe and respect values of different cultures, these values should not infringe upon fundamental freedoms.
>
> (UNESCO 2008g: 49)

One 2006 South African participant (SA_24) suggested that guidelines on 'community preparedness', which goes beyond community consent to see what community members think about a proposed research project and what they might want from it, would be useful. In 2012 the NHREC published its *Guidelines for Community Advisory Groups*, which meet this remit. Intended to 'promote the development of a mutually beneficial and meaningful partnership between health researchers and community stakeholders within a vibrant human rights environment', the guidelines explain:

> In many instances, community engagement may serve to increase the relevance and quality of proposed research, and its acceptance by affected communities. One way in which community engagement can occur is via Community Advisory Boards (CABs). CABs can provide a mechanism to harness the expertise of key stakeholders and offset potential power differentials that may exist between researchers and participating communities, amongst other functions.
>
> (NHREC 2012b: 1)

Like the 2005–6 interviewees, the guidelines recognize that 'community' is a complex term and, echoing Held's 'overlapping communities of fate' (Held 2003: 167), suggest that people can belong to multiple communities. They recommend that CABs should be involved at all stages of the research process, from protocol development, to the research itself, to the dissemination of results, one of their crucial roles being to help researchers understand the potential impact of cultural norms (NHREC 2012b: 1–2).

These are practices that the KEMRI-Wellcome Trust Collaborative Programme at Kilifi, Kenya, has spent several years developing. By involving communities in the planning of research, it can try to ensure projects are performed in ways appropriate to the local context. At the time of the first set of Kenyan fieldwork, in 2005, it had recently set up a network of community representatives from a wide range of backgrounds, through an exhaustive two-year recruitment process involving already existing community-based organizations. This culminated in large-scale meetings organized by local chiefs, to gain the endorsement of those nominated as representatives and promote their new role within the community. The system has led to better communications between the Collaborative Programme and its local population, in both directions; the representatives have been able to disseminate information on the Programme's work and feed back to it specific recommendations on research planning, as well as community concerns

(interviews with K_06, K_09 and K_23; Marsh *et al.* 2008: 727–8). The community representatives have also helped the Programme's Consent and Communication Committee, constituted in 2005, to develop consent form templates from scratch in the local languages (Kiswahili and Kigiriama), rather than translate them from English (Boga *et al.* 2011: e1001089).

The Collaborative Programme's broader community engagement strategy involves continuous evaluation and adaptation, with regular consultations and workshops with local leaders and health workers and training for research staff (Marsh *et al.* 2010). On a longitudinal genetic study involving 12,000 infants, for example, it held 40 public meetings (attended by 8,000 people) and 32 smaller meetings with religious leaders in 2006–7, as well as its regular (quarterly) meetings with the 14 groups of community representatives. There were also consultations with local chiefs, who correctly foresaw that the heel prick procedure for taking blood samples would be met with consternation by parents (ibid). The Programme has published widely on the challenges and complexities of community engagement in its particular setting, including overcoming mistrust, the 'therapeutic misconception' (when participants conflate research and treatment) and the often underrated but difficult role played by locally recruited field workers (see Gikonyo *et al.* 2008; Marsh *et al.* 2008, 2010 and 2011; Molyneux *et al.* 2010; and Kamuya *et al.* 2011).

Health development, capacity building and benefit sharing

The Kenyan and South African ethical guidelines of 2004 require research to be relevant not only to study populations but also to each country as a whole, by addressing 'health needs' and 'broad health and development needs' respectively (Department of Health 2004: 3; NCST 2004: 13 and 16). The South African ones deem it necessary for multinational collaborative research to be linked to capacity building in healthcare and economic and educational empowerment in the host country and to embrace the social responsibility ethos thus:

> With recognition of the role of social conditions in shaping the world, and how privileged people view the world and themselves, comes the realisation that research cannot be considered in isolation. Medical research, health care, conditions of life around the world and how humans flourish may seem disparate, but all are interdependent.
>
> (Department of Health 2004: 7)

That the guidelines should include this ethos is perhaps not surprising, given that Benatar was on the editorial team. In fact, this passage is almost identical to one from his commentary in the journal *Bioethics*, 'Justice and medical research: a global perspective' (Benatar 2001: 337). The South African National Health Act (2003) stipulates that the National Health Research Committee (a sister committee to the NHREC) must ensure that research addresses priority health issues, taking into account disease burden, cost, capacity and the needs of vulnerable groups and communities.

In 2005–6, several participants agreed that research should address the health and development needs of the country in which it is to be conducted (K_07,08,14,17,19,25 and SA_01,08,09,17,19,21,32). This is something that RECs in both countries were taking into consideration when reviewing protocols (interviews with K_17 and SA_19). A member of KEMRI (K_17) explained that they were not trying to limit basic research, but wanted to see this integrated with social aspects: 'We would like people to write more practical protocols.' Similarly, the Biotechnology Regional Innovation Centres (BRICs) that fell under the South African National Biotechnology Strategy of 2001 were not to invest in 'purely white elephant science development', but in strategic basic research that addressed national priorities (interview with SA_26).

Through such measures South Africa appeared to have embraced what the social responsibility article of the UDBHR (2005) deems to be a 'central purpose' of government, the promotion of health and social development (UNESCO 2005s: article 14). The BRICs were in place from 2002 to 2009, but did not produce the hoped-for return on investment and were absorbed into the Technology Innovation Agency (TIA), set up under the Ten-Year Innovation Plan and TIA Act of 2008 (NBAC 2010: 1 and 8). The Department of Science and Technology has since been working on a Bio-economy Strategy, with cabinet endorsement to be sought in 2012–13. This will bring together various initiatives, such as the National Biotechnology Strategy and the From Farmer to Pharma Grand Challenge (which seeks to tap South Africa's biodiversity by combining biotechnology with indigenous knowledge systems, for socioeconomic benefit), with the aim of harnessing the potential economic, social and environmental benefits of the health, agricultural and industrial sectors (Department of Science and Technology 2012).

Ensuring research is socially relevant is a complex process. As noted by Geoffrey Lairumbi *et al.* (2008: 734), writing in a Kenyan context, 'Ethical research should contribute to social value in the country where research is being carried out, but there is significant debate around how this might be achieved and who is responsible.' Debate also rages within the bioethics literature about how far research should address issues of social justice and inequality (Lairumbi *et al.* 2011: 2). Some 2005–6 participants (K_09, SA_12 and SA_20) did not think health and social development should be a requirement of research, as this could limit basic or innovative research that might have massive long-term but serendipitous benefits. Although a few interviewees thought that there might be more effective means to address poverty than 'high-flying scientific studies' (SA_03 [quoted] and SA_09,18,20), many more believed genetic research worth pursuing, because of its potential to produce treatments or cures for the diseases of the global South (K_08,11,25,26 and SA_21,27,30,32). Two interviewees from South Africa commented that it should not divert resources from meeting basic needs in the here and now, but that the two approaches could be complementary (SA_01 and SA_18).

Two people questioned the practical applicability of the UDBHR's social responsibility principle. The first, a scientist and ethicist (SA_24), wondered how

far the responsibility extends, given the enormous challenges poverty in the developing world presents:

> The needs, in developing countries, are of such a nature, you can't provide it all. And if you don't research, you're also not going to bring something better. So this is a major, major debate. I mean, I have a conflict in my own mind: to what extent do I have responsibility?

The second, a member of an ethics committee in South Africa (SA_10), approached the problem from a different angle. They said that while their committee was conscious that projects ought to have social value, in reality it would be difficult to reject one that did not, as this would mean turning down funding for the university. Similarly, Lairumbi *et al.* (2008: 744), in their study of the policy-research nexus in Kenya, found that local health initiatives can be overshadowed by 'the considerable power of the global health agenda'. The IBC's report on social responsibility (2010), citing the '10/90 gap', calls on governments and institutions in both developed and developing countries to address health inequalities through research, but adds little to the existing literature in terms of how the ensuing complexities can be managed (UNESCO 2010h: 24 and 31).

The principle of benefit sharing, like social responsibility, is applied to both specific communities and the wider national contexts in the Kenyan and South African guidelines, particularly in terms of health services and products (Department of Health 2004: 3, 7 and 9; NCST 2004: 5 and 16). According to interviewees in 2005–6, RECs in both countries, when reviewing protocols, try to assess the extent to which participants will benefit from a research project (K_25 and SA_05,10,19). Several thought it important that communities taking part in research should benefit in some way (K_10,14,18 and SA_04,12,13,17,19,25,33). One South African bioethicist (SA_09) said:

> The question is whether research is ethical if the people and communities who are the subjects of research have not benefitted from improvements in their health or their healthcare. If they have not benefitted then I am sceptical of how ethical it is to do research in those places.

As with social responsibility, however, some people raised issues with regard to the practicalities of actually implementing benefit sharing, in terms of making commitments to provide for communities before the results of research are known and determining exactly who should benefit and for how long. There is a fine balance between appropriate compensation for time and inconvenience and undue inducement, particularly among poor communities where even a small amount of money or payment in kind will be of high value to participants (interviews with K_10,14,18 and SA_04,12,13,17,19,25,33). These are difficult issues for researchers and ethics committees alike to manage and adjudicate (Molyneux *et al.* 2012; interviews with SA_05, SA_10 and SA_22). In South Africa, the NHREC has produced detailed guidelines for RECs on how to determine the appropriate level

of payment for research participants under various scenarios specific to the South African context (NHREC 2012d).

Benefit sharing can also take the form of capacity building for research. The Kenyan guidelines stipulate that externally sponsored collaborative research should develop research capacity in Kenya (NCST 2004: 16). In 2005–6 there was relatively little of this type of research taking place in either Kenya or South Africa. Geneticists in both countries (K_05 and SA_27) lamented the fact that, because developing countries were perceived as not having the capacity to deliver, funding for research tended to flow to Northern institutions. One scientist (K_13) commented, 'I think there is a lot of talk of goodwill, but they have been slow.' There was also insufficient local funding for research (interviews with K_05,10,14 and SA_27). 'Brain drain' was an ongoing problem. Even if African scientists trained in the global South, many were likely to develop their careers in Northern institutions (interviews with K_05,10 and SA_20,22,26,28).

Participants generally acknowledged that research capacity building requires the support of developed countries, but had firm ideas about what form that support should take. First, capacity-building programmes should be designed with the input of African scientists and policy-makers (K_01,07,13,16 and SA_15,26,27). The former UNESCO Bioethics Chair (K_01) said, 'Let the initiative come from our side. . . . If it comes from the other side, the success will be a little bit lower, because it is as if something is brought in.' Second, programmes should ideally represent long-term investment, in terms of training, infrastructure and salaried posts, rather than 'travel and tourism money', whereby people are sent abroad for a few months' training (interview with SA_27). Ethics committees preferred a project to train people to analyse data in-country where possible, rather than to ship samples abroad (interviews with K_17,21,25 and SA_19,21,30). The Kilifi KEMRI-Wellcome Trust Collaborative Programme again provided an example of good practice. Capacity building is its *raison d'être*. Rather than following past models that saw 'grateful African institutions' being invited to join Northern-led projects, the centre falls under KEMRI management. The long-term vision, stretching over 25 years, is to build up a 'cadre of international research leaders' from Kenya and the East Africa region. To achieve this, the Programme aims to develop research facilities of international standing and ensure sufficient funding to provide attractive career paths for scientists wishing to stay in Kenya (interviews with K_05 and K_07 [quoted]). The South African National Bioinformatics Institute has a similar vision, its 'key underpinning' being its aim to bring Africans to a competitive level in bioinformatics (interview with SA_02).

Questionnaire respondents in 2012 noted that brain drain and lack of funding remain problematic, but that there have been some improvements in human genetic research capacity, at least in the public sector (most felt unqualified to comment on the private sector). Biotechnology activities have increased in both Kenya and South Africa since 2005–6. Through initiatives like Vision 2030, indigenous capacity has grown in Kenya, with many more Kenyan postdoctoral geneticists working in the leading public universities and specialist research institutes than five years previously. The increased funding has given Kenya more

leeway in deciding what its research priorities should be, although the government's contribution is still dwarfed by those of international institutions. The US Centers for Disease Control, for example, 'has very significant influence and impact on the direction of research' (interview with K2_31). Human genetic research is done mainly within the national universities and KEMRI, in partnership with external research institutions in the US, Canada and the UK. A representative of the African Biotechnology Stakeholders Forum (K2_31), based in Nairobi, summarized Kenya's progress thus:

> So there is a lot more interest in genetics in this country than before, because there is realisation that through advanced research in genetics – human, livestock, crop – it is possible to start rolling out novel products that would do wonders in, for example, treating diseases that have proved so resistant to certain vaccines and drugs.

In South Africa, the H3Africa initiative has had a significant impact, according to questionnaire respondents, by enabling geneticists to access international collaborative funding and encouraging research partnerships across African countries. An ethics committee member also observed that they were seeing more genetic studies attached to clinical trial protocols. Universities have developed capacity in genomic research through local and international consortia such as the Southern African Human Genome Programme (SAHGP), noted one scientist. The SAHGP, funded by the Department of Science and Technology, was launched in January 2011. According to one of its coordinators, it is 'a ground-breaking national and regional initiative that aims to unlock the unique genetic character of southern African populations' (Pepper 2011: 286). Among other activities, it will create a sustainable source of research material, by establishing a regional sample repository and database. Crucially, the initiative is led by Southern Africans, for Southern Africans. Hopefully this will help to combat a problem raised by one questionnaire respondent, who said that the number of genetic researchers in South Africa had gone down since 2006: 'a lot of research is still being done on Africans without meaningful input from African scientists'. Like H3Africa (an allied project), the end goal of the SAHGP is to use discoveries to improve human health (ibid: 286–7).

Another issue that remains prominent in both countries is sample shipping. As intimated by the IBC member who complained that developing country scientists are often seen as little more than a 'post office box', collaborations with research institutions overseas can have implications for ownership of materials and intellectual property rights (Wasunna 2008; interview with K2_32). A desire to stem the flow of biological material abroad by enabling more research to be done locally lay behind the founding of the SAHGP (Pepper 2011: 287). More problematic still is the unregulated transfer of materials, which one Kenyan scientist (K2_31) described as happening at a 'very alarming rate'. They went on, 'I am of the view that if tissues and samples are being shipped out of the country, (1) it has to be done transparently and then (2) there has to be cause to indicate that

those samples cannot be tested here.' They explained that people have complained about samples being taken from HIV households, for example, who see themselves as being used as guinea pigs, with no indication of what the samples will be used for or with what result. Papers in the *South African Journal of Bioethics and Law* have raised similar concerns about human tissue or data being shipped out of the country unregulated, instead of resources being poured into building research capacity in-country, to the advantage of researchers and pharmaceutical companies in the global North and to the detriment of vulnerable and poor populations in South Africa (Clarke and Egan 2008: 45; de Haas 2011: 26–7; Sathar and Dhai 2012: 52–3).

Both countries are trying to address these problems, in South Africa through the promulgation of Chapter 8 of the National Health Act (note, however, that a provision in the draft regulations on DNA, RNA and other human samples of 2007, stating that intellectual property rights shall apply to all forms of genetic research, except stem cell research, does not appear in any of 2012 regulations) and in Kenya through NCST and NBC initiatives. Simon Langat (2005: 538) highlighted Kenya's need for specific guidance on the collection, use, storage, transfer and re-use of human biological materials several years ago, in the journal *Bioethics*. NCST's 2009 research clearance guidelines meet this need, as follows:

> All experimental tests, analyses and investigational procedures of materials should be undertaken within Kenya, but where it is proven that no capacity for a particular tests [sic], analyses and investigation of a material exists in Kenya, or where exchange is needed for quality assurance purposes, the researcher wishing to transfer or export samples abroad for research purposes shall write a letter of request for the exchange, transfer, acquisition or export to the Secretary, NCST.
>
> (NCST 2009: 4)

Building on this, at the final ABC training session in November 2011, the Kenyan NBC drafted a new materials transfer agreement template. Although the ABC facilitators had some input, the template was to be finalized by the NBC, to ensure its appropriateness to the local context. There will also be stronger monitoring at airports (interview with K2_25).

Ethical review capacity and ethics training for researchers

In 2005–6 interviewees in both Kenya and South Africa identified several ways in which research ethics could be strengthened. RECs had sufficiently diverse memberships, they felt, as stipulated in the two sets of national guidelines, but they highlighted deficiencies in capacity (interviews with K_06,09,17 and SA_10,19). (By contrast, a 2003 study of the 12 major health RECs in South Africa found that committees were well organized, given resource constraints, but did not have sufficiently diverse memberships in terms of race, gender and expertise. Those committees based in institutions that had been disadvantaged

under apartheid had less capacity than others. The investigators feared these committees would be further disadvantaged in the forthcoming NHREC registration exercise if they did not receive additional resources and training, thus forcing them to settle for the lower level accreditation [Moodley and Myer 2007].) Kenya needed more people with expertise in research ethics, not only to constitute new committees but also to relieve those who sat on existing ones, which were undertrained and overburdened (interviews with K_21, K_25 and K_27). At the time of fieldwork, there were no suitable courses in East Africa, so people were having to travel to South Africa if they wished to undergo training (K_17 and K_21). Not only REC members required instruction, but also scientists and students. Several people commented that Kenya did not have sufficient university courses in research ethics, which adversely affected the standard of applications for ethical review. One participant made a similar comment about South Africa, although it had more university courses than Kenya (K_01,02,03,17,19,21 and SA_17).

Both countries have since seen several initiatives to expand research ethics capacity, but the demands on RECs have grown in tandem. 2012 questionnaire respondents felt there had been progress in most areas – protection of vulnerable research participants, community engagement, the number of trained REC members, ethics training for scientists and students, training in African philosophical perspectives and ongoing monitoring of approved projects by RECs – but that there was still room for improvement. As one person put it, 'critical mass' had not yet been achieved. The review burden varies widely from committee to committee in South Africa. A 2009 NHREC report noted that the 22 RECs registered by February of that year had received a total of 3,682 protocols for approval in a 12-month period. Five committees had received more than 500 proposals, 756 being the highest number and five the lowest (one committee had not received any) (NHREC 2009: 3–4).

The busier South African committees are comparable with the Kenyatta National Hospital-University of Nairobi REC, established in 1974, which processes over 450 research proposals from local and international researchers each year (KNH-UoN REC 2011: 2) and the KEMRI ethics committee, which has seen a huge growth in applications, from an average of 55 a month in 2010 to 100 a month by November 2011. The KEMRI committee would like to expand its membership to accommodate this increase, but this requires more training (interview with K2_17). South Africa's oldest REC, the Witwatersrand Human Research Ethics Committee (Medical), is also straining to cope with its increase in general applications, which rose from 440 a year in 2002 to 685 in 2011, with an expected increase of another 250 per year in 2012–14 (clinical trial applications number another 100 per year) (Cleaton-Jones 2012: 44 and 38).

As several of the South African committees audited by the NHREC were not able to review all the applications they received, the report called for more RECs to share the load, as well as training to increase REC capacity. Of the 353 members of the 22 registered RECs, 64 per cent had undergone ethics training. Again, there was diversity among the committees; in some committees all members were trained, whereas in others very few were (two out of 11, for example) (NHREC

2009: 4 and 6–7). The NHREC's Training Subcommittee, tasked with deciding what basic competencies should be required of REC members and researchers, has drawn up minimum curricula for both groups, in consultation with stakeholders from academia, industry, private trainers and the HPCSA (NHREC 2010–11: 14 and 2012e).

The KEMRI ethics committee similarly requires all internal applicants for ethical approval to show that they have undergone ethics training (an online course, for example), which sometimes delays applications. In terms of general REC capacity in Kenya, a KEMRI member (K2_17) was concerned about maintenance of standards sufficient to protect research participants, given the recent proliferation of ethics committees and the possibility of decentralized control of RECs under the new Kenyan constitution:

> People just imagine that you throw CITI [an online ethics course] at somebody . . . and they are good to go. They aren't good to go. They really need to be with other people who have been doing it for a while . . . I just wonder about the quality – the depth – of review and whether we shall be able to maintain a minimum and whether we shall be able to be consistent. And, you know, the minute people realize they're not consistent, then they'll start shouting, won't they?

The courses in South Africa that Kenyan REC members, interviewed in 2005, had attended were run by SARETI and IRENSA, both sponsored by Fogarty International, of the US National Institutes of Health (NIH). Fogarty's rationale is to build capacity for ethical review that is appropriate to the local context. IRENSA, the International Research Ethics Network for Southern Africa, was based at the University of Cape Town and received funding up to 2010. SARETI, the South African Research Ethics Training Initiative, is run by a collaborative partnership between the University of KwaZulu-Natal, the University of Pretoria and Johns Hopkins University and is funded up to 2017. From 2011–16 Fogarty is also sponsoring the ARESA programme (Advancing Research Ethics Training in Southern Africa) at Stellenbosch University, which partners with the University of North Carolina. IRENSA ran a postgraduate diploma, as does ARESA, while SARETI offers a Master's degree in health research ethics. Shorter courses and workshops also form part of the programmes. Participants are primarily members of RECs from South Africa and other countries in the sub-Saharan region, but also number scientists, journalists, government officials and people from private sector companies. The aim is to have a good balance of working disciplines, genders and ethnic backgrounds (Benatar and Vaughan 2008: 440–1; Fogarty 2010 and 2012c; ARESA 2011a; SARETI 2011; Wassenaar 2011: 107–8; interviews with and SA_09 and SA_22).

Beyond the Fogarty initiatives, the Steve Biko Centre for Bioethics at the University of the Witwatersrand offers a Master's programme in Bioethics and Health Law (incorporating environmental and research ethics) to a similarly broad range of students from across the continent, as well as a yearly five-day course in

research ethics for REC members and researchers (Dhai 2011: 109; Gardner 2011: 102–3). The SARETI and IRENSA programmes have had a significant impact on health research ethics capacity in South Africa and further afield, having collectively trained several hundred people (Benatar and Vaughan 2008: 441; SARETI 2008–10; Nyika *et al.* 2009: 190; Ijsselmuiden *et al.* 2012: 76). A by-product has been the development of a network of REC chairs in South Africa, which has enhanced consistency and thus reduced the tendency for 'shopping around' for ethical approval (Benatar 2007: 595). ARESA will further build on the informal networking engendered by SARETI and IRENSA by establishing an online forum for REC members, to 'create a defined space for research ethics in Southern Africa outside the regulatory framework of RECs', to include a list of resources and online training (ARESA 2011b). The NHREC Training Subcommittee also has a mandate to 'facilitate the sharing of best practices in ethics training' and 'investigate the feasibility of web-based/on-line training' (NHREC 2012e).

While this growth in research ethics capacity building over the last decade or so is undoubtedly impressive, one ethics lecturer (SA_24), when interviewed in 2006, identified a gap in provision. No programmes taught African philosophical perspectives on ethics. They said:

> The one thing that I think is lacking in all these training programmes is that we don't often access African philosophers . . . because there is definitely a clear distinction between African philosophy and Western philosophy and I think that needs its space.

A member of the KEMRI-Wellcome Trust Collaborative Programme (K_09) detected a similar Western bias. They expressed the hope that people in Kenya and Africa as a whole might become more engaged in ethical debates and so progress from trying to make guidelines produced in the global North work in their settings to taking the 'slightly more challenging stance' of developing 'new ideas about what the guidelines should be'.

This need for a more holistically African perspective is perhaps being met through SAREN (Southern African Research Ethics Network), an initiative funded by the EDCTP. Recognizing that, through programmes like the Fogarty ones, Africa now has considerable expertise in research ethics, the project aims to harness this in the form of a textbook focusing explicitly on the African context. The project summary reads,

> Great care and attention will be spent in ensuring that this textbook incorporates issues especially relevant to Africa, such as the challenge of integrating a western model of informed consent into communitarian and patriarchal societies and issues particularly relevant to the review of both public health research and clinical trials in the areas of HIV, malaria and tuberculosis.
>
> (EDCTP 2011d)

A workshop held in Stellenbosch in 2011 brought together REC members from 11 countries across Africa, including Kenya, to plan the contents. The book was due to be published in English at the end of 2012, with translations into French, Portuguese and Swahili to follow (ibid). The ARESA diploma programme also aims to be 'locally relevant' and includes both Western and African philosophies of ethics in its first module (Moodley 2011: 105).

Kenya has likewise benefitted from Fogarty and EDCTP support, enabling REC members to now train in-country. The Indiana University-Moi University Academic Research Ethics Partnership received Fogarty funding for 2008–12. As well as its Master's programme, the partnership offers annual workshops on how to teach research ethics, with training materials to be distributed online in collaboration with CITI, the Collaborative Institutional Training Initiative (Fogarty 2012b). It thus mirrors UNESCO's EEP very strongly. In 2012 the grant was renewed until 2017. The new phase will see the partnership develop topic-based short courses and extend the teaching workshops to other East African researchers and institutions (Fogarty 2012a).

EDCTP-funded Kenyan initiatives of recent years include two capacity-building programmes at KEMRI and a nationwide project to strengthen RECs (EDCTP 2011b). The KEMRI-EDCTP Research Oversight Project ran from 2009 to 2011. It aimed to train KEMRI researchers and ethics committee members, together with members of the Expert Committee on Clinical Trials of the Pharmacy and Poisons Board (established under the Pharmacy and Poisons Act), in the ethical review, practice and oversight of research and to set up a joint electronic clinical trials registry (EDCTP 2009). Adili, a new Bioethics Center within KEMRI, has been funded from 2011 to 2013 and is specifically targeted at dealing with the KEMRI ethics committee's increased workload (EDCTP 2011a). Again providing training for researchers and reviewers, it is hoped this will simultaneously enable the committee to expand and lead to an improvement in the quality of submissions, so that less 'back and forth' with scientists is required. Some of these developments have been inspired by the South African model: 'they seem to be quite ahead', said a KEMRI member (interview with K2_17).

KEMRI had previously relied mostly on online ethics courses for its researchers (such as those offered by NIH, CITI and AMANET, the African Malaria Network Trust), but Adili staff believe that face-to-face training tailored to the Kenyan context will be more appropriate. In this they draw on the findings of a recent study by Rakesh Aggarwal *et al.* (2011), which showed that online ethics courses are good for delivering information, but are less effective than face-to-face training when it comes to application (interview with K2_17). (This also ties in with the findings of The Open University's study for UNESCO on the possibility of online ABC training.) A KEMRI member (K2_17) gave the following example of the type of teaching they hope to offer on a regular basis:

> I tell them, 'What if you go into the field and you're doing a study on ICTI, which is a preventive malaria treatment for women . . . you go into a home and you start consenting a pregnant woman because she's eligible to be in

> your study. And you're a third way through and the man comes in and says, "Get out. You're not going to."' So I ask them, 'What do you do?' . . . So that's the whole idea, because once you give people examples that they can relate to, then the concepts actually sink in.

The nationwide EDCTP-funded project ran from April 2011 to April 2012, with the hope of further funding. Awarded to the Kenyatta National Hospital-University of Nairobi REC, in collaboration with NCST, it tied in closely with the NBC's accreditation process, two of its aims being to take an inventory of all RECs in Kenya and to standardize ethical review processes (EDCTP 2011c; interview with K2_21). While visiting RECs to explain the roles of NCST and the NBC (some committees were unaware of these bodies), project members were able to conduct an assessment of training needs, which fed into a bioethics course held in January 2012 for 60 REC members from across the country. The idea was to have at least two people from every REC attend, to provoke a multiplier effect (KNH-UoN REC 2011: 4 and 6; interviews with K2_21 and K2_25). Another aim of the project was to create a database of approved studies, to reduce duplication (EDCTP 2011c). In an age of multi-centre trials, both in-country and international, coordinating ethical review is an increasing challenge, as picked up by the first Kenyan NBC training session (UNESCO 2009a: 3). A member of KEMRI (K2_17) explained:

> Ethics committees do not talk to each other and it becomes quite difficult when we are having multi-centre trials. . . . What happens now is that everybody does their own thing and then now we are busy trying to incorporate other people's changes. And sometimes you don't agree with them and it becomes . . . you keep delaying. You keep delaying the process.

They went on to express the hope that the NBC would play a coordinating role, so that RECs would have a better idea of what each other were doing and thus avoid 're-inventing the wheel'.

There remain some gaps in ethics provision in both countries. In Kenya, there is still little university education on bioethics. Few courses are available and they lack a definite pattern, with different practices being taught to different years in different institutions. The former UNESCO Bioethics Chair would thus like to see UNESCO's Core Curriculum rolled out in all universities teaching medical and life sciences, with an emphasis on practical application of ethical theory. They would also like to see UNESCO develop a postgraduate certificate in bioethics for the sub-Saharan region (interview with K2_01). An area where RECs in both Kenya and South Africa need support is the monitoring of research projects once they have been approved. One prominent Kenyan ethics committee had only recently carried out its first on-the-spot inspection at the time of the 2005–6 fieldwork. Prevented by financial constraints from conducting such inspections more frequently, committees in both countries generally relied on reports from investigators and word of mouth (interviews with K_17,19,25 and SA_14,19).

Members of two South African RECs described this as 'passive monitoring' (SA_10 and SA_17). The situation had not changed by the time the NHREC carried out its 2009 evaluation, which found that only 55 per cent of the 22 RECs surveyed actively monitored whether researchers were complying with their submitted protocols (NHREC 2009: 8). Another 2006 interviewee (SA_09) said that, in general, committees are inadequately funded:

> Even though thousands of millions of dollars are spent on research every year, the support that ethics committees receive for their evaluation of research is relatively skimpy. Scholars and professionals are expected to work on those committees in their spare time, as though it's work not worthy of any remuneration. In my view much lip service is paid to ethics, with inadequate commitment to providing the resources required to support the onerous work that needs to be done.

In October 2011, KEMRI started charging external applicants for ethical review a one-off fee of USD 1,000, to enable monitoring. Legislation might act as a further deterrent to unethical conduct, as the committee has no power to shut research down at present, meaning that follow-up can be an empty gesture: 'essentially it's just an exchange of words and we move on' (interview with K2_17).

Public engagement

The lack of input into the drafting of the UNESCO declarations among non-state actors in Kenya and South Africa may be partly attributable to a low level of engagement in bioethics and genetics policy-making generally, among both scientists and the general public. Although several geneticists, when interviewed in 2005–6, were sceptical of the declarations' legitimacy because they felt their views had not been adequately represented during negotiations, they were hesitant to involve themselves in policy-making. Their priorities were research and teaching, hence they had little time to spare for other endeavours, particularly given the small size of the scientific community in each country (K_03,05 and SA_03,04,05,07,21,30). Lairumbi *et al.* (2008: 746) made a similar observation in their investigation into the impact of research findings on health policy in Kenya: 'Importantly, our study points to a sense of isolation from the processes of agenda setting among local researchers and policy implementers and a disregard of policy implementers as a target for knowledge sharing.' Two interviewees (K_03 and SA_27) suggested that scientists would be more inclined to contribute to an initiative if they could see that the people behind it were serious and that it was going to translate into concrete outputs.

One organization that does represent scientists in policy debates is the African Biotechnology Stakeholders Forum (ABSF), an umbrella organization for institutions working in all areas of biotechnology. ABSF would expect to be included in the process of domesticating the UNESCO declarations, said a representative (K2_31) in 2011, having been intimately involved in drawing

up Kenya's Biosafety Act and Biotechnology Development Policy and as a member of various NCST committees and the National Biosafety Authority. A member of NCST (K2_16), also interviewed in 2011, explained that the system of public consultation on science and technology issues had improved since 2005:

> So now, as a Council, we have that mandate, we have some resources, so that, when we have such hot issues [GMOs, for example], you can call people and invite a debate and invite experts to come and share from their expert view; let other people who are not experts come, listen, ask questions; and, at the end of it, come up with a policy paper. . . . As the Council, that's how we get the position to advise the government.

They hoped that, with the rejuvenated NBC, consultation on bioethics issues would become much more thorough.

With regard to the general public's involvement in policy-making, the picture was somewhat mixed in both Kenya and South Africa in 2005–6. In South Africa, the mechanisms were in place for people to make comments on impending regulations or legislation (interviews with SA_04,10,16,22,24,29,33). Interviewees sensed that it was mostly activist groups taking advantage of these, however, rather than the public at large (SA_10,16,21,27,33). The problem, they felt, was poor understanding of ethics and genetics, a recent survey having shown that South Africans were 'woefully ignorant' about biotechnology (SA_26 [quoted] and SA_21,29,30,33). One geneticist (SA_27) commented, 'they wouldn't know what to ask'. To address this situation, the Department of Science and Technology launched the Public Understanding of Biotechnology (PUB) programme in 2003 (under the National Biotechnology Strategy), which engages in a wide range of activities, such as drama presentations, seminars and workshops, exhibitions, science fairs and supporting schools' curricula (PUB 2011; interviews with SA_26 and SA_29). The Africa Genome Education Institute (AGEI) also has a mandate to increase public knowledge about genetics and biotechnology (AGEI 2007; interview with SA_11).

Hardy *et al.* (2008a: S21) describe the AGEI, rather than PUB, as having 'taken the lead' in educating a public, nervous of researchers in the aftermath of apartheid, about genomic science. A study commissioned by the National Biotechnology Advisory Committee (NBAC) in 2008 found that awareness of the PUB programme beyond the scientific community was very low (NBAC no date a: 4). It also found that, while South Africans had fewer religious or moral objections to biotechnologies than people in other countries, concepts such as genetic screening and stem cells were foreign to many consumers. The authors thus concluded that 'the views of the general public regarding the development of such technologies are largely irrelevant at this stage due to the abstract nature of what is communicated' (ibid: 3 [quoted]; NBAC 2009: 4). This lack of awareness could have been because of under-reporting of biotechnology in South Africa, as identified by a second NBAC study, on biotechnology and the media (Gastrow 2010: 3). Questionnaire

respondents in 2012 confirmed that the public's knowledge of genetics was still very basic, having improved a little through national awareness raising programmes, but not sufficiently.

In Kenya, the Ministry of Health's 2005 guidelines for research into HIV/AIDS vaccines were developed in consultation with NGOs, community representatives, faith-based organizations and professional societies (as well as government officials, researchers and healthcare workers) (Ministry of Health 2005: vii). These recently published guidelines notwithstanding, several 2005 interviewees were of the opinion that there was little public participation in bioethics and genetics matters in Kenya, with discussions tending to be confined to certain specialized circles (K_01,02,14,18,19,21,26). Some (K_17, K_19 and K_25) intimated that public education would help to demystify the research process and enable people to engage with ethics and genetics issues. Others remarked that the connection between genetics and development, in terms of the opportunity to alleviate poverty through better health, had not been made by the public at large (K_04, K_08 and K_14).

An editor at *Biosafety News* (a newspaper and website active in the 2000s but now defunct, which aimed to provide a bridge between scientists and the general public) said of the UNESCO declarations, 'At the moment, even if we carried something like that on our paper, I think people would be like, "Whoa, what is this?" I can tell you that for sure' (interview with K_14). Other initiatives include ABSF, which (alongside its policy work) endeavours to provide credible, balanced and up-to-date information on biotechnology and NCST's National Biotechnology Awareness Initiative (BioAWARE), launched in 2008 to develop 'a well-informed and knowledgeable society that can make informed decisions on the use of biotechnology and its products' (Karembu *et al.* 2010: 49–50; NCST 2012c [quoted]; interview with K2_32). As in South Africa, questionnaire respondents thought that there had been some progress in public understanding through such initiatives, but that there was still a long way to go. They also noted that finding a way to accurately measure whether there has been a significant change in awareness would be difficult.

One biotechnology issue that has captured the Kenyan public's interest in recent years is GMOs (interviews with K2_01,16,31,32). A member of ABSF (K2_31) attributed the higher public awareness of crop genetics, compared to human genetics, to the relative openness of institutions such as the Kenya Agricultural Research Institute, which holds "seeing is believing" tours to demonstrate its work to the public. They said:

> So the reason why there has been less public awareness about human genetics is because the relevant institutions and scientists do not have an open system to interact with the public and tell them what they are doing. Either this is because they are doing it deliberately, because they know that it could be alarmist to the public, or maybe it is just by ignorance – they think the public may be too naïve for such an advanced level of research.

Human genetics did hit the public sphere, albeit briefly, when news of the cloning of Dolly the Sheep broke in 1997. The media went into 'a frenzy' and the Catholic Church organized demonstrations in Nairobi and other areas, denouncing both human and animal cloning as morally wrong (interview with K2_31). Religious groups and civil society representatives remain strongly opposed to human reproductive cloning (interviews with K2_01 and K2_16). Broader attention may since have waned, but it is still a 'no go' in Kenya, in terms of public acceptance (conversation at NCST in November 2011).

The GMO debate has led some scientists to reassess their level of engagement with the public, including members of the NBC. As one attendee at the third ABC training session (K2_32) commented:

> What I think is very critical is knowledge . . . because the debate on GMOs actually took a completely different direction and yesterday [at the session] we were discussing among ourselves, what did we do? And we realized that we did nothing – we left everything to the politicians.

A member of KEMRI also felt that better public engagement on ethics issues is sorely needed. This would help prevent exploitation of research subjects, as RECs can only do so much. If people knew how the informed consent process should work, for example, they would be able to refuse to participate in research when it is not conducted properly. This would be far more effective than 'having a whole bunch of people running around the country looking at people's informed consent documents' (interview with K2_17). Garnering public attention is by no means easy, however. The NBC held a press conference after its third ABC training session, but as it took place outside central Nairobi no-one attended. One possibility is the teaching of bioethics in schools through the domestication of UNESCO's Core Curriculum (interviews with K2_01, K2_21 and K2_32). But, as one 2011 interviewee (K2_17) pointed out, once a subject is formalized into the national curriculum there is a danger that it will become 'just another thing they [children] have to learn', rather than something they really take to heart.

Both Kenya and South Africa have made significant strides forward in the last six to seven years in several areas of bioethics governance. Some initiatives have tackled issues that are of particular concern to the UNESCO Bioethics Programme, such as community preparedness, social responsibility in research and ethics training and education, yet few have drawn on UNESCO resources. Other areas remain a serious challenge. Interviewees and questionnaire respondents, as well as South Africa's NHREC, have expressed concern about the level of protections offered to vulnerable populations in research projects. Whether or not the IBC's 2011 report on vulnerability provides states with the guidance they need on this issue remains to be seen. Also of concern are the shipping of biological samples to overseas laboratories and the low levels of

public understanding of genetics and bioethics. Since the IBC's Work Programme for 2012–13 includes an investigation into biobanking (on the back of requests by several states, particularly those in the global South) and the Bioethics Programme secretariat will be looking to reach out to the public in new ways in the same period, it may be that UNESCO can engage with both Kenya and South Africa to try to address these problems.

8 Conclusion

Bioethics and genetics stretch beyond national borders in several ways. Multi-centre research projects are increasingly common and require a coordinated system of ethical review. Tissue samples and genetic data frequently traverse national boundaries. Inequalities of health are considered a global injustice. The human genome has been designated the 'heritage of humanity' and so should be of benefit to all. As such issues are inherently global, they cannot be dealt with effectively at national level alone. Hence UNESCO's efforts to provide an international framework for their governance. Pablo Sader, Chair of the government experts charged with finalizing the draft UDBHR, made the following statement at their last meeting in June 2005:

> A bioethics-related event makes the international headlines nearly every week. It is a difficult topic. As we have all seen, there have been deep divisions in other meetings on specific bioethics issues. There are points of divergence within individual countries too. For this reason, it is doubly important for us to give a clear signal that we are capable of reaching agreement on important issues. If we do so, the declaration will be proof that multilateralism works, and that will be a boon to our Organization.
>
> (UNESCO 2005m: Annex III, 1)

This chapter assesses whether the UNESCO Bioethics Programme and its three declarations are indeed proof that multilateralism works, in the deliberation and implementation of bioethics.

Deliberation

The UNESCO Bioethics Programme encompasses several interweaving sets of relationships between different categories of actors: between member states; between state and non-state actors; between international and national bodies; and between diplomats, experts and civil society, at international and national levels. The ways in which these relationships played out in the drafting of the three UNESCO declarations on bioethics and genetics, in terms of the interface between power, interests and knowledge, render the declarations classic exemplars of a

formal international regime in several respects, not least the degree to which compromises on their nature and content proved necessary in order to facilitate agreement. This begs the question whether relations between actors can be improved, to foster stronger agreements in the future.

Drawing on the work of Chasek and Rajamani, Held argues that relations between states are often unequal in international regimes, despite formal parity, because developed countries are able to send larger and more expert delegations to meetings than are developing ones (Held 2004b: 95–6). This was indeed the case during the negotiations for the UNESCO declarations. Although procedures were followed scrupulously in terms of giving all countries equal voice and vote, delegates from the global North were both more numerous and more experienced than those from the global South. These trends have continued to a degree. Only 26 of the 36 member states of the IGBC attended its September 2011 meeting (UNESCO 2011k). Among those missing were four of the eight from Group Va (African states): Mauritius, Togo, Côte d'Ivoire and Zambia. Yet of the 23 non-member states that sent observers, five were from Group Va, four from Group III (Latin American and Caribbean states) and four from Group IV (Asian and Pacific states). Group I (Western Europe and North American states), with five observers, again had the highest proportionate number, being one of the smaller groups (UNESCO 2011j). Nevertheless, that developing countries felt it worthwhile to send delegates to both this IGBC session and the public hearings on human cloning in 2008 perhaps indicates that their interests in bioethics are growing.

Questionnaire respondents in 2012 from sub-Saharan African National Commissions (NCs) and Permanent Delegations (PDs) confirmed that some of the problems affecting meeting attendance are ongoing. In answer to the question 'Do you think that all member states have the opportunity to participate equally in UNESCO meetings on bioethics?', one West African NC wrote, 'Yes, because the invitation is open to all member states to attend either as members or observers.' Several others acknowledged this, but noted that states may not be able to take up this invitation due to limited resources; for example, a Southern African NC reasoned, 'Yes – however, only those that have the resources attend more often and their voices are heard more than those without the resources.' An East African PD made a similar observation about the capacity of Paris-based offices:

> It highly depends on the availability of staff at the Mission. Very often developing countries do not have a budget for the participation of experts in such technical meetings. Many of the delegations are understaffed and cannot cover all the meetings taking place at UNESCO.

A second Southern African NC pointed out that those states with seats on the IGBC have more opportunities to participate and that these will tend to be those states for which bioethics issues are a priority. A third cited both the lack of resources and the lack of concern with bioethics (which means that low-income countries 'have little or nothing to contribute in the meetings'), while a West African PD commented on the want of both resources and expertise: 'No – the

main reason, particularly for African Member States, derives from either not having the appropriate experts or lack of funds to sponsor their participation or both.' A Southern African PD combined all three reasons: 'In theory yes, in practice no. Impediments to equal participation are cost of attendance at meetings, technical capacity to participate in debates and general interest in or awareness of the subject matter.'

In future endeavours, UNESCO might try to avoid such problems by implementing some pragmatic changes. It could help low income countries meet the travel costs of their delegations, for example, through a participation fund, as suggested by Chasek and Rajamani. Indeed, at its 2009 meeting the IGBC decided to invite the Director-General of UNESCO to look into the possibility of financial provision to enable members from the least developed countries to participate in its meetings (UNESCO 2009f: 5). This move was primarily aimed at very small states, such as Samoa and Kiribati and would be applied on an *ad hoc* basis (interview with K2_01). It could be a positive step, providing it does not fall prey to some of the problems that the allocation of daily subsistence allowances (DSAs) to delegates can engender. Chasek (2010: 29), in her more recent studies of multilateral environmental agreements (MEAs), has shown that, while DSAs enable developing countries to send representatives to negotiations when they would not otherwise be able to do so, they have generated something of an 'international MEA meeting "industry"', which serves to exacerbate some of the problems she and Rajamani had earlier identified and which are seen within the UNESCO Bioethics Programme. Government officials may vie for the opportunity to attend meetings, for example, in order to supplement meagre salaries, with the result that the chosen representative is not always the most appropriate: 'such would be the case if a foreign affairs official attends a scientific working-group meeting'. Alternatively, a state may opt to 'share the wealth' by appointing a different representative to each meeting, with ensuing continuity problems.

Subsidized travel alone would not address the problem of lack of expertise in delegations. Yet here, too, there have been improvements. Where IGBC representatives were, in the past, often from a country's Permanent Delegation in Paris, some states are now appointing bioethics experts as their IGBC delegate for the duration of their membership of the committee (interview with F2_03). At the IGBC meeting in September 2011, for example, the majority of states sent at least one specialist alongside a Permanent Delegation member (UNESCO 2011j). This may help to promote a more symbiotic relationship between the IGBC and the IBC. At the joint meeting in October 2010, both chairs were keen to foster better communication and cooperation between the two committees. The following year, Evans, the outgoing IBC Chair, said in his presentation to the IGBC at its September session that the October 2010 meeting had seen a 'sea change' in the relationship, citing the IGBC's input into the vulnerability report as an example (personal observations). What is more, the key difference between the two committees – one is independent, while the other represents member states – can be brought out in a complementary way. A member of the Bioethics Programme (F2_03) explained that the joint meetings can be a useful way for the IBC and the

secretariat to get an indication of what states' reactions to a possible programme of action are likely to be (and hence its viability), ahead of the General Conference. This was the case with the proposed convention on cloning.

Although the formal procedures of IGOs cannot guarantee equality among states, they do offer some form of protection to the interests of weaker members. As Slaughter (2004: 28) acknowledges, the lack of 'representation rules, voting rules, and elaborate negotiating procedures' in less formalized government networks can result in the deliberate exclusion of weak states. Another boon for these states is the advent of group bargaining, offering strength in numbers. The negotiations for the UDBHR (2005) demonstrated how collaborations within and between regions of the global South afforded them a platform from which to demand an article on social responsibility. These collaborations formed around a special issue, as recommended by Chasek and Rajamani, but maintained the power of a broad coalition. The factions that formed during the UN's cloning debate offer another, less salutary example of group bargaining. In this case the intransigence of both sides meant that the original aim of a binding convention had to be abandoned, in favour of the weak and ambiguous *Declaration on Human Cloning* of 2005, for which almost half of member states did not vote.

The difference between the resolution of the UN debate and any decision-making within the UNESCO Bioethics Programme is that the latter always operates by consensus. This can be both a strength and a weakness. It means that the three bioethics and genetics declarations enjoy the backing of all member states, but this was only possible because decisions on difficult issues such as stem cell research, which came up in the deliberations on the UDBHR (2005), were postponed until a change in the international political climate should render agreement possible. Biller-Andorno (2005: 63), in her *Journal of Medical Ethics* editorial, drew a direct comparison between the two efforts:

> If no meaningful universal agreement can be reached on reproductive cloning, at least not at the level of the United Nations, the prospect for reaching a global consensus on other issues in bioethics is rather bleak. It will be interesting to see if UNESCO will have more luck in its development of a declaration on universal norms on bioethics, which is currently in preparation.

Although this statement fails to recognize that it would be through leaving out controversial topics like cloning that UNESCO would be able to achieve consensus on 'other issues in bioethics', Biller-Andorno went on to make a pertinent observation about the need for ongoing discourse, which may be of greater long-term benefit. Echoing Slaughter's call for positive deliberation, she wrote:

> But no matter what the outcome is, it certainly makes us aware of the need to foster a genuine, world-wide discourse on bioethical issues (rather than leaving the field to political power games), which may be even more important than reaching immediate substantive conclusions.
>
> (ibid)

Given that UNESCO, like the UN General Assembly, has failed to reach a consensus on cloning, we can ask whether there are limits to the power of deliberation, such that discussion cannot breed consensus where the lines are clearly drawn. An alternative reading would mirror the sentiments of the Swiss IGBC representative who called for a conference on cloning to deepen international dialogue on the issue. Discussions at UNESCO meetings are often rushed. At the May–June 2011 IBC meeting, for example, little more than an hour was spent on cloning at the public sessions, members having been asked to keep their comments brief (personal observation). A more in-depth consideration might allow the debate to move forward. Of course this is speculative, but that is the point: we cannot predict what the outcomes of a free-flowing discussion will be.

Slaughter (2004: 27 and 203–4) advocates discussion and argument, developed in a positive, trust-building manner over time, as a means to achieve 'reasoned consensus'. These developments are more likely, she says, in networks where membership is based on common professional standards and ethics, or 'network norms', than in fora characterized by interest-based bargaining, such as regime negotiations. In this respect, informality may be a strength, as illustrated by the following example. During the intergovernmental meetings of experts charged with finalizing the UDBHR in 2005, Chairman Sader arranged an extramural session, at which he requested that participants refrain from taking positions and instead engage in open discussion. This helped enable consensus, even on the previously fractious topic of social responsibility. Sader also produced a 'non paper' on how outstanding issues might be addressed, which he distributed to member states (UNESCO 2005g).

Another way to improve the quality of dialogue is to involve as broad a range of stakeholders as possible. As would be expected in a state-centric regime, it was government representatives who made the final decisions on the UNESCO declarations, but non-state actors played a part in the various drafting stages, through written and verbal consultations. In line with Samhat's observations about how IGOs have evolved, UNESCO has opened its deliberations to non-state actors to a significant degree, directly and through documentation, most of its meetings being held in public and recorded in the public domain. Yet Williams and Macpherson have criticized the closed nature of the negotiations in prominent ethics journals and significant numbers of bioethics and genetics specialists in Kenya and South Africa were unaware of the declarations when interviewed in 2005–6, not having been asked to feed into their country's negotiating position. The problem for these states, then, seems to have lain in their incapability (financial or otherwise) to harness expertise, as much as a lack of expertise *per se*. ten Have (2006: 349) acknowledges that UNESCO and its member states could do better in this regard, but also warns that it should not be assumed that ethicists are willing to work with governments and IGOs.

Some of those interviewed were concerned not only that experts in the field had not had input into the draft UNESCO declarations, but also that those who might be affected by their provisions, such as potentially vulnerable research subjects, had not been consulted either. The problem is that UNESCO cannot guarantee

how far those at the negotiating table actually represent their constituents. Chasek and Rajamani's suggestions of national policy debates, strategic consultations and greater networking between relevant government ministries would seem relevant here (although the reluctance on the part of Kenyan and South African scientists to get involved in policy-making sounds a note of caution). On the challenge that the interdisciplinarity inherent in bioethics presents for UNESCO's Bioethics Programme, ten Have (2010: 14) writes:

> The challenge here is to bring together policy-makers, scientists, health professionals and citizens, so that they engage in dialogue and debate in order to determine what is in the best interest of all. It is only by situating itself in a really global perspective that bioethics can be translated into practical activities that contribute to improving the condition of everyone.

This raises the question of what system of deliberation will best serve UNESCO in bringing together the required mix of people in a way that generates meaningful and fruitful dialogue. Slaughter recommends (2004: 225) that government networks – which the IGBC and the National Commissions arguably are or could be – should engage systematically with their counterparts in the corporate and civil society sectors. Similarly, under Samhat's and Ellis' schemata, regimes would be framed to include all those affected by a specific issue, through the conduit of civil society organizations. These suggestions are very close to the pleas of IBC and IGBC members themselves, who would like to see better communications between the Bioethics Programme secretariat, National Commissions, national bioethics committees and other ethics bodies, to aid broader dissemination of the declarations and their principles.

Held's model goes further, proposing a cosmopolitan democracy through 'an overarching network of democratic public fora', from the local to the global. A diverse range of public spheres would enable informed participation and deliberation, guided by the 'requirements of impartiality'. 'Being impartial here', writes Held (2004b: 109), 'means being open to, reasoning from, and assessing all points of view (especially those of people in urgent need); it does not mean simply following the precepts of self-interest.' In reality, though, impartial and informed participation is difficult to guarantee, particularly among the broader public. This has been the case in Kenya and South Africa, where those who might be significantly affected by decisions in bioethics and genetics (in vulnerable communities, for example) have little knowledge of these subjects. To address this, programmes like South Africa's Public Understanding of Biotechnology aim to inform citizens about biotechnology, so that they can participate in policy-making. The programme tries to be neutral in the information that it gives, but finding the right balance has proved difficult, particularly in terms of assessing how best to offset information given out by interest groups (interviews with SA_27 and SA_29). Moreover, its success in generating interest and understanding has been limited.

Implementation

Each of UNESCO's declarations on genetics and bioethics was adopted by acclamation at its designated General Conference. Yet it does not necessarily follow that all member states immediately rushed to align their national laws, regulations and policies with the provisions of the declarations, particularly as these are non-binding. On this point Lenoir (1998–9: 550–1) writes:

> For some, the achievement of consensus on a declaration is a short-lived victory, because declarations are not binding and there is nothing to prevent states from later revoking the commitment they made when the text was adopted. For others, on the contrary, the contrast between treaty law and declaratory law is artificial. In their view, what matters is the formalization of common principles whose moral force arises from their solemn and public acceptance by the community of states.

Do the declarations (and their associated activities) indeed have the moral force to effect significant change in bioethics practice? Victor *et al.* (1998: 18) advocate systems of implementation review (SIRs) as a means to encourage states to honour their non-binding commitments. Precisely because the declarations are non-binding, however, member states of UNESCO have seen even self-reporting requirements as something of an impertinence. This, like many instances of reluctance on the parts of states to fully uphold their international obligations, pours cold water on Held's and Archibugi's visions of a world in which coercive power is shared between government and meta-governmental institutions, which would enable UNESCO to enforce its declarations as human rights instruments.

It remains to be seen whether the Bioethics Programme secretariat will (and will have the capacity to) offer member states a 'user-friendly template' for providing feedback on dissemination and implementation of the UDBHR (2005) within their countries, as requested by the IGBC in 2011 (UNESCO 2011c: 2). More successful thus far has been the system of devoting a day of the IBC sessions, when held outside Paris, to presentations on bioethics activities in the host country and region (interview with F2_03). GEObs is another source of information on implementation. Slaughter (2004: 237) predicts that one of the merits of linking governments in 'virtual space' would be that government officials would know they were under scrutiny. It does not appear that GEOBs is having this effect as yet, but as its usage figures continue to grow it may gain the leverage common to long-standing regimes.

According to Slaughter (2004: 153), treaties and agreements trigger the formation of government networks as an 'inevitable part' of their implementation. In the new world order she envisages, IGOs would play something of a secondary role:

> Imagine a global governance system principally composed of horizontal government networks of counterpart national officials, working on their own

> behalf or to implement formal international obligations. . . . Many, if not most, of the international organizations dotting this landscape, regardless of form or title, are in substance largely facilitative 'information agencies'; their job is to collect, distill, and disseminate information needed by network participants and to help the networks coordinate their work.
>
> (ibid: 164–5)

There would appear to be no valid reason why UNESCO should drop its capacity-building activities and become merely a facilitator, but it may be that it could draw on the government network framework to promote stronger implementation of the declarations among member states, if it could encourage the National Commissions to act as such. Rarely are the Bioethics Programme secretariat, National Commissions, relevant ministries in member states (of health or science and technology, for example), NBCs and IBC and IGBC representatives all communicating with each other to coordinate bioethics activities.

The potential for better networking within UNESCO has been recognized by two separate Internal Oversight Office (IOS) evaluations. A 2011 review of the general relationship between UNESCO's Secretariat (that is, the organization's headquarters in Paris) and the National Commissions found that what could be a multilayered 'array of fora' *à la* Held (2004b: 115) is in fact disaggregated in an unhelpful way, mainly due to lack of resources. Calling for improved relations not only within UNESCO but also with other IGOs and non-state actors, it concluded:

> While there are many examples of effective cooperation between the Secretariat and National Commissions, the network of National Commission [sic] presents opportunities to function better. Strengthening and retooling of cooperation arrangements between UNESCO's Secretariat and National Commissions are needed. This includes efforts to clarify the roles of each partner and to establish organization-wide working processes, including those related to knowledge management and to cooperation with partners such as civil society, the private sector and other parts of the United Nations system.
>
> (UNESCO 2012h: 2)

More specifically on bioethics, the 2010 evaluation of UNESCO's ethics activities recommended better coordination between the Bioethics Programme secretariat and the regional field offices, to generate 'a more efficient use of resources and an increase in operational synergies' (UNESCO 2010d: 33). The Bioethics Programme does indeed appear to work best where this is happening. In the former Eastern Europe, for example, the Moscow Office (the regional field office) worked to establish NBCs in all its cluster countries by 2007; from 2008, the focus shifted to networking and capacity building among these committees (UNESCO 2011p). At optimum, these different (but related) UNESCO networks might induce greater peer pressure on states to adopt the declarations, while at the same time providing them with a source of mutual support to do so, as Slaughter deems important.

Given the difficulties in enforcing compliance with non-binding norms, the UNESCO Bioethics Programme has chosen to concentrate its resources on a management approach to encouraging implementation of the declarations. The various capacity-building programmes – GEObs, the ABC initiative and the EEP – have been very active since the adoption of the UDBHR in 2005, especially in developing countries. As indicated by interviewees in 2005–6 and questionnaire respondents in 2012, the most favourable kind of capacity building is that which is planned in response to local needs, as identified by those on the ground. Reinicke (1999–2000: 55–6) notes that global policy networks must be genuinely inclusive at all stages to be successful: 'the mere façade of inclusiveness may prove their fatal weakness. . . . The inclusion of less powerful yet important groups from the developing world is critical not just for designing policies but even more so for implementing them.'

The problems of ensuring equal representation during deliberations notwithstanding, UNESCO appears to be doing reasonably well on this front when it comes to implementation. Requests for assistance come from the countries themselves and programmes are administered through national structures. Furthermore, training sessions on the ABC programme are tailored to the local context, and users of the Core Curriculum (which was written by people from all over the world) are encouraged to adapt the materials in whatever ways they see fit to ensure applicability. This has implications for Slaughter's model. She places great emphasis on capacity building as a means to improve compliance, but focuses almost entirely on initiatives designed and led by developed countries (Slaughter 2004: 229–30). She does acknowledge that knowledge could flow from South to North, but within an overall framework that hints at condescension: 'Where possibilities of genuine learning exist, representatives of even the world's most powerful nations are likely to be surprised by what they do not know or have not thought of . . . successful mentoring can often produce students who turn the tables on their teachers' (ibid: 229–30).

One hindrance to UNESCO's capacity-building efforts is its reputation in the field of bioethics. Faunce and Nasu (2009: 317) posit that the UDBHR should be seen to have 'fundamental cosmopolitan normative ground', concerned as it is with the 'universal interests of humanity', while ten Have (2010: 9–10) declares,

> This new constellation of fundamental principles is not only the outcome of a process of internationalization of bioethics but it will also be the starting point for a true globalization of bioethics, – a global bioethics that cares about issues and problems in all areas of the world and that responds to the needs and concerns of all human beings on this planet.

The analogies with Held and Archibugi's visions for cosmopolitan democracy are clear, but does the UNESCO bioethics declaration (and its predecessors) live up to these grand claims? Despite being the first bioethics instruments to be adopted by an intergovernmental body, the declarations are usurped in some countries by longer-standing texts such as the *Declaration of Helsinki* and the CIOMS

guidelines. It is thus taking time for the UDBHR (2005), for instance, to become a 'normative reference' or a 'reference text . . . for all the stakeholders concerned', as intended by UNESCO's IGBC and the April 2005 meeting of government experts respectively (UNESCO 2003i: 8; UNESCO 2005c: 3).

More broadly, the UNESCO Bioethics Programme is still establishing itself as a provider of bioethics capacity building. As ten Have (2010: 14) has acknowledged:

> In the past period, emphasis has been on standard setting. The drafting and adoption of Declarations had a high profile. Currently, the focus is on implementation activities; these have a larger span of time and are less visible at a global level.

This is typical of international regimes post-adoption. The 2010 IOS evaluation stated that UNESCO had gained the comparative advantage of 'being recognized as an honest broker on bioethics issues by a large part of the international community of bioethics experts' (UNESCO 2010c: 2). But only two of a recent spate of articles on training for RECs mention UNESCO's efforts (Rwabihama *et al.* 2010: 245; Ijsselmuiden *et al.* 2012: 82). (In line with ten Have's statement, people have been more inclined to write – often critically – about the negotiation and content of the UDBHR than its implementation.) In 2005–6 many stakeholders in bioethics and genetics in Kenya and South Africa were unaware of the organization's activities in their field, as well as of the declarations themselves. By 2011–12 a few more were familiar with UNESCO's programmes, their reactions ranging from censure to ambivalence to strong interest. The most enthusiastic take-up was in Kenya, where the newly constituted National Bioethics Committee became the first to complete the ABC training.

A member of the Bioethics Programme interviewed in 2011 (F2_03) believed that UNESCO's reputation as an appropriate forum for bioethics had improved since 2005, when its suitability as a purveyor of bioethics principles had been questioned; where people used to refer to the *Declaration of Helsinki*, the CIOMS guidelines and WHO documents, they would now also add UNESCO. The difference with UNESCO, they said, is that it is not as narrow as the others, as it is positioned to look at ethical issues beyond research. Nevertheless, the proliferation of ethical guidelines at all levels has proved confusing and counter-productive for some practitioners (although a perceived need to comply with international standards as laid out in the *Declaration of Helsinki* and the CIOMS guidelines provided a catalyst for the strengthening of national systems in Kenya and South Africa in the mid-2000s [and later the UDBHR, in the case of Kenya]). Moreover, having to respond to requests for similar information from several different bodies (for databases of RECs, for example) can be burdensome for stakeholders.

This has implications for both Slaughter's and Held's models. Officials might consider it an inefficient use of their limited time to become involved in more than a few of the 'countless government networks' Slaughter (2004: 15) envisages. Held's 'overarching network of democratic public fora' (2004b: 109) might face

similar problems, with the confusion of responsibility Held has identified in the current international system simply being perpetuated. Slaughter (2004: 254) endorses 'an affirmative norm of friction and constructive ambiguity', but the bioethics case demonstrates that friction and ambiguity may be neither affirmative nor constructive. UNESCO has attempted to mitigate the overlap at international level by establishing the UN Inter-Agency Committee on Bioethics. As this committee is open to non-UN bodies, it may be a forum through which UNESCO and other organizations can coordinate their programmes and thus provide mutual reinforcement, in line with Young's positive views on different institutions having similar mandates. But further clarification on how the roles of the WHO and UNESCO should be split is needed, as became clear at the September 2011 IGBC meeting.

The overlap in remits at international level is mirrored at national level. In Kenya and South Africa in 2005–6, for example, there were poor communications within and between different government ministries working in related areas, namely health, education and science and technology. This meant that Kenya's system for the regulation of bioethics was incoherent, while in South Africa the Department of Science and Technology had no opportunity to feed into the negotiations on the content of the UDBHR (2005). The situation had improved by 2011–12, with the advent of the NBC in Kenya and the coalescence under the National Health Act in South Africa. IGBC members have been instrumental in promoting bioethics capacity building in Kenya (as UNESCO would like to see happen in other countries too), yet there is still some confusion over the respective roles of the National Commission and the National Council for Science and Technology.

Cosmopolitan democracy does not presume national governance capacity, but does require it; effective multilayered democratic governance would comprise accountable, responsive and meaningful politics at local to global levels (Archibugi 1998: 209; Held 2004b: 102 and 113). Slaughter, similarly, recognizes that sufficient national level capacity would be crucial to her vision of global governance through a lattice of government networks. Some states might struggle to meet these requirements, because of national level inefficiencies. Slaughter (2004: 5 and 12–13), like some regime theorists, criticizes international relations scholars for seeing states as single units in the international arena and thus ignoring what happens domestically. Under her notion of 'disaggregated sovereignty', government units within states would have discrete mandates to meet international legal obligations. But, for cross-cutting issues like bioethics, which ministry should house what mandate is not always obvious. Thus networking at national level between the disaggregated units would be essential, in order to avoid confusion.

When Slaughter (2004: 232) first outlined her model, she seemed to believe this coordination would be straightforward, commenting only briefly, 'Regulators of all kinds, from health to education to the environment, would conduct their own foreign relations, subject to some kind of domestic interagency process that accepted this phenomenon but nevertheless attempted to aggregate interests.' As the Kenyan and South African cases demonstrate, the existence or efficacy of such

a process should not be presumed. Slaughter (2012) has since acknowledged this, stating that, for global governance through government networks to be effective, many governments will need to build 'intra-government networks', to enable far more unitary policy-making.

Kenya and South Africa

ten Have (2005: 746) writes of the UDBHR, 'The Universal Declaration helps put bioethics on the agenda of States.' This has been the case in Kenya, where a new NBC and attendant systems for the accreditation of RECs have been formed with explicit reference to the UDBHR and UNESCO's Bioethics Programme. It appears to have had little or no impact in South Africa, however, on what is a growing and developing bioethics community. Meagre input into the drafting of the UNESCO declarations by the scientists and ethicists who must apply ethical principles in their everyday work, together with the lack of an in-country champion (a UNESCO chair or IGBC member, for instance), may have hampered take-up. Nevertheless, both countries have seen an increasing emphasis on ethics issues that UNESCO deems important, such as the need for more ethics training for students, researchers and REC members, tailored to the local cultural context. South Africa, in particular, is making significant progress in this regard, playing a leading role in the development of an Africa-specific ethics textbook.

Above all, there is an acceptance that ethics deserves to be more than simply an afterthought. This was captured by a Kenyan interviewee in 2011 (K2_17), in the context of the Adili Center and other changes at the Kenya Medical Research Institute:

> You know how sometimes things just come together and then you're in the right place at the right time? . . . I mean, we had been saying, saying, saying and then suddenly we said the last time and people said, 'Of course you must have your own centre' and 'Of course you must have your own vote' and 'Of course you must charge'. And it's something we've been saying for the last six years. So we now actually are in a position to do things fairly well – fairly correctly – and then we hope that others might look at our model and maybe think that there are some good things about it. . . . Because once that one person has done something it's easier for others now to say, 'Oh, okay, this is the way it was done. Why can't we do that too?'

Where challenges remain – protecting vulnerable research participants, developing meaningful ways of sharing benefits, dealing with the complexities of sample shipping, ensuring RECs have the capacity to review and monitor research as demand for their services grows, increasing public understanding and engagement in ethics – the question for the UNESCO Bioethics Programme must be what role it might play in the continuing development of African bioethics.

The governance of human cloning

When intergovernmental organizations are unable to agree on a piece of binding legislation such as a convention, they often compromise with a less demanding declaration instead. This is what happened at the UN in 2005 when negotiations on a convention on human cloning reached an impasse. UNESCO, in its bioethics standard-setting endeavours, has opted straight for a declaration each time, as these are considered quicker to draft, more flexible and more likely to engender consensus. But this was not a viable option when it came to human cloning, since an international declaration already exists. UNESCO was thus faced with an 'all or nothing' choice – and it chose nothing. There was initially a tension between IBC members, who as independent experts supported a ban on human reproductive cloning and IGBC members, who as representatives of member states were fearful of entangling themselves in a fractious political debate akin to that at the UN a few years before. Eventually, though, both committees seemed to tire of the topic. As consensus on the issue both within and between them has become less rather than more likely, the idea of a convention to ban human reproductive cloning has, effectively, been shelved.

There are ethical and scientific consequences to this decision. Although controversial, human cloning has the potential to contribute to scientific and medical advancement, through the replacement of damaged tissue, for example. The debate over whether therapeutic cloning should be allowed spills over into reproductive cloning and vice versa, with disputes over terminology reflecting deeper concerns with the moral status of the embryo and, more broadly, what it means to be human. As things stand, there is nothing at global level that either definitively bans human reproductive cloning or sanctions therapeutic cloning. This legislative 'black hole' is unhelpful for those states that would draw on international law in formulating their own national regulations or policies. As ten Have (2006: 339) states:

> The desire to develop international frameworks therefore often is articulated by the least developed countries that are in need of normative guidance and that want to have the certainty that ethical principles are formulated on a global level so that the same standards are used everywhere.

Compared to other, more immediate concerns in developing countries, particularly in Africa, cloning may seem unimportant. This is often given as a reason for assuming that these countries will be uninterested in such issues, despite science being seen as key to development by NEPAD (the New Partnership for Africa's Development) and the African Union (NEPAD Office of Science and Technology 2006; Juma and Serageldin 2007). Yet the situation leaves African researchers (at least, those quoted in this book) who wish to pursue scientific advancement in a responsible manner frustrated at the lack of guidance and support and worried that they will be left behind by rogue scientists less concerned for the welfare of vulnerable populations, who may be cajoled into undergoing unnecessarily risky

procedures. Thus the continued inability of intergovernmental organizations to find a way to reach an agreement on human cloning acceptable to all parties is deeply problematic.

Pragmatic suggestions

To change the nature of an organization's governance structures to enable deeper deliberation and multisectoral decision-making is a big ask. But there are smaller adjustments that could be made relatively easily and yet have a significant impact. It is rare, for instance, for a UNESCO bioethics meeting to start on time. This may seem a facile point, but the consequence of the perpetual tardiness is that debates which have already been allocated only a few hours (in which the 36 members of each committee, plus observers, must all try to have their say) are truncated even further, to the detriment of the depth and quality of the discussion. Of course, informal negotiations over coffee may be just as important and valuable as officially timetabled meetings, but ample time for this is already built into the programmes. Redressing this balance does not require a new theory of governance, only a more pragmatic outlook. Given the considerable resources that go into holding these meetings, they should be used to their full potential.

Other seemingly simple improvements might be possible with more funding; covering some of the participation costs for developing countries, for example. But these would be very difficult to instigate in the current climate. In 2011–12 the Director-General of UNESCO, Irina Bokova, instigated a cost-saving drive, after the US withdrew its funding of the organization (which accounted for 22 per cent of the total budget) in the wake of the General Conference's decision to admit Palestine as a member state. She also launched an Emergency Multi-Donor Fund to make up the shortfall. 18 countries, including several from the global South, had pledged contributions as of November 2012 (Algeria, Belize, Cameroon, Chad, Gabon, Iceland, Indonesia, Kazakhstan, Mauritius, Monaco, Namibia, Norway, Qatar, Republic of Congo, Saudi Arabia, Oman, Timor Leste and Turkey). These contributions ranged from USD 20,000 and 50,000 from Mauritius and Namibia respectively, to USD 2 million each from Oman and Gabon, to USD 20 million each from Saudi Arabia, Norway and Qatar (UNESCO 2011n; UNESCO 2011o; UNESCO 2012c; UNESCO 2012f). While some of these amounts are tiny in comparison to a budget deficit for 2012–13 of USD 167 million, they may have symbolic relevance. If the organization can survive the immediate crisis and thus become less dependent on a single state for such a large section of its budget, the balance of power may shift. Significantly, the US remains a member state of UNESCO, but if it is no longer contributing financially, it cannot expect to have the influence it once did. Those countries which have heeded the Director-General's call and stepped into the breach may hope to fill the void.

Appendix

Interviews

Code	*Location and date*	*Description or affiliation*
K_01	Kenya, Oct 05	Kenyan representative at the UNESCO IGE meetings, April and June 2005
K_02	Kenya, Oct 05	Social and Human Sciences Committee of the Kenya National Commission for UNESCO
K_03	Kenya, Oct 05	Social and Human Sciences Committee of the Kenya National Commission for UNESCO
K_04	Kenya, Oct 05	African Technology Policy Studies
K_05	Kenya, Oct 05	KEMRI-Wellcome Trust Collaborative Programme
K_06	Kenya, Oct 05	KEMRI-Wellcome Trust Collaborative Programme
K_07	Kenya, Oct 05	KEMRI-Wellcome Trust Collaborative Programme
K_08	Kenya, Oct 05	KEMRI-Wellcome Trust Collaborative Programme
K_09	Kenya, Oct 05	KEMRI-Wellcome Trust Collaborative Programme
K_10	Kenya, Oct 05	African Biotechnology Stakeholders Forum
K_11	Kenya, Oct 05	Inter Region Economic Network
K_12	Kenya, Oct 05	Attendee at a 2002 genomics policy course
K_13	Kenya, Oct 05	Natural Sciences Committee of the Kenya National Commission for UNESCO
K_14	Kenya, Oct 05	Biosafety News
K_15	Kenya, Oct 05	World Health Organization, Kenya office
K_16	Kenya, Nov 05	Kenya National Commission for UNESCO
K_17	Kenya, Nov 05	Kenya Medical Research Institute
K_18	Kenya, Nov 05	Advisor on national biosafety policy
K_19	Kenya, Nov 05	Member of a research ethics committee
K_20	Kenya, Nov 05	Kenya National Biosafety Committee
K_21	Kenya, Nov 05	National Council for Science and Technology
K_22	Kenya, Oct 05	African Technology Policy Studies
K_23	Kenya, Oct 05	KEMRI-Wellcome Trust Collaborative Programme

(Continued)

(Continued)

Code	*Location and date*	*Description or affiliation*
K_24	Kenya, Oct 05	Africa Centre for Technology Studies
K_25	Kenya, Oct 05	Member of two research ethics committees
K_26	Kenya, Oct 05	Geneticist at a university
K_27	Kenya, Nov 05	Ministry of Health
K_29	Kenya, Nov 05	Geneticist at a research institute
K_30	Kenya, Nov 05	Ministry of Foreign Affairs
K2_01	Kenya, Nov 11	Former UNESCO Bioethics Chair
K2_16	Kenya, Nov 11	National Council for Science and Technology
K2_17	Kenya, Nov 11	Kenya Medical Research Institute
K2_21	Kenya, Nov 11	National Council for Science and Technology
K2_25	Kenya, Nov 11	Member of the National Bioethics Committee
K2_31	Kenya, Nov 11	African Biotechnology Stakeholders Forum
K2_32	Kenya, Nov 11	Regional Documentation Centre, Egerton University
SA_01	By telephone, Jul 06	Center for the AIDS Programme of Research in South Africa
SA_02	South Africa, Mar 06	South African National Bioinformatics Institute
SA_03	South Africa, Mar 06	Geneticist at a university
SA_04	South Africa, Mar 06	Division of Human Genetics, University of Cape Town
SA_05	South Africa, May 06	Faculty of Health Sciences Research Ethics Committee, University of Pretoria
SA_06	South Africa, Mar 06	Senior member of a commercial genetics company
SA_07	South Africa, Mar 06	South African National Bioinformatics Institute
SA_08	South Africa, Mar 06	Centre for Applied Ethics, University of Stellenbosch
SA_09	South Africa, Apr 06	International Research Ethics Network for Southern Africa (IRENSA)
SA_10	South Africa, Apr 06	Member of a research ethics committee
SA_11	South Africa, Apr 06	Africa Genome Education Institute
SA_12	South Africa, Apr 06	Centre for HIV/AIDS Networking
SA_13	South Africa, Apr 06	LifeLab
SA_14	South Africa, Apr 06	School of Philosophy and Ethics, University of KwaZulu-Natal
SA_15	South Africa, Apr 06	National Research Foundation
SA_16	South Africa, Apr 06	Bioethics Division, University of the Witwatersrand
SA_17	South Africa, Apr 06	An academic in a senior position in bioethics at a health sciences faculty
SA_18	South Africa, Apr 06	Geneticist at a university
SA_19	South Africa, Apr 06	Human Research Ethics Committee (Medical), University of the Witwatersrand

Code	*Location and date*	*Description or affiliation*
SA_20	South Africa, Apr 06	Geneticist at a university
SA_21	South Africa, Apr 06	Geneticist at a university
SA_22	South Africa, Apr 06	Research ethicist
SA_23	South Africa, Apr 06	South African representative at the UNESCO IGE meeting, June 2005
SA_24	South Africa, Apr 06	Geneticist, research ethics committee member and ethics lecturer
SA_25	South Africa, Apr 06	Senior member of an independent ethics institute
SA_26	South Africa, Apr 06	Department of Science and Technology
SA_27	South Africa, Apr 06	Geneticist at a research institute
SA_28	South Africa, Apr 06	Advisor on national innovation policy
SA_29	South Africa, Apr 06	Public Understanding of Biotechnology programme
SA_30	South Africa, Apr 06	Geneticist at a university
SA_31	South Africa, Apr 06	Department of Science and Technology
SA_32	South Africa, May 06	Advisor on national innovation policy
SA_33	South Africa, Apr 06	Council for Scientific and Industrial Research
F_01	Paris, Aug 05	UNESCO Bioethics Programme secretariat
F_02	Paris, Aug 05	Attendee at the UNESCO IGE meetings, April and June 2005
F_03	Paris, Sep 11	UNESCO Bioethics Programme secretariat
UK_01	By telephone, Sep 05	Attendee at the UNESCO IGE meetings, April and June 2005
UK_02	London, Nov 05	Attendee at the UNESCO IGE meetings, April and June 2005

Notes

2 Bioethics

1 The report generated commentaries in the journals *Science* and *Nature Genetics*. It was also announced in newspapers around the world, including *The New York Times*, *The Washington Post*, *The Toronto Star*, *Financial Times*, *Agence France Presse*, *New Straits Times* (Malaysia), *The Independent* (The Gambia) and *Africa News* (as revealed by a search of the database Nexis UK, 23 February 2007).

2 For simplicity, the term 'Bioethics Programme' is used throughout the book. At one time it was known as the 'Bioethics Section', led by a Chief of Section. In 2012 it became the 'Bioethics Team', led by a Team Leader, although its homepage still refers to the 'Bioethics Programme'.

5 Implementing bioethics

1 A search of the following journals was made on 31 May 2012: *Science*, *Nature*, *Nature Biotechnology*, *Nature Genetics*, *Nature Reviews Genetics*, *European Journal of Human Genetics*, *EMBO Reports*, *Annual Review of Genomics and Genetics*, *Trends in Biotechnology*, *British Medical Journal*, *PLoS Medicine*, *The Lancet*, *Journal of Medicine and Philosophy*, *Bioethics*, *Developing World Bioethics*, *Journal of Medical Ethics*, *Social Science and Medicine*, *International Journal of Biotechnology*, *Journal of Law, Medicine and Ethics*.

6 Contextualizing bioethics

1 The chapter focuses particularly on the UDBHR (2005) because more data were available on this declaration than on the previous two, not least because fieldwork was conducted during and immediately after its negotiation, which meant that it was possible to interview some of those who had been involved. The various meetings leading up to its adoption are also better documented by UNESCO.

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