Annual report of the Human Genetics Commission : 2003-2005

Human
Genetics
Commission

Human Genetics Commission

Fourth Report from July 2003 to April 2005

Chair's introduction

I am delighted to present this fourth report from the Human Genetics Commission. Since our inception in December 1999, the HGC has looked closely at aspects of genetic technology and development and has advised the Government on the wider implications of these, with a particular focus on their social and ethical impact. Genetic science is a fast moving area with new developments arising every year. Whether we are aware of it or not, decisions about the use of genetic information will affect most of our lives at one time or other. For this reason, it is an increasingly important factor, not only to our public health, but also to the legal and ethical framework of our society.

For my fellow Commission members and I, it has been a fascinating and rewarding endeavour, not least because, from the beginning, we have sought out the views of the public on genetic issues; an aspect of our work which we plan to continue in the coming year. More on that later. First, I would like to set out some of the HGC's key achievements over the past 18 months.

One of the questions the Government had highlighted in the Genetics White Paper *'Our inheritance, our future – realising the potential of genetics in the NHS'* was, should we as a society build up a genetic profile of every newborn baby? Would it be useful and right to do so and, could the National Health Service afford it? The Government recommended that the HGC work with the UK National Screening Committee to provide an initial analysis of the ethical, social, scientific and economic implications of genetically profiling babies.

The Commission, together with the UK National Screening Committee set to work. We were particularly keen to learn the views of young people on the costs and benefits of genetically profiling babies at birth and so in May 2004, we took part in a youth forum discussion in Bristol. Their comments, together with those of professionals working in the field, were extremely useful to us and were reflected in the final report, *'Profiling the newborn: a prospective gene technology?'*, which was published in March of this year.

In *'Profiling the newborn'*, we and the UK National Screening Committee concluded that there are important ethical, legal and social barriers to the introduction of genetic profiling of babies at birth as a public health service and we recommended to Government that the entire topic should be revisited in five years, when technologies will have moved on and the prospect of this becoming a reality is closer.

Another area of work that we identified in our last annual report was trying to get to grips with issues around genetics and reproductive decision making. One of the key issues to emerge from meeting the public has been advances in genetic technology and what these mean for reproductive choice.

For that reason, over the last two years, the we have been working to address a number of the complex issues around genetics and reproductive decision making. In June 2003, we held the first meeting of the Working Group and since then have had a number of meetings and heard a range of evidence from experts and stakeholders. The views of the HGC's Consultative Panel have been particularly important here.

In July 2004, we published *'Choosing the future'*, our discussion document on this topic. This document summarises information and views that we had considered to that point. It included

an examination of the history of genetics and reproduction, prenatal screening, diagnostic and genetics services, potential changes in the near future and some of the key arguments and concerns about where society is heading in the future. In building on dialogues with a range of stakeholders, the Consultative Panel and the public, we wrote to a number of organisations and individuals to seek their views, and we received about 200 responses. In addition, we engaged with a number of organisations whom had an interest in this topic and will be using the outcomes of their meetings as part of HGC's evidence gathering on this topic.

This exercise was another example where we received invaluable input from members of the HGC Consultative Panel. We formed the Consultative Panel in December 2001, when we invited around 100 people who are affected by a genetic disorder, to actively assist us with the HGC's work. Membership of the Consultative Panel requires a good deal of commitment as members are consulted on all our reports, the overall work plan of the Commission and are occasionally invited to attend meetings to discuss genetic issues. Their continued help has proved invaluable as they provide a unique insight into issues relating to genetics and ensure that our suggestions and recommendations to Government take account of the every-day experience and concerns of people affected by genetic disorders. We plan to hold an event this autumn for Consultative Panel members, to thank them for their support and to, once again, seek their views on HGC business and areas of work that we could look at in the future.

There were many other significant developments over the past 18 months in which the HGC has played an important role. One of our primary concerns over the past five years has been that genetic information about individuals is not used by the insurance industry in a discriminatory manner. Our consultations have shown very real public concern about the issue of genetics and insurance. These have shown that some people are put off taking genetic tests as they fear that they may be seriously disadvantaged as a result. We were, therefore, delighted when the Government announced in March this year that it had negotiated a new voluntary agreement with the Association of British Insurers. This ensures insurers' use of predictive genetic tests is transparent, fair, and subject to independent oversight. Further, as part of the new agreement, the existing genetics and insurance Moratorium will also be extended by an extra five years to 1 November 2011.

I am pleased that the views of the Human Genetics Commission have continued to have a positive impact on the insurance industry. Those who are affected by generic conditions should not feel excluded from the normal benefits of society, which includes access to life insurance and I hope that the extension of the Moratorium goes some way to reassure the public about these concerns.

Another issue on which the HGC has issued strong advice to Government is that it should be an offence to test an individual's DNA without their permission. We welcomed the introduction of this offence as a clause in the Human Tissue Act (2004) and will continue to feed-in to the accompanying guidance which the Department of Health is expecting to come into force in early 2006.

One of our key concerns has always been that we should strive to bring the work of the HGC to the public view as much as possible, encouraging feedback at all times. In our work plan for 2003-2005, we set ourselves the goal of further expanding our involvement with the public and identified our website as a crucial resource in this respect. We recognised that, whilst the old HGC website was functional and informative, there was real room for improvement. The Public Involvement Working Group were tasked with re-designing the website to make it a more accessible and interactive site for the public and other HGC stakeholders. I hope you will agree that the finished website – www.hgc.gov.uk – achieved exactly that. The website now contains up-to-date information about every aspect of the Commission's work and links to other helpful national and international sites. It is also more straightforward and simple to use. I was particularly impressed that members of the

public who are unable to attend our public plenary meetings can listen to an audio record of them, rather than reading through the minutes of the meeting.

Finally, as with all Commissions and advisory bodies which have an on-going role, the HGC's membership changes over time, as some members move on to other projects and commitments and we welcome new faces to join us in our work. The past 18 months have been no exception and I would like to take this opportunity to thank all my fellow Commission members – past and present – and offer my particular thanks to Alexander McCall Smith, who previously served as Vice-Chair and to Sir John Sulston who replaced Sandy in this role. Sandy's and John's support and personal commitment to the work of the HGC has been remarkable and I am deeply grateful to them.

I hope that you find this report useful and informative and that you will continue to engage with us over the coming year.

Helena Kennedy.

Helena Kennedy
Chair, Human Genetics Commission

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Our meetings between July 2003 and April 2005

"The Government is also committed to ensuring that its regulatory framework around genetics and health anticipates and reflects public concerns.

The Human Genetics Commission (HGC) has a critical role to play here... In conducting its work, the HGC has been a model of openness and transparency. It has sought innovative ways of engaging the general public and ensuring that people with genetic conditions are represented."

Secretary of State for Health, Genetics White Paper (June 2003)

We have an ongoing commitment to holding our main meetings in public and throughout the country. Over this period, we have visited a number of places. The minutes of our meetings and reports of proceedings are published on our website (www.hgc.gov.uk).

Our meetings

September 2003 – Cardiff

We held our September 2003 meeting in Cardiff. Our thanks go to Professor Peter Harper and his colleagues for organising this visit. We spent our first day at Techniquest, Cardiff's science discovery centre. Here we heard about the work of the Genetics Knowledge Parks and the collaborative work between them. We then had a very interesting Q&A session with sixth formers from two local schools. Members noted that the students were very articulate and raised a number of issues that they themselves had not yet identified.

The following day, we held our 13th Plenary meeting at City Hall. Our discussions focused mainly on the government's White Paper on Genetics, their response to HGC's report, *Inside Information*, and the Review of Forensic Science Service. Members also noted the progress to date of the Commission's work on genetics and reproductive decision-making, their work on paternity testing, as well as the draft of UK Biobank's Ethics and Governance Framework.

November 2003 – London

Our November meeting, which was held in London, included a presentation on the Human Tissue Bill and gave Members a chance to discuss the proposals in detail with lead policy officials at the Department of Health. We were pleased that our recommendation from *'Inside Information'* that taking someone's DNA without their consent for the purposes of genetic testing was taken into account in the drafting of the Bill. Members also heard about the Human Fertilisation and Embryology Authority (HFEA) report on sex selection and discussed the thinking behind the report's recommendations. There were discussions on a number of areas of ongoing work, such as on genetic discrimination with Members reiterating their commitment to the need for anti-discrimination legislation in this area. Members also considered the work on genetics and reproductive decision-making in detail, how HGC should work with the HFEA without duplicating work and what issues our consultation document of genetics and reproductive decision making should cover.

Our meetings

February 2004 – London

On the first day, we held an information event on genealogy testing – sometimes referred to as ancestry testing – to inform our review of DNA relationship testing services. Members found it a very useful seminar and heard from academic scientists, a company offering genealogy testing and from the makers and contributors of the television programme *'Motherland'*.

At our public meeting the following day, Dr Bob Bramley, the custodian of the National DNA Database, spoke about the database and the safeguards governing the way it was used. We decided that genetic equality and discrimination was an important issue for future discussion.

Following this event, it was becoming clear that the science of DNA testing in relation to genealogy was at an early stage and there was still a lot of research to be done. This was something the Human Tissue Authority would be issuing detailed guidelines on and we would hope the Commission was able to play a part in this work.

We were very sorry to have to say goodbye to Professor Sandy McCall Smith who had stepped down as Vice-Chair but pleased that Sir John Sulston had agreed to take on this role.

May 2004 – Bristol

In May 2004 we went to Bristol. This was the last meeting for Dr Hilary Harris, Professor Elizabeth Anionwu, Mr Philip Webb and Professor Harper. We are grateful for all their hard work and support during their time with the Commission.

At the plenary meeting, we talked about a draft of our discussion document on genetics and reproductive decision-making. Members also discussed the issue of genetic equity agreeing that this was an area in which the Commission could look to setting out some fundamental principles.

We spent the following day at the @Bristol Science Centre. In the morning, we spoke to a number of students from schools in the area about the case for and against genetically profiling babies at birth. Following this, we spoke to a number of people involved with the Avon Longitudinal Survey of Parents and Children (ALSPAC). This was invaluable for our project on profiling babies at birth. Our thanks go to ALSPAC and the staff at the @Bristol Science Centre for all their hard work in putting this event together.

September 2004 – York

The meeting was held in York and was the first meeting for a number of newly appointed Members. The Chair welcomed the new Members and one returning Member. Professor Andrew Webster, the Director of the ESRC/MRC Innovative Health Technologies Programme, spoke about a number of projects relevant to HGC's work. We focused our discussions on the issue of genetic equity and how to move forward on this area of work.

The following day, a number of Members attended the annual British Society for Human Genetics conference.

December 2004 – London

Our final meeting for the year was held in London. The focus of discussion was on the report from the Joint Human Genetics Commission/UK National Screening Committee on the case for and against profiling babies at birth. The following day, we held a useful information day on genetics and employment. We invited speakers from the Trade Union Congress, the Institute of Directors, the Disability Rights Commission, the Health and Safety Executive, as well as a number of leading academics in the field.

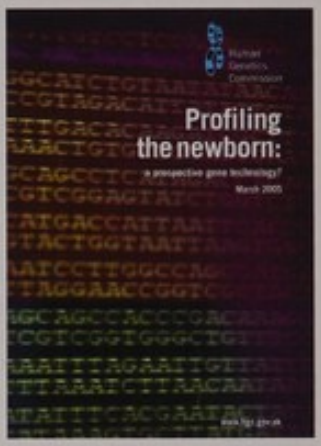
February 2005 – London

We met again in London in February. Before our main meeting, we heard from a representative of the Department of Health, and Dr Kathy Liddell from the Cambridge Genetics Knowledge Park, about the Human Tissue Act. After this, we had our public meeting at which we launched our new and updated website. We would particularly like to thank members of the Public Involvement Monitoring Group, the Business Committee and the Secretariat for all their hard work in completing this project. The main item for discussion was the draft report on the case for genetically profiling babies at birth.

This was also Professor John Burn's last event as a HGC Member. Baroness Kennedy, thanked him warmly on behalf of all Members for his contribution and support.

Key Pieces of Work

Profiling the Newborn



In 2003, Ministers published the White Paper on Genetics and asked the Human Genetics Commission (HGC) to work with the UK National Screening Committee (NSC) to conduct an initial analysis of the ethical, social, scientific, economic and practical considerations of genetic profiling (the analysis of a person's entire genome in order to reveal their personal genetic information) at birth.

This work was taken forward by a Joint Working Group which included both HGC and NSC members. The Group was Chaired by Sir John Sulston and it met a total of seven times. This collaboration provided a wide range of experience and opinion, and the Joint Working Group produced their report which was published in March 2005.

A wide range of people contributed to this report. In May 2004, we took part in a youth forum discussion in Bristol to hear the views of young people on the costs and benefits of genetically profiling babies at birth. We also spoke to researchers involved with the Avon Longitudinal Survey of Parents and Children. We would like to thank everyone who took part in these discussions. Members of HGC's consultative panel also provided important contributions. Once again, their comments gave us a vital insight into the feelings of people who have personal experience of living with a genetic disorder.

We concluded that there are important ethical, legal and social barriers to the introduction of genetic profiling of babies at birth as a public health service. Apart from these, it is unlikely to be publicly affordable within the next 20 years, though commercial services are likely to be offered in this timeframe, potentially raising issues of regulation. It is important that research continues in order to establish how far profiling could be clinically useful, and it is critical that developments are kept under review. Specifically, we recommended to Government that the entire topic should be revisited in five years, when technologies have advanced and the prospect of this becoming a reality is closer.

A full list of the conclusions and recommendations contained in the report are as follows:

- Genetic profiling is feasible and likely to become available commercially in less than 20 years.
- Before the offer of universal genetic profiling can be considered at a population level, steps need to be taken to preclude any misuse of information derived from it.
- Genetic profiling is unlikely to be publicly affordable within 20 years.
- For newborn genetic profiling, issues of consent and the welfare of the child are problematic.
- Genetic profiling may, in the future, have clinical potential but its effectiveness cannot yet be judged.
- There is a pressing need to develop a programme of research to define the full costs and potential benefits of genetic profiling for the health of children and adults.
- Genetic profiling cannot be applied as an NHS screening programme in the near future. The topic should be kept under review and revisited in five years.

Membership (joint with the UK National Screening Committee)
Sir John Sulston (HGC) (Chair)
Dr Bill Albert (HGC)
Professor Brenda Almond (HGC)
Professor Elizabeth Anionwu (HGC, to August 2004)
Dr Celia Brazell (HGC)
Professor John Burn (HGC)
Professor Carol Dezateux (NSC)
Dr David Elliman (NSC)
Dr Frances Flinter (co-opted HGC and NSC)
Professor Neva Haites (NSC)
Professor Peter Harper (HGC, to August 2004)
Dr Hilary Harris (HGC, to August 2004)
Professor John Harris (HGC)
Mr Michael Harrison (HGC) (from September 2004)
Professor Theresa Marteau (NSC)
Ms Hilary Newiss (HGC)
Dr Christine Patch (HGC)
Professor Martin Richards (HGC)
Mr Peter Sayers (HGC)
Dr Rosalind Skinner (HGC)
Professor Martin Whittle (NSC)
Dr Ron Zimmern (NSC)

Meetings
The Joint Working Group met in November 2003 to discuss the topic. It met a further six times between March 2004 and February 2005.

Key Pieces of Work

Genetics and Reproductive Decision-Making

Progress in molecular biology means we know an increasing amount about our genetic make-up. It also means we will be more informed about the genetic make-up of our children. While many people welcome progress in genetics science and what it means for identifying and reducing the risk of having children with genetic disorders, some concerns have been expressed about the impact of this science not only on society generally, but also on our understanding of the meaning and value of human life. In response to this, the Commission has undertaken a major piece of work on genetics and reproductive decision making.

Over the last two years, the we have been working to address a number of the complex issues around genetics and reproductive decision making. In June 2003, we held the first meeting of the Working Group. Since then have had a number of meetings, heard a range of evidence from experts and stakeholders, and sought the Consultative Panel's views on this subject.

In July 2004, we published *'Choosing the future'*, our discussion document on this topic. This document summarises information and views that we had considered to that point. It included an examination of the history of genetics and reproduction, prenatal screening, diagnostic and genetics services, potential changes in the near future and some of the key arguments and concerns about where society is heading in the future. We invited all individuals and organisations with an interest, to write to us to share their views. This led to dialogues with a range of stakeholders including the Consultative Panel, members of the public and a number of organisations. We were delighted to receive around 200 written responses.

In addition, we engaged with a number of organisations with an interest in this topic, and used the outcomes of their meetings as part of HGC's evidence gathering on this topic. Some examples include:

- the Wales Gene Park Youth Citizen's Jury on *'What's wrong with designer babies'* (Sept 2004)
- Progress Education Trust, *'Testing Times: the ethics of genetic screening'* (June/September 2004)
- DANA Centre event *'Naked Science: Gene screen'* (Sept 2004)
- *'Choosing the Future'* Seminar at the Newcastle Life Knowledge Park (Sept 2004)
- St. Peter's Church in the Parish of Central Wolverhampton discussion with young people (November 2004)

This Working Group is co-Chaired by Helena Kennedy and Martin Richards.

Further details of this work including reports of meetings, the discussion document, and progress to date, can be found on HGC's website.

The HGC Consultative Panel

The HGC set up a Consultative Panel of people affected by a genetic disorder. The panel, made up of over 100 people with direct experience of living with genetic disorders, acts as a sounding board for our reports and recommendations, as well as giving us insight into their concerns about genetic issues.

Much of the Panel's work is by correspondence, with Panel Members being sent summaries of reports we are writing or issues we are discussing for comment. It is planned that annual meetings will also be held to allow Panel Members to meet with Commissioners and to discuss issues in depth.

The Panel includes people who have experience of single gene, chromosomal or multifactorial disorders, which may have become apparent in either childhood or adulthood. Some people are affected themselves or are carriers, some have experience as a parent of a child affected by a genetic disorder and some are carers for someone in their family who is affected. The Panel membership has a wide age range and includes people who live in England, Scotland, Wales and Northern Ireland.

We established the Panel because we wanted to hear from people directly affected by a genetic disorder so that they can help us make informed decisions. We need to learn from people who know about the reality of living with a genetic disorder, their experience in deciding whether to take a genetic test and whether, for example, they have concerns about insurance and employment issues. Our hope was that the Panel would let us do this in a way that was very useful for the HGC while also being rewarding for those who participate.

The Panel has been a tremendously valuable resource for us. Since it was set up, members have assisted us with several consultations, meetings and the overall work-plan of the Commission. Panel Members give us a unique insight into issues relating to genetics and ensure that our suggestions and recommendations to Government, take account of the every-day experience and concerns of people affected by genetic disorders.

Panel Members have been involved in a number of areas of work. This year Members have helped us with our work on profiling newborns and reproductive choice in particular. We are currently planning an event later this year for Consultative Panel members, to thank them for their support and to seek their views on HGC business and areas of work that we could all look at in the future.

We first invited Panel Members to come on board in 2001 and specified that appointments would be for an initial term of three years. We were delighted that so many Members chose to remain a member of the Panel for its first three years.

However, we are well aware that membership requires a good deal of commitment so we are currently giving Members an opportunity to either renew their membership for a further two years or to step down. We may therefore be recruiting some new Panel Members in the coming year, depending on the numbers of Members who decide to leave.

Intellectual Property and Genetics Monitoring Group

The issue of patents, intellectual property and genetics continues to be debated widely in many national, regional and international forums. In February 2003, HGC established an Intellectual Property and Genetics Monitoring Group in order to monitor the issues including European and International developments of relevance to the UK.

The role of this group is primarily to build on the work done by other bodies in fostering debate, and to monitor developments and publications by other bodies.

Members of the group have regular email contact to monitor the work of key stakeholders, new research findings as well as to begin to form views on a variety of topics. This is then reported to the main Commission at its plenary meetings.

The issues we look at include:

- Ethics and gene patents
- Should genetic material be patentable?
- Ethical concerns
- Application of the law
- Competition and access to information
- Informed consent, donor identification and confidentiality
- Other issues: stem cells, incentives

Our role is to identify and monitor developments relating to intellectual property and report these back to HGC to inform and consider.

Members during the reporting period

Hilary Newiss (Lead)
Brenda Almond
Celia Brazell
Alastair Kent
John Sulston

In February 2003, an Intellectual Property monitoring group was formed to build on the work done by other bodies in fostering debate, to monitor developments as well as publications by other bodies. The Lead and Group members have regular email contact to monitor the work of key stakeholders, new research findings as well as to begin to form views on a variety of topics.

Research Database Monitoring Group

The Group was formed in 2003 to continue to track developments in the UK Biobank. Following the publication of 'Inside Information' which addressed general research issues like consent and feedback, HGC were asked to submit a formal memorandum on the UK Biobank. We have held meetings and informal liaison meetings with the Biobank funders. HGC commented on the draft ethics and governance framework produced by the Biobank Interim Advisory Group.

In 2005, we have also begun to consider some of the wider issues with research databases. The main topics in this area that HGC continue to pursue include:

- Ensuring that consent is fully informed and covers questions like feedback and intellectual property
- Ensuring strict confidentiality, by effective anonymisation, encryption and by controlling access by groups such as the police
- Maintaining public confidence, particularly ensuring that large research databases remain a trusted public resource
- Promoting realistic expectations of the pace of scientific and medical research and the role of partnerships between public and commercial research

The role of this group is to oversee HGC activities relating to genetic research and databases, particularly the ethical, social and legal implications of large projects such as the UK Biobank.

Members during the reporting period

Martin Richards (Lead)
Stephen Bain
Celia Brazell
John Burn
John Harris
Hilary Harris
Veronica van Heyningen
Hilary Newiss

Horizon Scanning Monitoring Group

An important role of the HGC is to provide Government with advice on advances in human genetics and their implications for healthcare as well as the broader social and ethical issues.

The Horizon Scanning group has continued its work by considering a number of important issues. These include:

- **Advances in technology**

It is important to focus on technological advances because of the impact this can have on specific issues – for example improved and cheaper rapid sequencing techniques may alter the way in which we view neonatal profiling. The human rights and societal aspects should always be considered in parallel to these advances.

- **Pharmacogenetics**

The exact responses to drugs show significant individual differences. Some people need higher or lower doses of a drug to achieve the required effect, some people fail to respond at all to some pharmaceutical interventions, while others suffer toxic effects. Underlying genetic differences in the body's drug handling ability can now be identified in many cases and it is envisaged that in the future there may be much more tailor-made prescribing. This could mean that useful drugs that are toxic or ineffective for a few people can still be used for the majority who respond well.

- **Stem cell research and technology**

Stem cells have the potential to divide and differentiate into a number of different cell types. They have great promise as therapeutic tools to combat many different types of diseases. There are very wide ranging ethical and societal issues involved in the derivation and use of all embryonic derived cells and in the UK these procedures are tightly regulated and licensed by the Human Fertilisation and Embryology Authority.

The role of the group is to take account of the work of existing bodies with a horizon scanning role to identify and report back on the key issues for HGC to consider.

Members during the reporting period

Veronica van Heyningen (Lead)
Celia Brazell
John Harris
John Sulston

- **Ageing research**

We are all aware that many biological changes occur as we age. Not everyone seems to age at the same rate and exactly which processes go awry when also varies from person to person. The underlying differences are to some extent influenced by genetics and all biological processes are regulated by genes. Therefore there is a lot of work in progress to understand how these changes arise and how the deleterious aspects might be prevented, controlled or delayed. A longer lifespan will have enormous resource implications for the increasing requirement for age-related health care and this may impact on the retirement age for society.

- **Nanotechnology**

This is an area where novel molecular constructs may be produced for drug delivery and novel approaches even to surgery. The technology may also be used for new ways of making clinical and biological measurements. This is a controversial emerging technology which may bring great benefit, but the potential harmful side effects foreseen by some people must be explored with great care, if these are to be avoided.

- **Consent issues**

Because of the changing nature of medical and genetics research, we may need to address anew the principles which govern the establishment of informed consent in these and related areas.

- **Human rights issues**

There will be some surprising new issues raised by the availability of genetic testing. There was a report last year that young athletes diagnosed with a genetic predisposition to sudden death, are fighting for their right to continue to risk their lives.

Genetic Discrimination Monitoring Group

The role of this group is to oversee HGC activities relating to genetic non-discrimination, particularly in insurance and employment and monitor the work of other relevant bodies to ensure effective and efficient collaboration.

Members during the reporting period

Bill Albert (Lead)
Stephen Bain
John Harris
Iona Heath
Alastair Kent
Martin Richards
Peter Sayers
John Sulston
Patrick Morrision (co-opted)

Genetics and Insurance

Over the past 18 months, the discrimination monitoring group has continued to work with the Genetics and Insurance Committee (GAIC). A HGC representative is invited to all GAIC meetings and the discrimination subgroup have held joint meetings with GAIC on three separate occasions. The idea for a joint group arose from the discussions at a HGC plenary meeting as a means of addressing long-term developments in genetics and the implications for insurance, for example the use of family history, evidence of adverse selection, monitoring and complaints procedures during the moratorium. At the meetings, the Joint Group discussed developments in the understanding of complex conditions and possible developments of tests for biomarkers that may act as surrogates for genetic/DNA testing.

On 22 September 2003 and on 13 July 2004, the Genetics and Insurance Committee (GAIC), in conjunction with HGC, held a public meeting on insurance, genetics and fairness. The audience at these meetings consisted mainly of representatives from various insurance companies and patient interest groups as well as members of GAIC and the HGC.

"Very good level of debate."
"Fantastic day. Very helpful and informative."

Delegates at GAIC/HGC public meeting

In March 2005, the group was pleased to see that the moratorium on genetics and insurance between the Association of Genetics and Insurance and the Government had been extended to 2011.

Genetics and Employment

In December 2004, the discrimination monitoring group was involved in the design of the information gathering session on genetics and employment. The Trade Union Congress, the Institute of Directors, the Disability Rights Commission, the Health and Safety Executive, and a number of leading academics in the field attended.

The Group also had input to the Information Commissioner – worker's information on health. In February 2005, the monitoring group published an information page on genetics and employment on the revised HGC website.

Public Involvement Monitoring Group

Engaging the public in issues relating to genetic science has always been a principal aim of the HGC. Our terms of reference clearly state that we should:

"develop and implement a strategy to involve and consult the public and other stakeholders and encourage debate on the development and use of human genetic technologies and advise on ways of increasing public knowledge and understanding."

The Group was formed in 2003 to co-ordinate the ways in which the Commission involves people in its work. Monitoring Group members hold meetings or discuss issues via email to oversee HGC's activities relating to public involvement, in particular to promote debate and achieve effective representative dialogue with a wide cross-section of people. The main areas overseen by the Group are:

- Public Involvement Strategy
- HGC's Consultative Panel
- HGC's Press Office
- Website
- Liaising with other organisations
- Relevant publications

We have always strived to conduct HGC business in public and we continue to make regular trips to other cities in the UK in order to ensure that people in other parts of the country have an opportunity to visit our public plenary meetings. We also recognised the importance of an effective website for the Commission as a crucial resource in this respect. We recognised that, whilst the old HGC website was functional and informative, there was some room for improvement. The Public Involvement Working Group working with the HGC Business Committee were tasked with completely re-designing the website to make it a more accessible and interactive site for the public and other HGC stakeholders. In our view, the new website, which was launched in February of this year, achieved that. The website now contains up-to-date information about every aspect of the Commission's work and links to other helpful national and international sites. It is simpler to use and we have found, by monitoring the number of hits which the site receives, that it is a valuable tool for people all over the world who share an interest in issues relating to genetics.

For the coming year, we are planning a public event which will look at the subject of the forensic use of genetic information and the knowledge we gain from this event will inform our future work in this area.

Members during the reporting period

Geoff Watts
Elizabeth Anionwu
John Burn
Paul Debenham
Alastair Kent
Christine Patch
Peter Sayers

Identity Testing Monitoring Group

The Identity Testing Monitoring Group was formed in 2004 to look at issues relating to the commercial and forensic use of genetic information for purposes of establishing the identity of an individual. The Group is particularly interested in the various forms of relationship testing which are now available to the public and the collection and retention of DNA samples by the police.

In February 2004, the HGC held an information gathering event in London on genealogy testing to inform our review of DNA relationship testing services. Members found it a very useful seminar and heard from academic scientists, a company offering genealogy testing and from the makers of and contributors to the television programme *'Motherland'*. The following day at the public plenary meeting, Dr Bob Bramley, the custodian of the National DNA Database, talked to Members about the database and the safeguards governing the way it was used.

An important aspect of the Commission's role is to provide advice to inform Ministers' decisions on broad social and ethical issues relating to human genetics. It was within that context that in June 2001, the HGC visited the Forensic Science Service to learn about the organisation and management of sampling, profiling and the National DNA Database. Following this, in May 2002, the Commission published Inside Information – Balancing interests in the use of personal genetic data, which contained the following recommendation:

"We recommend that, at the very least, the Home Office and ACPO establish an independent body, which would include lay membership, to have oversight over the work of the National DNA Database custodian and the profile suppliers."

Further, we recommended that: *"In the short term the Home Office and FSS introduce an independent research ethics committee, to approve such research."*

The role of this group is to oversee HGC activities relating to genetic research and databases, particularly the ethical, social and legal implications of large projects such as the UK Biobank project.

Members during the reporting period

Stephen Bain (Lead)
Paul Debenham
Alastair Kent
Hilary Newiss
Martin Richards
Geoff Watts
Philip Webb

The main areas of interst to the Monitoring Group include:

- Ensuring consent that is fully informed and covers questions like feedback and intellectual property
- Ensuring strict confidentiality, by effective anonymisation, encryption and by controlling access by groups such as the police
- Maintaining public confidence, particularly ensuring that large research databases remain a trusted public resource
- Promoting realistic expectations of the pace of scientific and medical research and the role of partnerships between public and commercial research.

Following publication of that report, the National DNA Database Board invited us to put forward one of our members to sit on the Board and this arrangement has continued to this day. Currently, Dr Stephen Bain, the lead member of the Identity Testing Working Group, represents the Commission on the Board.

The HGC continues to emphasise the need for lay involvement on the National DNA Database Board and request that a system of formal ethical oversight be established. The Commission submitted written evidence to that effect to the Science and Technology Committee to that effect in February this year.

Following publication of the Science and Technology Committee report, *Forensic Science on Trial*, in March 2005, the Identity Testing Working Group is engaging with the Home Office and other stakeholders to examine how safeguards can be put in place without hindering the work of the police and forensic science unit.

More broadly, the Human Tissue Authority, has issued detailed guidelines on and DNA testing in relation to genealogy, and has issued codes of practice covering consent, communicating with relatives regarding post mortems, anatomical examination, import and export of tissue, existing holdings, disposal of tissue and definition of death. The draft codes will be issued by the Human Tissue Authority in July 2005 for a period of three months consultation and the HGC plans to submit a formal response.

Keeping in touch

Tell us what you think

We are always keen to hear what you think and would welcome your comments about any aspect of our work.

The Secretariat for the HGC is provided by the Department of Health and the Office of Science and Technology officials and may be contacted at:

The Human Genetics Commission
6th Floor, North
Wellington House
133–155 Waterloo Road
London
SE1 8UG

If you would like to receive HGC's news and publications, please register your details with us.

Press enquiries: 07990 550026 or 020 8675 1066

Public enquiries: 020 7972 4351

Fax: 020 7972 4300

E-mail: hgc@dh.gsi.gov.uk

If you contact the Secretariat by e-mail, we would appreciate it if you could include your contact details. These will not be revealed to any third parties, but may be used to keep you informed of the work of HGC, unless you state that you do not wish to receive any further information.

Details of HGC publications are given in Annex H.

Annex A: Membership

The Human Genetics Commission

Chair
Baroness Helena Kennedy
Barrister and broadcaster

Vice-Chair
Sir John Sulston (from February 2004)
Former Director of the Wellcome Trust Sanger Institute, Hinxton, Cambridge

Professor Alexander McCall Smith (until January 2004)
Professor of Medical Law, University of Edinburgh

Members
Dr Bill Albert
Chair of the Norfolk Coalition of Disabled People

Professor Brenda Almond
Professor of Moral & Social Philosophy
Hull University

Professor Elizabeth Anionwu (until July 2004)
Professor of Nursing, Head of Mary Seacole Centre for Nursing Practice, Thames Valley University

Dr Stephen Bain
Reader in Diabetic Medicine at Birmingham University and Consultant Physician at Birmingham Heartlands Hospital NHS Trust

Dr Celia Brazell
Director of Science and Technology
GlaxoSmithKline

Professor John Burn (until February 2005)
Professor of Clinical Genetics, University of Newcastle upon Tyne and Director, Northern Genetics Service

Dr Paul Debenham
Professor of Bioethics, School of Law, University of Manchester

Professor John Harris (reappointed for a second term in September 2004)
Sir David Alliance Professor of Bioethics, University of Manchester

Dr Hilary Harris (until July 2004)
General Practitioner, Manchester

Mr Michael Harrison
Barrister

Dr Iona Heath
General Practitioner, London

Dr Susan Johnson
Lecturer in Adult Health, School of Nursing, University of Nottingham

Mr Alastair Kent
Director, Genetics Interest Group

Ms Suzi Leather (ex-officio)
Chair of Human Fertilisation and Embryology Authority

Ms Hilary Newiss
Solicitor

Dr Christine Patch
Senior Research Fellow, University of Southampton

Professor Martin Richards
Professor of Family Research, Centre for Family Research, University of Cambridge

Mr Peter Sayers
Former Chair of the Telecommunications Advisory Panel

Professor Veronica van Heyningen
Head of Cell Genetics Section, MRC Human Genetics Unit, Edinburgh

Mr Geoff Watts
Journalist and presenter of BBC Radio 4's Leading Edge

Mr Philip Webb (until July 2004)
Member of the Board of Trustees of Genetic Interest Group

Representatives of the Chief Medical Officers
Each of the four UK Chief Medical Officers will be able to participate in HGC or nominate a representative with observer status.

Dr Paul Darragh (Northern Ireland)
From March 2005
Consultant, Public Health Medicine Eastern Health & Social Services Board

Professor Robert Stout (Northern Ireland)
Until February 2005.
Director of Research and Development for the Northern Ireland Research and Development

Professor Angus Clarke (Wales)
From August 2004
Honorary Consultant in Clinical Genetics, University of Wales College of Medicine

Professor Peter Harper (Wales)
Until July 2004.
Professor and consultant in medical genetics, University of Wales

Dr Stephen Singleton (England)
Medical Director, Northumberland and Tyne & Wear Health Authority

Dr Rosalind Skinner (Scotland)
Principal Medical Officer of Public Health Medical Division, SEHD

Co-opted Members
Dr Heather Draper (Co-opted Member, Working Group on Reproductive Choice)
Senior Lecturer, Centre for Biomedical Ethics, University of Birmingham

Dr Frances Flinter (Co-opted Member, Genetic Services Sub-group and Working Group on Reproductive Choice)
Clinical Director and Consultant Clinical Geneticist, Genetics Centre. Guy's and St Thomas' Hospital Trust

Secretariat
Mrs Gwen Nightingale, Secretary (from January 2005)
Dr Mark Bale, Secretary (until September 2004)
Dr Manny Chandra (until September 2003)
Miss Sarah Connelly (from February 2005)
Mrs Margaret Straughan
Dr Sophie Taysom
Ms Emma Wilbraham (until January 2005)

Annex B: Published responses and memoranda

HGC response to *'Fairness for all: a new Commission for Equality and Human Rights'* Department of Trade and Industry document on he establishment of a Commission for Equality and Human Rights.

CEHR Project Team
Women and Equality Unit
Department of Trade and Industry
35 Great Smith Street
London
SW1P 3BQ

23 August 2004

Dear CEHR Project Team,

Re: Fairness for all: a new Commission for Equality and Human Rights

Thank you for the opportunity to comment on the above document. I am replying on behalf of the Human Genetics Commission (HGC), an independent advisory body established to advise the UK Government on developments in human genetics, and particularly the ethical and social implications. We welcome the Government's intention to establish a single Commission for Equality and Human Rights.

Our response is aimed at drawing your attention to one area not addressed in your document, that is the use and potential misuse of personal genetic information. Many of our concerns in this area have been raised in our report, *Inside Information* (enclosed).

In our report, we sought to identify principles related to equality and human rights as the basis of an ethical approach to the handling of personal genetic information. We drew on two international statements of principle which are directly relevant. These are UNESCO's Universal Declaration on the Human Genome and Human Rights (1997), and the Council of Europe's Convention on Human Rights and Biomedicine (1997). Discussions at the international level are ongoing as evidenced by the United Nations Economic and Social Council draft resolution on Genetic Privacy and Non-Discrimination published July 2004.

The most relevant principle we developed in relation to our consultation was the principle of respect for persons. This principle affirms the equal value, dignity and moral rights of individuals where each person is entitled to lead a life in which genetic characteristics will not be the basis of unjust discrimination or unfair or inhuman treatment. From this, we derived a number of secondary principles including those of non-discrimination, confidentiality, consent and privacy. As we have observed prior to and post the publication of this report, there is a high level of public concern over the potential for unfair discrimination on the grounds of personal genetic information.

While many forms of discrimination are now unlawful, such as racial or sexual discrimination, and will be covered by the remit of the new Commission for Equality and Human Rights, this is not the case with genetic discrimination. As we raised in our report, we are particularly concerned about the possibility of genetic labelling which may result in some people being treated as less employable, less reliable or less valuable than others. For example, in relation to employment, personal genetic

information indicative of inherited disease could potentially be used to deny people employment. This would not fall under the current legislative framework if the person concerned was pre-symptomatic and/or was not considered disabled.

The Government response, published in June 2004 in the White Paper *Our inheritance, our future* (Cm5791-II) welcomed the over-arching principles and undertook to "consider the evidence for unfair discrimination on the basis of a person's genetic characteristics and the appropriate means of addressing any concerns in this area". It also asked HGC to work with Disability Rights Commission (DRC) to monitor developments and, with the DRC and Health and Safety Commission, to informally consider and advise on any plans to introduce genetic testing in the workplace (Open letter from Dr John Reid, 24 June 2003, enclosed). We hope that this liaison function will be taken on board within the new CEHR structure.

We look forward to seeing the outcomes of this consultation and to liaising with the new CEHR once it is established.

Helena Kennedy.

Yours sincerely,
Helena Kennedy QC,
Chair, Human Genetics Commission

HGC response to *'Information about Worker's Health'*, a consultation by the Information Commissioner.

David Smith
Assistant Information Commissioner
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire SL9 5AF

1 March 2004

Dear David,

Re: Consultation on Part 4: Information about Worker's Health

Thank you for the opportunity to comment on the above document. I am replying on behalf of the Human Genetics Commission, an independent advisory body established to advise the UK Government on developments in human genetics, and particularly the ethical and social implications. We welcome your plans to provide employers with clear and practical guidance about how to comply with data protection law when handling information about worker's health. The following comments reflect discussions held by HGC's Discrimination Monitoring Group and relate specifically to Section 3.5: Genetic Testing.

The emphasis of this section is on genetic testing and the offer of tests. As you have pointed out, while such testing has the potential for some predicative value, this is still very much largely under development. As such, the efficacy of such testing is highly questionable. On this basis and the potential implications of what such tests may reveal, we would have significant concerns about any such testing being offered in the workplace. Underlying our report, *Genes Direct: Ensuring the effective oversight of genetic tests supplied directly to the public*, was the notion that predictive testing should only be offered in a context where there is the appropriate level of information and counselling given that the implications of such tests can be properly understood by the person being tested.

In addition, we would argue that the emphasis in this Code of Practice as it relates to genetics needs to be shifted from genetic tests to genetic information. Part of the reason for this is it is our understanding that the role of the Information Commissioner is to promote good information handling practice and to enforce data protection and freedom of information legislation. The issues around testing are of a practical nature that would seem to be more appropriately handled and managed by specialist NHS genetics clinics or occupational health services. In shifting the emphasis from genetic tests to genetic information, genetic information could be treated in a way similar to medical information.

As well as introducing the term genetic information in place of genetic tests or genetic testing, the four main duties might be re-ordered (and consequently shortened). This section could begin with paragraph 3.5.1 (do not use genetic information to make predictions about future general health) and followed by 3.5.4 (do not require a worker to disclose the results of previous genetic tests). However, in keeping with the earlier sections, there could be a caveat here about information that might be relevant for health and safety or other legal duties.This would lead naturally into the

current 3.5.2 (only use genetic information where it is clear that a worker....is likely to pose a safety risk to others or might be at risk...).

We would suggest removing the references to accuracy and reliability of genetic tests (3.5.3). As stipulated in Section 3.1 Information about workers' health: general considerations, there would be a need to consider an impact assessment identifying the purpose of the collection and the specific business benefits it would be likely to bring. HGC has encouraged employers to inform HGC of proposals to use genetic testing for health and safety or recruitment purposes (para 8.19, *Inside Information: Balancing interest in the use of personal genetic data).* The Government has responded by saying that for the time being HGC, the Disability Rights Commission and Health and Safety Commission should informally consider and advise on any such plans and that this is likely to be of value to employers (Open letter from Dr John Reid, 24 June 2003, enclosed).

In this regard, we would like to suggest adding reference in the supplementary guidance to HGC's report on this topic in our *Inside Information.* This could amplify many of the requirements in the Code, and stand in addition to the more general views made by the European Group on Ethics and Science and New Technology. For example, we recommend that in general, employers must not demand that an individual take a genetic test as a condition of employment. In addition, given the uncertainties about interpreting genetic information, we concluded that at present it might be more appropriate to monitor the health of a person by other, more direct means. You will find attached a copy of the relevant chapter from our report and would ask you to consider including it in your guidance as it relates to genetics.

Finally, I would like to take this opportunity to let you know that HGC maintains a watching brief of issues to do with genetics and employment as part of the work of its work in the area of genetic discrimination. We have kept a close eye on possible cases here and abroad where genetic information has been used in discriminatory ways. We would be happy to meet with you to discuss these and other areas of common interest around the use of genetic information.

Yours sincerely,
Dr Bill Albert
Lead Member, Genetic Discrimination
Human Genetics Commission

HGC response to the Home Office's, *'Consultation on Policing: Modernising police powers.'*

Mr Alan Brown
Police Leadership and Power Unit
2nd Floor, Allington Towers
19 Arlington Street
London
SW1E 5EB

26 November 2004

Dear Alan,

Re: Consultation on Policing: Modernising police powers

Thank you for the opportunity to comment on the above document. I am replying on behalf of the Human Genetics Commission (HGC), an independent advisory body established to advise the UK Government on developments in human genetics, particularly their ethical, legal and social implications. We welcome your public consultation on plans to review police powers in order to meet community needs. Our comments on this consultation are focused on Chapter 6: Identification; and reflect discussions held at HGC's September plenary meeting, and by the Commission's Identity Testing Monitoring Group.

With regard to the use of speculative searches of the National DNA Database (paras. 6.14-6.15), HGC is broadly content with the development of a Missing Person's DNA Database and the notion that police would need a separate authority to speculatively search these profiles against the National DNA database subject sample record and other profiles held by, or on behalf of, the police for identification purposes. There are however two caveats to this.

The first is that HGC would like some clarification on how the separate authority would operate and whether or not it would be lead by the ACPO Chair of the National DNA Database Board.

The second relates to the Missing Person's DNA database and the questions around taking samples from a missing person's genetic relatives. We would be concerned by there being any legal obligation for missing person's genetic relatives to provide samples. The emphasis should be on requesting information and we would appreciate some clarification on this matter. In addition, as you may be aware, an area of interest to HGC is relationship testing, and the capacity of such testing to potentially reveal non-paternity. We feel that due consideration must be given to weighing up the value of the genetic information (i.e. identification of missing person) against the harm that the revelation of inadvertent information may do (eg. revelation of non-paternity). We would suggest though that on balance, however, and with the suitable emphasis on the proper use of DNA testing, any possible harm would be outweighed by the potential benefit of such testing.

The final point we would like to make refers to the taking of DNA samples covertly (para. 6.19). In our report, *Inside Information: Balancing interests in the use of personal genetic data*, (May 2002; copy enclosed), we recommended that consideration be given to the creation of a criminal offence of the non-consensual or deceitful obtaining and/or analysis of personal genetic information for non-medical purposes (Chapter 3). This recommendation has now been taken on board in the new *Human Tissue Act (2004)*. While we understand that such a law should not interfere unduly with police powers, we would like to seek some assurances of the circumstances under which such

samples would be taken and clarification on what happens to samples after the completion of such an investigation. Finally, we believe that such circumstances would need to be governed via a tight set of regulatory and/or legislative controls.

We would appreciate being kept up to date on the progress of your work in this area.

Yours sincerely,
Dr Stephen Bain
Lead Member on Identity Testing
Human Genetics Commission

Human Genetics Commission response to the House of Commons Science and Technology Committee hearing on 9 February 2005. This response was published in the *"Seventh report from the Science and Technology Committee: Forensic Science on Trial: Session 2004/2005."*

In June 2001, the Human Genetics Commission (HGC) visited the Forensic Science Service to learn about the organisation and management of sampling, profiling and the National DNA Database. In May 2002, the Commission published their report *Inside Information - Balancing interests in the use of personal genetic data*, which contained the following recommendation:

"We recommend that, at the very least, the Home Office and ACPO establish an independent body, which would include lay membership, to have oversight over the work of the National DNA Database custodian and the profile suppliers."

Further, it recommended that: *"In the short term the Home Office and FSS introduce an independent research ethics committee, to approve such research."*

Following publication of the HGC report, the National DNA Database Board invited the HGC to put forward one of their members to sit on the Board and this arrangement has continued since that time.

You indicated that the Science and Technology Committee was particularly interested in the HGC's view of the current custodianship arrangements for the database and what changes, if any, need to be made.

I can confirm that the HGC stands by the recommendations contained in *'Inside Information'* and continues to make the case for the establishment of an independent body to oversee the work of the custodian of the database, which would include lay membership. As the Science and Technology Committee heard at the hearing, work is underway to separate the roles of the custodian of the National DNA Database from that of Forensic Science Service and the Commission views this an ideal time for it's recommendations to be taken forward.

Currently, there is no ethics structure that properly assesses the research proposals which are submitted to the National DNA Database Board. The presence of an HGC member on the Board does not provide for adequate consideration on the ethical issues involved in research proposals.

The HGC are also concerned about the nature of research proposals, specifically around what constitutes 'research'. As the respondents to the Committee correctly said in their evidence, the number of external applications submitted to the Board to use National DNA Database samples are few. However, requests to carry out internal development, for example to develop familial testing, are more frequent. This kind of work could be regarded as research and previously went ahead without ethical review. Project proposals of this kind are now discussed at the Board but, again, they are discussed in the absence of formal ethical oversight.

Finally, it is worth noting that the HGC member currently sitting on the National DNA Database Board, Dr Stephen Bain, has professional experience of designing and working with large DNA databases and he also sits on an multi-research ethics committee. However, not all HGC members have this level of experience or knowledge of the moral and legal issues involved. That is why the Commission has continued to request that there be lay involvement on the National DNA Database Board and that a system of formal ethical oversight be established. Furthermore, it is important that these measures are not dependent upon the continued existence of the HGC.

HGC Secretariat
February 2005

Annex C: How HGC works (role, terms of reference, methods of working and code of practice)

Role

The Human Genetics Commission (HGC) is the UK Government's advisory body on how new developments in human genetics will impact on people and on health care. Its remit is to give Ministers strategic advice on the "big picture" of human genetics, with a particular focus on social and ethical issues.

HGC was established in 1999 following the UK Government's comprehensive review of the regulatory and advisory framework for biotechnology. Its role should also be seen in the context of other advisory and regulatory bodies in the framework for human genetics. HGC does not direct these bodies or interfere with their lines of accountability, but works with them and help form links between them. HGC reports to Health and Science Ministers and works within the context of devolution settlements for Scotland, Wales and Northern Ireland. Government policy on human genetics is generally developed on a UK basis, but responsibility for National Health Service (NHS) genetics services is the responsibility of each devolved administration.

Terms of Reference

- To analyse current and potential developments in human genetics and advise Ministers on:

  – their likely impact on human health and healthcare;

  – their social, ethical, legal and economic implications.

- To advise on strategic priorities in the delivery of genetic services by the NHS.
- To advise on strategic priorities for research.
- To develop and implement a strategy to involve and consult the public and other stakeholders and encourage debate on the development and use of human genetic technologies and advise on ways of increasing public knowledge and understanding.
- To co-ordinate and exchange information with relevant bodies in order to:

  – identify and advise on the effectiveness of existing guidance and of the regulatory and advisory framework as a whole, taking account of European and global dimensions;

  – look at the lessons learnt from individual cases requiring regulatory decision to build up a wider picture.

- To consider specific issues related to human genetics and related technologies as requested by Ministers.
- To operate in accordance with best practice for public bodies with regard to openness, transparency, accessibility, timeliness and exchange of information.

Ways of working

A constant theme and priority within our work is to actively seek input from the public and other stakeholders and this involves a variety of consultation exercises and open meetings.

We work in accordance with best practice principles on openness and transparency. We also exchange information with other bodies in the advisory and regulatory framework, including meetings at secretariat level and between chairs.

We have established sub-groups or panels which involve both Members and external participants, and which may co-opt input from individuals. We use email and telephone conferencing when this is useful, particularly for the work of the Monitoring Groups described below.

HGC may commission work from individuals or organisations on a consultancy basis.

How we organise our work

The full Commission meets around four times a year, in different parts of the country. We meet over two days, usually holding an information-gathering session, when we invite a number of people to talk to us about a particular issue, on one day and the plenary meeting on the other.

In 2003 we set up a more flexible structure for the way the Commission carries out its work, which is shown in the diagram on page 40. We agreed to continue to focus the main areas of work in task-orientated working groups. We also identified HGC Members to lead on a number of key issues and who work with Monitoring Groups to keep a watching brief on these areas and keep them high on our agenda.

Lead Members are asked to:

- keep HGC up to date on developments and make sure the issue remains on HGC's agenda
- advise on the need for meetings of the Monitoring Group and suggest specific pieces of work as needed
- lead on liaising with other relevant organisations and co-ordinating responses to consultations

We have set up the following **Monitoring Groups**:

- Genetic Discrimination Monitoring Group, led by Bill Albert
- Horizon-Scanning Monitoring Group, led by Veronica van Heyningen
- Intellectual Property and Genetics Monitoring Group, led by Hilary Newiss
- Public Involvement Monitoring Group, led by Geoff Watts
- Research Databases Monitoring Group, led by Celia Brazell
- Identity Testing Monitoring Group, led by Stephen Bain

The work of the Monitoring Groups is described in the body of this report.

The **Business Committee** continued with its existing role:

- to provide a more responsive executive structure so that HGC can react to developments quickly and involve the Membership as fully as possible.
- the Committee will have a rotating membership, and the Chair will report directly to the HGC Chair.

and also should:

- liaise with lead members between plenary meetings and continue liaison with key organisations such as Nuffield, Wellcome
- oversee external communications:
  - press office
  - website
  - newsletter/annual report
  - editorial oversight of briefing notes

Geoff Watts has been Chair of the Business Committee since February 2003. It has a rolling Membership and details of its meetings and Membership are on the website (www.hgc.gov.uk).

Genetic Services Sub-group

This group revised its remit in 2003 but is currently on hold. For more information about the Groups findings and minutes of their meetings, please visit the HGC website at www.hgc.gov.uk

Working Groups

We decided that our working groups were very good models for taking forward large pieces of work and that we would continue to set up a specific group to deal with an individual area of work.

Working Group on Genetics and Reproductive Decision Making

This Working Group was set up in May 2003 to take forward our work consider the issues around new and developing technologies associated with human reproduction and their implications for society. It superseded the earlier Scoping Group on Genetics and Reproduction.

Terms of Reference

1. To collate information, take evidence and consider past, current and future developments in genetic services related to reproduction within the current legal framework and in terms of the technology and public attitudes towards its use.

2. To examine, in particular, advances as they relate to prenatal genetic screening services, prenatal genetic diagnosis and preimplantation genetic diagnosis.

3. To work with existing bodies responsible for regulating and/or advising Government on genetics and reproduction including the National Screening Committee and the Human Fertilisation and Embryology Authority.

4. To work with HGC groups as appropriate to develop strategies for public consultation and discussion, to develop the working group's knowledge about genetic services and horizon scan in the area of genetics and reproduction.

5. To contribute to and/or respond, where appropriate, to emergent national debates about genetics services and their implications for reproductive decision making.

6. To prepare and publish a consultation document and to consider other methods for obtaining the views of stakeholders and others.

7. To identify from consultation and deliberation, sound ethical principles appropriate to genetic advances and services related to reproduction.

8. To publish a report identifying our conclusions and recommendations pertaining to the ethical principles on genetic advances and services related to reproduction and to communicate these to Health & Science Ministers.

Members during the reporting period

(some members listed here may now have left the Group)

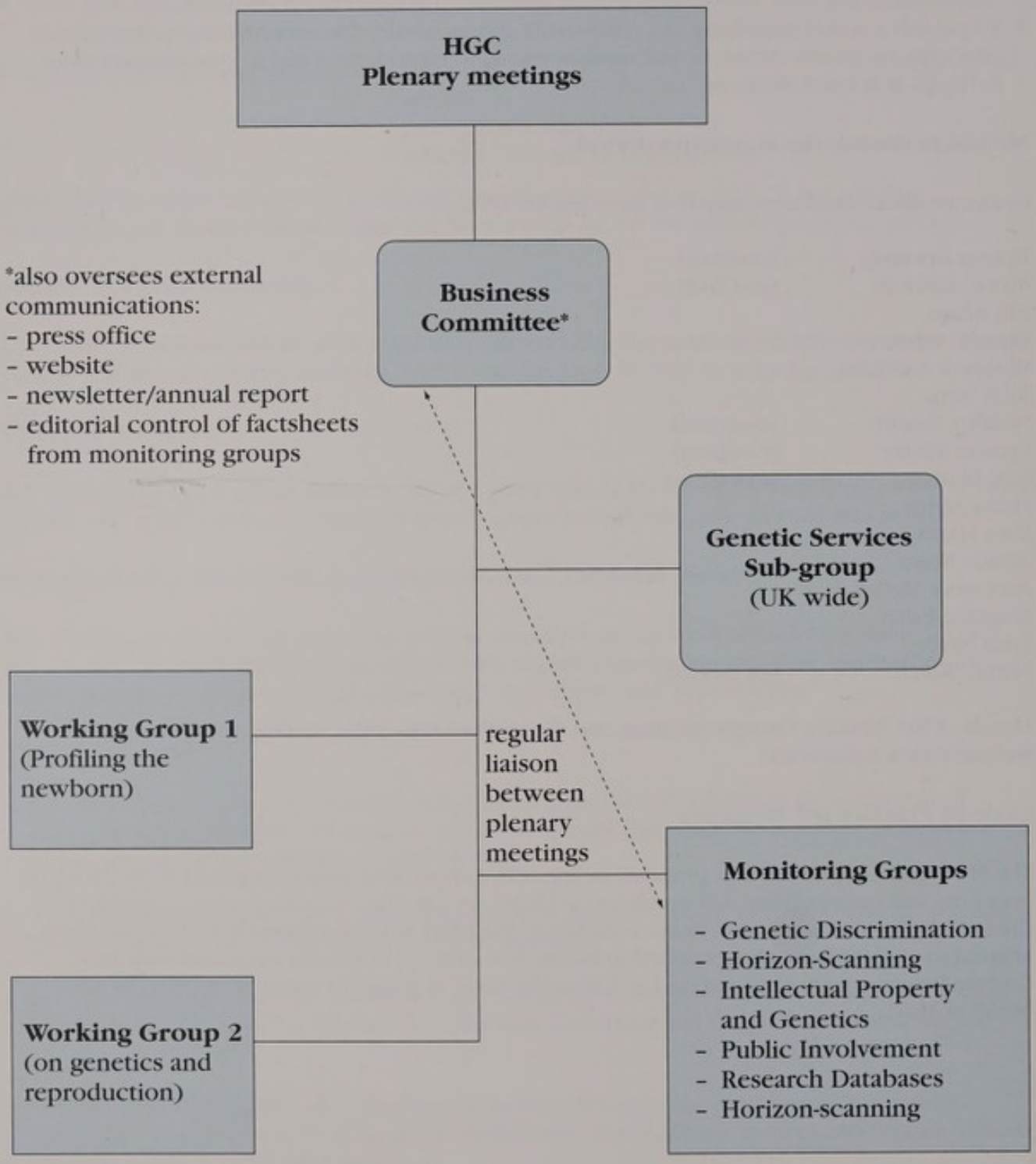
Helena Kennedy	(co-Chair)
Martin Richards	(co-Chair)
Bill Albert	
Brenda Almond	
Elizabeth Anionwu	
John Burn	
Heather Draper	(co-opted)
Frances Flinter	(co-opted)
Suzi Leather	(ex officio)
Hilary Harris	
John Harris	
Alistair Kent	
Alexander McCall Smith	
Christine Patch	
Peter Sayers	
Martin Whittle	(ex officio)

Details of the Working Group's meetings and the work of the earlier Scoping Group are on the website (www.hgc.gov.uk).

Code of Practice for Members

The HGC Code of Practice was prepared in line with Government policy on standards in public life, openness and accountability, full details are available on the HGC website: www.hgc.gov.uk. The Chair, Vice-Chair, Members and Representatives of the Chief Medical Officers (CMOs) (collectively referred to as "Members") are expected to follow it in carrying out duties associated with HGC. Co-opted members are also expected to follow the Code as it applies to the work they do on behalf of HGC.

Structure of HGC's sub-groups



Annex D: Register of HGC Member's Interests

(This register provides details in respect of all HGC Members for the period July 2003 to April 2005)

Dr Bill Albert

Remunerated employment, office, profession, *etc*

Chair, Norfolk Coalition of Disabled People
Director, Nordat Limited, a disability awareness training organisation

Professor Brenda Almond

Remunerated employment, office, profession, *etc*

Author, editor, lecturer (occasional, free-lance).
Belle van Zuylen Visiting Professor, University of Utrecht, April-July 2003.

Miscellaneous and unremunerated interests

President of Philosophical Society of England
Vice-president of Society for Applied Philosophy
Honorary Senior Research Fellow, Social Values
Research Centre, University of Hul
Overseas Member of Austrian Academy of Sciences
Honorary Fellow of Academy of Moral Sciences, Beijing University, Chin
Member of Societas Ethica (European Society for Ethical Research) and of European Ethics Network.

Professor Elizabeth Anionwu

Remunerated employment, office, profession, *etc*

Professor of Nursing, Head of Mary Seacole Centre for Nursing Practice, Thames Valley University

Dr Stephen Bain

Remunerated employment, office, profession, *etc*

Reader in Diabetic Medicine, University of Birmingham & Honorary Consultant Physician, Birmingham Heartlands Hospital, Birmingham, UK
Dr Bain has also received lecture fees from Aventis, Boehringer Ingelheim, Eli Lilly, GlaxoSmithKline, Merck Sharp Dome, Novartis, Novo Nordisk, Pfizer, Servier & Takeda. He has been awarded research & clinical grants by Aventis, Eli Lilly, Novo Nordisk & Sequana Inc.

Miscellaneous and unremunerated interests

Member, West Midlands Multi Research Ethics Committee
Chairman of the Pan-Birmingham Diabetes Advisory Group and the East Birmingham and Solihull Local Diabetes Services Advisory Groups.

Dr Celia Brazell

Remunerated employment, office, profession, *etc*

Director, Genetics Science and Technology, GlaxoSmithKline Research and Development

Registrable shareholdings

Aberdeen Technology Trust
The AIM Trust plc
Fidelity American Fund
Fidelity UK Aggressive Unit Trust
Fidelity Special Sit Trust (1) & (2)
GlaxoSmithKline
Invesco Perpetual: Far Eastern Growth
Schroders: Tokyo Fund

Miscellaneous and unremunerated interests

Member, Department of health Advisory Group for Genetics Research
Member, the Council for International Organisations of Medical Sciences (CIOMS)
Member, Working Group on Pharmacogenetics and Pharmacoeconomic
Member, European Commission Expert Group on the Ethics of Genetic Testing

Professor John Burn

Remunerated employment, office, profession, *etc*

Professor of Clinical Genetics, University of Newcastle (tenured chair, part funded by National Health Service)

Remunerated Directorships

Honorary Director, Imperial Cancer Research Fund, Clinical Cancer Genetics Network
Executive Chairman of Northgene (Identity testing) Limited, a small not-for-profit company providing a commercial paternity testing service

Miscellaneous and unremunerated interests

Director Northern Genetics Service, Newcastle NHS Hospitals Trust
Chair, Cancer Genetics Group of British Society of Human Genetics (formerly Cancer Family Study Group)
Member, Medical Advisory Board of Genetics Interest Group
Member, Ethics in Medicine Committee of Royal College of Physicians
Member, Scientific Committee of Royal College of Obstetricians & Gynaecologists

Professor Angus Clarke

Remunerated employment, office, profession, *etc*

Professor of Clinical Genetics, Department of Medical Genetics, Cardiff University.
Salary sourced from NHS (60%) and HEFC (40%)
Recipient of research funds from The Wellcome Trust, The Health Foundation and the ESRC.
Author and editor of several books.

Miscellaneous and unremunerated interests

Fellowships of Royal College of (1) Physicians of London and (2) Paediatrics and Child Health.
Membership of: British Medical Association; NHS Consultants' Association; Clinical Genetics Society; British Society of Human Genetics; European Society of Human Genetics; European Society for the Philosophy of Medicine and Health Care.
Member, Research Committee, Wellbeing/Royal College of Obstetricians and Gynaecologists
Chair, Medical Advisory Board, Ectodermal Dysplasia Society.
Medical Advisor, Rett Syndrome Association UK.
Member, Editorial Boards of: journal of Intellectual Disability Research; Archives of Disease in Childhood.
Chair, Ethical Advisory Group, North Cumbria Community Genetics Project
Supporter of Greenpeace; Religious Society of Friends; Oxfam; Christian Aid.

Dr Paul Debenham

Remunerated employment, office, profession, *etc*

Director, Life Sciences, LGC Limited.

Registrable shareholdings

Astra Zeneca
Syngenta

Dr Peter Harper

Remunerated employment, office, profession, *etc*

Professor of Medical Genetics, University of Wales College of Medicine, Cardiff

Professor John Harris

Remunerated employment, office, profession, *etc*

Sir David Alliance Professor of Bioethics, University of Manchester
Member, Data Safety Monitoring Board, Chiron Corporation

Dr Hilary Harris

Remunerated employment, office, profession, *etc*

General practitioner, Manchester

Mr Michael Harrison

Remunerated employment, office, profession *etc*.

Barrister

Dr Iona Heath

Remunerated employment, office, profession *etc*

General Practitioner, Kentish Town, London

Miscellaneous and unremunerated interests

Nationally elected member of the council of the Royal College of General Practitioners
Chair of the Ethics Commjittee of the British Medical Journal
Member of Medact and British Medical Association
Fellow of the Royal Society of Arts.
Supporter of Oxfam, Amnesty International, Friends of the Arch, Medical Foundtion for the Victims of Torture, Centre for Young Musicians, Little Sparta Trust

Mrs Susan Johnson

Remunerated employment, office, profession, *etc*

Lecturer, School of Nursing, University of Nottingham
Research Fellow, Institute for the Study of Genetics, Biorisks and Society, University of Nottingham
Staff Nurse, United Lincolnshire Hospitals NHS Trust

Baroness Helena Kennedy QC

Remunerated employment, office, profession, *etc*

Board Member, Independent Newspapers
Member of the Bar

Miscellaneous and unremunerated interests

Advisory Council Member of the Foreign Policy Centre
Bencher of Gray's Inn Chambers
Board Member, British Museum
Chair of Standing Committee for Youth Justice
Fellow of the Royal Society of Arts
Fellow of the City and Guilds Institute
Fellow of the Institute of Advanced Legal Studies
Member of Academie Universalle des Cultures
Member of Foreign Policy Centre Advisory Council
Member of the External Advisory Council, World Bank Institute
Patron, Charter 88
Patron, Liberty
Patron, Howard League Reform
President, Civil Liberties Trust
President of The School of Oriental and African Studies
Trustee, KPMG Charitable Trust
Vice-President, Association of Woman Barristers
Vice-President, Haldane Society

Political activity

Labour Peer

Mr Alastair Kent

Remunerated employment, office, profession, *etc*

Director, Genetic Interest Group
Non-Executive Director, Cambridge City Primary Care Trust

Miscellaneous & unremunerated interests

Member, Joint Committee on Medical Genetics
Member, Association of British Insurers (ABI) Genetics Committee
Member, Genetic Commissioning Advisory Group (DH)
Member, Genetics Commissioning Group (London NHS)
Member, Orphan Medicinal Products Committee (EMEA)
Member, Progress Educational Trust Advisory Committee
Justice of the Peace, Cambridge

Ms Suzi Leather

Remunerated employment, office, profession, *etc*

Chair, Human Embryology and Fertilisation Authority

Miscellaneous and unremunerated interests

Member, Christian Socialist Movement
Individual Member, National Heart Forum
Member, Child Poverty Action Group
Member, Organophosphate Information Network
Member of Council, University of Exeter
Member of the Chancellor's Advisory Council, University of Exeter
Glasgow Centre for Population Health – Member of the External Advisory Group
Member of the Better Hospital Food Forum
Chair of Steering Committee (Tommy's the Baby Charity) – Teenage Pregnancies: Dietary Measures to improve nutrition and pregnancy outcome
Fellow [ad eundem], Royal College of Obstricians and Gynaecologists
Member of the International Advisory Board of the 6th EU Framework Programme for Research and Technology Participatory, Governance and Institutional Innovation Project (PAGANINI), University of Vienna

Political activity

Labour Party Member

Professor Alexander McCall Smith

Regististrable shareholdings

GlaxoSmithKline (family)

Miscellaneous and unremunerated interests

Chair, Independent Ethics Committee, The Roslin Institute
Occasional lectures at meetings supported by pharmaceutical and other companies.

Professor Patrick Morrison

Remunerated employment, office, profession, *etc*

Consultant in Clinical Genetics, Belfast City Hospital Trust (fully funded by National Health Service)
Postgraduate Tutor and Director of the Belfast Postgraduate Centre (funded by Northern Ireland Council for Postgraduate Medical and Dental Education)

Miscellaneous and unremunerated interests

Director of Cancer Genetics, Northern Ireland Regional Genetics Service.
Member, Northern Ireland Ethics Forum

Ms Hilary Newiss

Miscellaneous and unremunerated interests

Member, BioIndustry Association (BIA)
Member, Intellectual Property Advisory Committee of DTI
Member, External Ethical Advisory Board, Pharmagene Limited

Dr Christine Patch

Remunerated employment, office, profession, *etc*

Senior Research Fellow School of Medicine University of Southampton funded by The Health Foundation.
Honorary contract Specialist Nurse/Genetic Counsellor Wessex Clinical Genetic Service.

Miscellaneous and unremunerated interests

Joint chair of the Ethics and Public Policy Committee International Society of Nirses in Genetics.
Member of: British Society for Human Genetics, Association of Genetic Nurses and Counsellors, British Association for the Study of the Liver, Royal College of Nursing.

Professor Martin Richards

Remunerated employment, office, profession, *etc*

Professor of Family Research, Centre for Family Research, University of Cambridge
Grants, Wellcome Foundation
Previous grants, Medical Research Council and Cancer Research Campaign
Member, Wellcome Trust Biomedical Ethics Panel

Registrable shareholdings

CGNU Ordinary CBPO. 25 shares (formerly Norwich Union)

Miscellaneous and unremunerated interests

Member, Friends of the Earth
Member, North Cumbria Community Genetics Project Ethics Committee
Member, Human Fertilisation and Embryology Authority, Ethics and Law Committee
Member of Advisory Boards of the Cambridge Genetic Knowledge Park and Cesagen
Adviser to Genetics Interest Group

Political activity

Member of the Labour Party

Mr Peter Sayers

Remunerated employment, office, profession, *etc*

Director, IDM Ltd. (Internet Design company)
Non-Executive Director NHS Cheltenham and Tewkesbury Primary Care Trust

Miscellaneous and unremunerated interests

Director, New Harmony Press (non-profit publishing co-operative)
Director, Accessible Globe International Ltd (non-trading disability travel company)
Company Secretary, Salt Marketing Ltd (without remuneration)

Dr Stephen Singleton

Remunerated employment, office, profession, *etc*

Medical Director, Northumberland and Tyne & Wear Health Authority

Miscellaneous and unremunerated interests

Trustee, Children's Foundation
Member, NICE Joint Planning Group

Dr Rosalind Skinner

Remunerated employment, office, profession, *etc*

Principal Medical Officer in the Scottish Executive Health Department

Miscellaneous and unremunerated interests

Former clinical geneticist in the University of Edinburgh

Professor Robert Stout

Remunerated employment, office, profession, *etc*

Director of Research and Development for the Northern Ireland Health & Personal Social Services
Professor of Geriatric Medicine, Queen's University Belfast
Consultant Physician, Belfast City Hospital.

Miscellaneous and unremunerated interests

Member of numerous committees in my role as Director of Research & Development including the United Kingdom Clinical Research Collaboration
Member of the Health Research Board, Dublin

Sir John Sulston

Remunerated employment, office, profession, *etc*

None, except for occasional freelance payments

Miscellaneous and unremunerated interests

Supporter of Oxfam, Amnesty, Greenpeace.

Professor Veronica van Heyningen

Remunerated employment, office, profession, *etc*

Head of Cell Genetics Section, Medical Research Council, Human Genetics Unit, Edinburgh

Registrable shareholdings

GlaxoSmithKline
Unilever
Bernard Matthews (family)
Boots (family)
Diageo (family)
Elan Corp. (family)
ICI (family)
J Sainsbury (family)
Nycomed Amersham (family)
PPL Pharmaceuticals (family)
Zeneca (family)

Mr Geoff Watts

Remunerated employment, office, profession, *etc*

Journalism (writing and broadcasting), often requiring the collection of information on, the description of and the expression of opinions about topics in biology and medicine lying within the Commission's remit.
Occasional chairs meetings and conferences, participant in recorded discussions and occasional paid consultant to organisations which may have an academic or commercial interest in some of the topics considered by the Commission. (No regular or continuing commitments of this kind.)

Mr Philip Webb

Remunerated employment, office, profession, *etc*

Self-employed Independent Business Advisor
Director, Hydroponic Herbs Ltd
Retired General Manager, AstraZeneca Diagnostics

Registrable shareholdings

AstraZeneca Group
Oxford Biomedica
Syngenta

Miscellaneous and unremunerated interests

Member of the Board of Trustees of the Genetic Interest Group
Chairman, Witney United Football Club

Register of Co-opted Members' Interests

Dr Heather Draper (Scoping Group on Genetics and Reproduction)

Remunerated employment, office, profession, *etc*

Senior Lecturer, Centre for Biomedical Ethics, University of Birmingham
Occasionally paid for lectures on different aspects of medical ethics by eg hospitals, institutes of higher education and professional bodies such as the Association of Anaethetists

Miscellaneous and unrenumerated interests

Member, Unrelated Live Transplantation Regulatory Authority (ULTRA)
Member, Advisory Committee on Ethics for the Assisted Conception Unit, Birmingham Women's Hospital
Member, Ethics Advisory Board of the UK Human Tissue Bank
Member, Local Ethical Review Process, Medical School Committee, University of Birmingham

Dr Frances Flinter (Genetic Services)

Remunerated employment, office, profession, *etc*

Senior Lecturer/Honorary Consultant in Clinical Genetics, King's College London (NHS funded)

Annex E: Finance

The Human Genetics Commission is funded by the Department of Health, Office of Science and Technology and devolved administrations in Scotland, Wales and Northern Ireland. In 2004/05 HGC received a special grant for £6,000 to assist in developing the website from the Department of Trade and Industry's Bioscience Unit.

The majority of the HGC's operation budget (running costs) was spent on working in an open manner and public engagement work, with roughly:

- £95,000 spent on plenary meetings, monitoring groups and information gathering sessions in both 03/04 and 04/05;
- £50,000 spent on external communications, including the Press office, the PR function and printing and publishing in 03/04 and £15,000 in 04/05, and
- £6,000 spent on consultations and surveys in 03/04 and £2,000 in 04/05.

In addition, HGC also had access to central funding that enabled the publications produced in the past 18 months to be done so without cost to the Commission. HGC also received additional funds for the recruitment process for members.

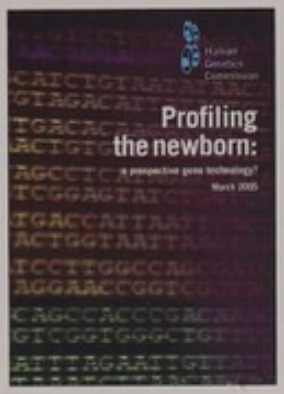
In 2004/5, £20,000 was spent on revising the HGC's website.

Fees are payable to Members at a rate of £148.59 per meeting, £180.40 per meeting for the Chair, and members are reimbursed for all reasonable travelling expenses.

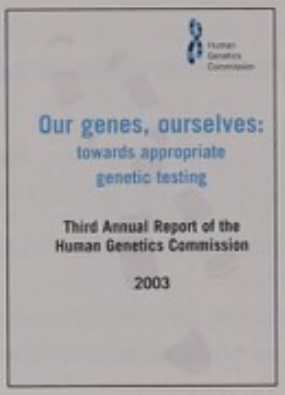
Annex F: Publications

The following publications are downloadable from the HGC website (hgc.gov.uk) and in hard copy from the addresses stated.

Reports and Publications



Profiling the newborn: a prospective gene technology?
March 2005 (ref 267377)*

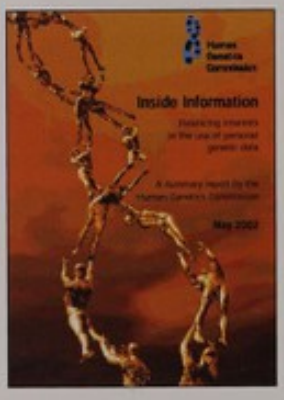


Our genes, ourselves: towards appropriate genetic testing.
Third Annual Report of the Human Genetics Commission,
2003 (ref 34587)

Choosing the future: genetics and reproductive decision making
July 2004 (ref 40293)*

Genetic information, public consultation
Second Annual Report of the Human Genetics Commission 2002
(ref 30449)*

Genes direct: Ensuring the effective oversight of genetic tests supplied directly to the public
April 2003 (ref 31433)*



Inside Information
Balancing interests in the use of personal genetic data May 2002
(ref 27907)*

Debating the ethical future of human genetics
First Annual Report of the Human Genetics Commission
2001 (ref 25256)*

Whose hands on your genes?
November 2000
(ref 228048)*

Public attitudes to human genetic information,
March 2000. (ref 23992)*

*Copies of these reports can be obtained by writing to:
PO Box 777
London
SE1 6XH
Or by faxing: 01623 724524
Or by emailing: dh@prolog.uk.com

You can also download the reports from our website: www.hgc.gov.uk

Also available on the website:
HGC press notices
HGC plenary audio files
HGC meeting papers

Human
Genetics
Commission

269491 1p 1.5k Nov 05 (MWL)
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Further copies of this document are available from:
PO Box 777
London SE1 6XH

It is also on our website on http://www.hgc.gov.uk/