PUBLIC ATTITUDES TO RESEARCH GOVERNANCE

A qualitative study in a deliberative context

wellcome trust

Public Perspectives on the Governance of Biomedical Research: A qualitative study in a deliberative context

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EXECUTIVE SUMMARY

Introduction

This report, commissioned by the Wellcome Trust in 2006, presents the results of qualitative research exploring public attitudes towards the governance of biomedical research. The purpose of this research was to investigate what members of the public think about issues of biomedical research governance. We define research governance as 'the systems in place for ensuring that medical research on human beings is safe, conforms to ethical standards and is likely to contribute to scientific understanding'.

The research comprised a series of reconvened discussion groups with members of the general public, with patients who had a long-standing illness or medical condition and with people who had prior experience of participation in biomedical research. Four short films were developed in order to stimulate discussion in the groups. These addressed the issues of personal information, informed consent, databases and committees. Prior to setting up the reconvened discussion groups, a secondary analysis was conducted on data from general public focus groups and expert stakeholder interviews from an ESRC-funded research project entitled Attitudes to Genomics.

The reconvened groups were held between July and November 2006 in Birmingham, Guildford and Woking. There were four general public groups and four mixed general public groups: two that included some patients and two that contained some biomedical participants. In addition, there were two patient groups and two biomedical participant groups. In each case the initial group ran for approximately five hours (including lunch). Participants were asked for views and understandings of biomedical research using structured activities, and there were four discussion group sessions, covering personal data, informed consent, databases and models of governance. In each session the participants watched one of the short films and were presented with relevant material on the topic. Approximately one week later the participants returned for 1.5 hours and were presented a series of vignettes to stimulate further discussion. Discussion was audio recorded, transcribed and subsequently analysed to capture the key points, positions and opinions that were expressed.

Overview of the topics

As other studies have shown (see 1.4 for full discussion), the way in which science is regulated is an unfamiliar topic to the public and one in which they might be thought to have little interest outside the realms of their own experience. We therefore devised this study in a way that would anchor the somewhat intangible aspects of biomedical research governance around concrete concepts such as informed consent, databases, and personal information, thereby making the notion of governance accessible and meaningful for participants to engage with.

As each topic was introduced to participants through the films we endeavoured to accord equal status to each and no one topic was accorded priority in the way in which the ensuing discussion was framed. As the discussion groups progressed, however, it became apparent that participants themselves attributed more importance to those topics that better enabled them to appraise the efficacy, trustworthiness and transparency of research governance.

The key way in which the adequacy of research governance was signalled was through the process of providing consent. The ways in which personal data were handled, the care that was afforded to guarantees of anonymisation, the handling of sensitive material and the security of databases, were also diagnostic of whether research governance was working well and could be trusted. Of least importance were the models of governance themselves. Which structures of governance were in place made little difference to participants' willingness to participate in biomedical research. They played a limited role in participants' constructions of what constituted 'proof' that governance was working or in providing reassurance in the face of concern. It was rather the outward manifestation via material 'proofs', such as seeking explicit consent, for example, that signalled that governance was working.

The four topics that form the basis of this study: personal data, informed consent, databases, and models of governance, provided a useful framework for initiating discussion via the films and as a means for organising the complexity of the subsequent analysis. They were, however, inextricably linked in the ways in which participants made sense of the data. Each topic was used to illustrate and make sense of another. This was evident in a number of ways. For example, personal data (whether patient records, human tissue, or health status) is the actual material with which biomedical research proceeds. The handling or mishandling of this data is an integral part of how a model of governance is appraised. Moreover, rights over personal information with regard to issues of consent are invariably viewed as related; it is not enough to identify what personal data means but rather what people decide they will or will not allow with regard to that information. Strongly related to this are concerns about the use, storage, access, and protection of personal data via different types of databases. Discussions invariably alluded to a combination of these topics whereby one would impinge on the other. For example, a discussion about sensitive personal information would also bring in issues about storage or third-party access. Personal information is subsequently linked to the topic models of governance because the handling and protection of this information are the outward signals that mechanisms are functioning, thereby offering the necessary assurances.

Results

E1 Across the public, the patient and the biomedical participant groups there was strong support in principle, with only marginal hesitations, for the value and importance of carrying out, and participating in biomedical research. On the whole each of the groups had a sense of what biomedical research was. There was initial mention of some dramatic images ('baby in jars', 'elephant man'), although many more 'everyday' examples were also mentioned.

E2 Altruistic motivations were identified as the primary reason why people would take part in biomedical research. There were, however, also reservations about participation which were linked to press coverage of things going wrong, to anxieties about experiencing pain or death as well as more pragmatic considerations around a lack of time and family commitments. Participants could also identify why *other* people might not wish to participate, for example, for ethnic or cultural reasons, lack of information about the study, or fears that research might be taken too far.

E3 Participants, even those that had taken part in biomedical research, acknowledged that their awareness of issues around biomedical research was

low and that they needed and wanted to know more than they currently did; they desired greater research literacy.

Personal data, anonymity and confidentiality

E4 Participants all felt that any information unique to an individual could be considered to be personal data but whether this was seen as being of consequence or not depended on how it linked to questions of anonymity and confidentiality. If the data could be used to identify the individual then it was felt to be personal and hence needed to be protected from misuse. Aggregate level data and data about an individual that could not be linked to that individual were seen to be no longer personal. Some data were seen as simply private and therefore to be provided only with a good reason. This included information such as name, address, occupation and marital status. Participants frequently did not feel such information was relevant in research and as such voiced reservations about providing this kind of information.

E5 Information that was categorised as sensitive was always seen as personal data and included not only matters relating to sexual health and behaviours, but also to other potentially stigmatising situations or conditions such as mental health problems. The sensitivity of data could be increased by certain contexts: who might get to know the information, other personal identities such as ethnicity, or what might be done with the information.

E6 Participants indicated that they were not unwilling to provide personal data for research if they understood why it was wanted and had confidence in the integrity of the research process. However, this confidence could be undermined by the involvement of particular actors: GP receptionists, insurance companies, and other non-health or non-research agencies. Some groups, such as older people, were seen as being less able to exercise their rights not to provide personal information.

E7 Tissues and waste material were not necessarily considered to be personal but they could become so if the research revealed information about the individual's health or health risks, or the tissue could provide a link back to the individual. This posed a conundrum regarding anonymity. Irreversible anonymity was seen to remove the personal data connection. This generally desirable state of affairs became problematic where participants believed that health information pertinent to them could emerge from the research and not be conveyed back to them.

E8 Where personal data were required for biomedical research anonymity was generally seen as important, but there was scepticism about guarantees of anonymity based on people's experiences in their everyday lives of anonymity and confidentiality being breached through error, deliberate intrusion or lack of care. This reflected more general concerns about privacy, hacking and surveillance in contemporary times although this was tempered by doubts that individuals' health data would attract deliberate breaches of confidentiality. The GP was seen as a repository of public trust and a good mediator between individuals and research. Within this largely watertight system doctors' receptionists are seen as the primary way in which the system is likely to leak and guarantees of anonymity and confidentiality be breached. 'Drug' research

companies were seen as trustworthy and professional because of their focus on doing research. Concerns were voiced about other types of commercial companies, such as insurance companies, gaining access to personal data or data being sold on for commercial gain.

Consent

E9 Consent is a very familiar concept in everyday life. Understandings of consent in the research process are borne out of general conventions of courtesy in interpersonal interactions. There was strong agreement across all the groups that explicitly being asked for their consent to take part in biomedical research was a good thing. Even those that were very positive about taking part in biomedical research, and would readily give consent, stressed the importance of the consent-seeking process. There was some variation in how stringent the consent requirements were for different types of research: the most minimal consent procedures were required for routine compilation and analysis of statistics.

E10 Implied consent was not welcomed as a model of the consent process. Implied consent was equated to no consent. Routinely proceeding with a variation in the agreed use of the data was generally seen as unacceptable. People find it easier to envisage anonymity for tissue rather than personal information. The consent process was seen as less significant around the use of their own waste tissue (materials such as the products of a termination of pregnancy were, however, not seen in this way).

E11 People recognised that there will be a wide variety of views of consent, which implies that there will be difficulties for a 'one size fits all' consent process. They recognised that there were big differences between people in the safeguards they required from the consent process. A one-off consent process that allowed people to choose between different levels of consent would provide an acceptable solution.

E12 Considering potential consequences of giving consent is an important heuristic in judging whether to grant consent, mainly in terms of weighing risk to self and benefit to others. If participants were going to be involved in research they wanted to know what the aim of the research was and what it was going to be used for. People appreciated that withholding consent may lead to detrimental consequences for the public good.

E13 People were reassured by the accountability of signatures but valued the personal approach in seeking consent. The GP was clearly the most trusted mediator for the consent process though people were aware that this was often likely to be an unrealistic ideal. The qualities attributed to doctors' receptionists meant that they were seen as inadequate for mediating the consent process.

Databases

E14 People did not relate any positive experiences of databases. On the contrary, many participants had stories of databases not working well. For some this led to great negativity; others were more sanguine and resigned to this.

E15 Drug companies were seen as very professional in their conduct of biomedical research. However, the profit motive was seen to potentially undermine the likelihood that the benefits of medical research will be available to all, and this possibility was strongly resisted. The motives of insurance companies were seen to be diametrically opposed to the interests of the individual and participants expressed concern around the potential for access of insurance companies to medical and health information.

E16 The concept of the NHS Connecting for Health database was a novel one; almost none of the participants had heard of it. The focus of discussion was upon the implications for everyday health practices; ideas of its being used for research were considerably more remote. Connecting for Health was viewed positively where it offered the promise of practical health benefits for individuals. Where it was discussed, access to the Connecting for Health database was recognised to be a useful and a permissible route for medical research purposes. There was considerable concern about the possibility of linking it with non-health-related information. Participants found little to reassure them in the care record guarantee.

E17 An aspect of Connecting for Health that caused concern was where there was the possibility of the patient adding information: this signalled the possibility of exploitation or abuse. On the other hand the interactive component of Connecting for Heath via the patient summary was seen as a possible way in which individuals could signal both their willingness to participate and the extent of the desired participation.

Models of governance

E18 Questions of the adequacy of research governance were more strongly anchored around concrete concepts like consent and databases than in the much less tangible concepts of legislation, self-regulation or external regulation. There was general awareness of the Data Protection Act (DPA) some awareness of the General Medical Council (GMC) and British Medical Association (BMA), less so for peer review and ethics committees and none for the Patient Information Advisory Group (PIAG).

E19 Although people were positive about the concept of the Data Protection Act, they had many reservations largely related to its not being seen as likely to work effectively in practice. Self-regulation was seen as positive because it includes doctors and experts. Participants also valued lay involvement in self-regulation bodies such as the GMC, BMA and ethics committees. Although lay involvement was viewed positively there was concern about how members were chosen and how representative they could be seen as being.

E20 Ethics committees were viewed positively but their regional nature was seen as a negative aspect. Although generally positively regarded there was concern that PIAG could override the wishes of individuals.

Implications from the research

- The role of bodies involved in the governance of biomedical research should be more visibly grounded in the mechanisms of participating in research, e.g. consent, protection of anonymity, etc., since these bodies are currently seen as remote by potential research participants.

- Researchers need to proactively engage with participants' desire for more transparency about the research process, including why certain data are required, how data are stored and who will have access to their data.

- Implied consent should be conceptualised as no consent.

- Explicit consent can be refined to be more permissive by providing opportunities on the consent form to specify a range of potential future/other uses of data. One way in which this might be useful could be to signal the agreed use of Connecting for Health data in research.

- Research participants require evidence and reassurance on the security of databases.

- The ideal brokers of research participation are GPs, although participants are also mindful of the issues of workload that personal contact would entail.

- Doctors' receptionists are not seen as appropriate to be part of the research process.

- Reflecting people's wishes for more active involvement, a website (one-stop shop) could be developed where participants could access information on aspects of participation in research, e.g. rights, explanation of terms, route for complaints, FAQs, links to other relevant sites.

CHAPTER 1: INTRODUCTION

This report, commissioned by the Wellcome Trust 2006, presents the results of qualitative research exploring public attitudes towards the governance of biomedical research. For the purposes of this study, biomedical research is defined as "any health-related research that involves humans, their tissue and/or their data. Public attitudes concerning animal research are therefore outside the remit of this study.

1.1 Aims and objectives

The purpose of this research was to investigate what members of the public think about issues of biomedical research governance. We define research governance as "the systems in place for ensuring that medical research on human beings is safe, conforms to ethical standards and is likely to contribute to scientific understanding". The aim was to report to the Wellcome Trust about public awareness, perceptions and attitudes about biomedical research governance, thereby informing their policy, advocacy and engagement work in this area. In order to achieve this aim, the objectives were to:

1 *Situate the role governance plays in shaping attitudes towards biomedical research.* We consider how important it is that people feel they are aware of regulations and controls or that they have confidence that such matters are taken care of. We investigate the extent to which people view human biomedical research as having an intrinsic value for the good of society and our future health and how far this may outweigh perceived costs to the individual in terms of their privacy and confidentiality.

2 *Explore public responses to the principles and processes associated with different models of governance.* Here we focused on how members of the public appraise systems of legislation, of oversight bodies and self-regulatory processes along parameters including their efficacy, transparency and trustworthiness.

3 *Investigate the processes that function to reassure the public and give them confidence in the way biomedical research is governed.* Equally, we discerned boundaries of people's 'comfort zones' where public anxieties are not easily allayed by existing systems of governance.

1.2 The research

The key findings of this research are from reconvened discussion groups held with a total of 89 members of the general public between July and November 2006. Fifteen participants had specific experience of participating in some sort of biomedical research and formed two biomedical participant groups. Fourteen participants identified themselves as having a long-term illness and formed two patient groups. Sixty general public participants formed four main general public groups and a further four mixed general public groups (two included a minority that had experience of long-term illness and two included a minority that had some experience of participating in biomedical research).

The discussion groups took place in Birmingham, Guildford and Woking. All groups initially took part in a one-day workshop. At this workshop, group discussions about biomedical research governance were facilitated by a series of short films compiled by the research team in association with Glasshead film production company. Approximately one week later, the same discussion groups were reconvened for a shorter session that drew on people's reflections over the intervening period. The stimulus material used in the discussion groups is available in Appendix 1.

Prior to conducting this fieldwork, our research team conducted a secondary analysis of qualitative data. This data was originally collected as part of an ESRC-funded study in 2004 and 2005 to understand public attitudes towards genetic technologies (Shepherd et al., 2006). The dataset comprised focus groups and individual in-depth interviews with members of the general public and with people who have a genetic illness. Interviews with 27 experts from industry and research were also included. The re-analysis of this dataset with the current aim of understanding what people think about biomedical research governance enables us to report on a range of viewpoints held by experts and publics as a precursor to presenting our primary research findings.

Both pieces of qualitative research permitted a detailed exploration of people's views, with reconvened discussion groups in particular representing an interaction between the researcher and participants that afforded insight into the reasoning behind particular viewpoints. Although not a 'representative sample' in quantitative terms, participants in the study were diverse in age, ethnicity and social class, were drawn from two different geographical locations, and a balance of genders was ensured. In this respect the results from this study meet the criteria of Mason's (1996) concept of being 'theoretically generalisable'. This requires certain criteria to be met, including: that there is no reason to assume that our sample of participants is specifically atypical (e.g. all middle class, or all men); that the analysis has been rigorous and systematic and encompassed responses from all the participants including disconfirming and contradictory data; that our analysis suggests that some participant characteristics could bear further research (e.g. a sample composed entirely of people over the age of 70; a sample drawn from a community with strong religious affiliations). In respect of these points the findings presented here can be taken to indicate current public attitudes towards the governance of biomedical research, although not the quantitative distribution of those attitudes.

1.3 The report

In the remainder of this chapter we present an overview of background material relevant to the aims of this project. In Chapter 2, we show how our secondary analysis of qualitative data informs our understanding of what experts and members of the public think about biomedical research governance. Chapter 3 outlines the research methods we used and further details on this are provided in Appendix 2. Chapter 4 presents the results of an initial exercise carried out by the discussion group participants exploring understandings of what constitutes biomedical research. The content of the next four chapters mirrors the topics of the films that all participants watched and discussed: personal data (Chapter 5), informed consent, anonymity and confidentially (Chapter 6), databases (Chapter 7) and models of governance (Chapter 8). We provide a separate chapter which offers reflections on the deliberative methodology used in this study (Chapter 9). Chapter 10 presents a general discussion of the findings from the research and their implications.

1.4 Background

Surveys of the public show a high appreciation of, and interest in, scientific research. A recent survey of citizens in EU countries reveals that this applies particularly to medical discoveries (European Commission, 2005). However, such attitudes co-exist with concerns that science is increasingly losing its independent credibility due to commercial funding. Scientific knowledge is also seen as being implemented too quickly, with insufficient scrutiny of its moral and ethical implications (OST, 2005).

These concerns are consistent with the notion that governance is an issue people take into account when considering their attitude towards science and scientific research. However, somewhat paradoxically, most people admit they do not know much about it. A survey of the UK public in 2005 reported that 84 per cent feel they know 'nothing at all' about the way science is regulated; this percentage was higher among women and manual workers. More than half (55 per cent) in this survey did not know that scientists are regulated by government and only one in four were of the view that regulation applies to scientists working for medical charities (OST, 2005).

It would be misleading, however, to conclude that public anxieties around the regulation and control of science are a direct consequence of their perceived lack of knowledge about it. Traditionally, the answer was seen to lie with promoting public education and awareness to fill the 'deficit' in knowledge. However, there are a number of reasons why we should perhaps not be surprised that members of the public lack factual knowledge and awareness of scientific regulation.

Firstly, research findings tend to show that regulation in general is an area where public understanding and awareness is low. This is not unique to science but applies equally to the monitoring of government and local authorities (OST, 2005). In 2006, a nationally representative telephone survey of the UK public found that only 31 per cent were aware of the Data Protection Act, a decrease of 9 per cent since the previous year. However, 'the protection of personal information' was ranked the fourth most important social issue after crime, the NHS and equal rights (SSMR, 2006).

Secondly, scientific research and biomedical research in particular are characterised by rapid change and uncertainties. In the last two years alone, major new legislation has been introduced in biomedical research, which has an impact on human tissue donations and the conduct of clinical trials, for example. Governance bodies in the NHS have been merged and the United Kingdom Clinical Research Collaboration (UKCRC) is currently looking at how governance processes and procedures in biomedical research could be streamlined. The domain of biomedical research is so broad and wide ranging that no one body can, in the public mind, be held responsible for its governance.

Under everyday circumstances, the prevailing public assumption is that science is regulated and that this regulation is governmental (OST, 2005). Only a minority believe that science is self-regulating in terms of ethical or peer review processes. The need for, and importance of, governance is commonly acknowledged. In 1999, 88 per cent of the surveyed public in England and Wales said that it was 'very important' that rules and regulations are in place to control biological developments and scientific research (OST, 1999). However, the same survey found a general dissatisfaction with the perceived amount of regulation in this area; 38 per cent felt there was 'too little' and only 3 per cent that there was 'too much' regulation. It was notable; however, that three in ten people

surveyed responded ‘don’t know’ to this question, again suggesting a lack of public awareness about formal mechanisms of governance.

When people are probed further about their reservations, what does emerge is an overall lack of public confidence or trust in the regulatory process. When asked to say why, in their own words, rules and regulations are important, responses such as ‘things could go too far’ or ‘scientists could get carried away’ (OST, 1999: p.69) are suggestive of a lack of trust in key stakeholders for scientific research. This apparent distrust extended to perceived ability of government to provide citizens with information that is honest and balanced. More recent research in 2005 shows a consistent picture. A MORI survey found that one-third of people who said science is regulated lacked confidence in that regulation (OST, 2005). A further one in ten were undecided. Of the majority who did express confidence in regulation, this seemed to stem from the notion that we have no choice but to trust and no option to forgo regulation in science (OST, 2005). Focus group discussions with members of the public convey the sense that people feel they only find out about regulation and governance when something goes wrong with it (OST, 2005). Examples include the controversy over the MMR vaccination and, more recently, the serious health problems caused to participants in a clinical drug trial at a London hospital. Such cases may erode public trust and fuel beliefs about a culture of secrecy, scientists closing ranks and a general lack of accountability.

It is much debated whether overall levels of trust have declined in the UK (O’Neill, 2002) and the extent to which this can account for public cynicism towards regulation and control. Survey research in 2003 shows that the vast majority of the public trust doctors and their ability to make decisions on their behalf about the regulation of biological science (BMRB, 2004; MORI, 2003; OST, 1999). More than half (65 per cent) trust scientists (MORI, 2003), with public confidence remaining unchanged over the last five years (OST, 2005). However, public trust is lower for institutions such as the NHS and people do markedly discriminate between scientists on the basis of where they work and how they are funded. Scientists working in the commercial sector are typically judged to be least trustworthy while those employed by publicly funded medical charities are viewed more favourably (OST, 2005).

Research for the Audit Commission in 2003 suggests that accountability and trust are closely linked (MORI, 2003). Members of the public expect that mistakes will happen but judge the trustworthiness of organisations on how they respond to it. Perceptions that a mistake is ‘covered up’ or that an organisation ‘closes ranks’ seriously undermines trust and credibility. Focus group discussions with members of the public further suggest that people are becoming less likely to defer to an expert opinion (MORI, 2003). Increasingly, it would seem that people do not accept that experts have the ‘right’ answer and may reject the idea that they should listen to scientific experts in order to become more knowledgeable about science and its processes of regulation.

General public distrust reportedly extends to the ability of government to regulate in a number of risk areas, including genetic testing. People did not perceive government values to be similar to their own and questioned the ability of government to listen and respond to the public on these issues (Poortinga and Pidgeon, 2003). Recent research by Duffy et al. (2005) highlights a number of changes that contribute to the growing trend for people to question or ignore government information. Based on qualitative discussion groups, they found great awareness among the public of ‘government spin’ placed on statistics or policy to make them more appealing. The proliferation of information, including the internet and the ‘audit explosion’ over recent years, has made people feel

confused about who to trust and arguably help create a ‘culture of suspicion’ among the British public (O’Neill, 2002). Duffy et al. (2005) also draw attention to a public ‘perception gap’ whereby generally favourable views based on personal experience of local services such as the NHS are not replicated at a national level where more negative opinions are likely to derive from so-called ‘second-hand personal experience’ embedded in anecdotes and media sources.

If this is the case, it further undermines longstanding efforts to improve public understanding of science through education and the top-down transfer of factual knowledge from ‘expert’ to lay public. Today, the assumptions often implicit in this approach, that it will soften public attitudes towards science and those involved in its governance, are largely discredited in favour of a more democratic model of public engagement (House of Lords, 2000). However, even from this perspective, the provision of information continues to play a vital role in enabling the public to become well informed about an issue, hence fully equipped to participate in policy debates such as the one held on GM foods in 2003 (DTI, 2003).

Research shows a high ‘information need’ among the public with regard to the regulation of scientific research. Public discussion groups reveal a general feeling among people that they are given too little information on rules and regulations pertaining to biological developments (OST, 1999). Public surveys report that 81 per cent agree that the public should be consulted on ‘decisions about scientific developments’ (MORI, 2005: p.15) and 27 per cent are of the view that having more information would give them greater trust in systems of regulation (OST, 1999). However, findings from Duffy et al. (2005) suggest that providing a greater volume of information may be less productive than giving more ‘information about the information’ to allow people to judge for themselves its reliability.

The research method of reconvened discussion groups used in this research provides a forum within which to give information to lay public. This information is a tool with which to promote and inform dialogue around various issues associated with biomedical research governance. By bringing together a small number of participants over two sessions to discuss and challenge this information, such an approach can be classed among a range of new approaches to understanding public attitudes and priorities called deliberative methods (Abelson et al., 2003).

Within this medium, it is possible to explore in depth some key strands of debate in national policy and patient groups. Recent reports on behalf of the Genetic Interest Group (Gillot, 2006) and the Academy of Medical Sciences (2006) both raise concerns about the increasing legislative weight given to an individual’s right to privacy in the context of medical research. These rights, enshrined in recent legislation such as the Human Tissue Act (2004) have arguably created confusion, delay and uncertainty about acceptable practice on fundamental issues such as obtaining informed consent from individuals. The direction of government policy in this area is seen as creating “political, legal and social turmoil that is disruptive for the public, regulators and the research community” (Gillot, 2006: p.3).

Others have questioned the operating assumptions that we now have a ‘crisis of trust’ (O’Neill, 2002), that the public are actively distrustful of personal information about their health, for example, being used for any purpose other than their direct care (Barrett et al., 2006). The Academy of Medical Sciences (2006) drew attention to a general lack of research evidence in this area that affords an in-depth investigation of what the public thinks about biomedical research in different contexts. Recent survey work suggests that

a sizeable majority of the British public are accepting of personal information about them being used for the purpose of public health research. Barrett et al. (2006) examined people's attitudes using the British Cancer Registry as an example and found that although only 18 per cent were aware of its existence, 95 per cent felt it collected personal information that was useful. Perhaps contrary to the current legislative and regulatory climate, there was little evidence from the public that having their name and postcode held by the Registry or being personally contacted as a direct result of this database was construed as a threat to privacy.

The role of context was investigated by Shickle et al. (2002) in a multi-method study of public attitudes towards the use of their personal health information. A quantitative survey in Great Britain included 200 vignettes that presented different scenarios about personal data varying along the dimensions of: who requested it; why the information was required; the content of the information and the level of personal detail required. Statistical analysis of rated responses showed that nearly one-third of the public were 'very happy' to allow access to their personal health information in any context. The person requesting personal health information was the most important factor distinguishing people's willingness to permit access to it, far more so than the content or detail of the information required. In a series of qualitative focus groups there was surprise and concern among the public at the range of people having potential access to personal health information. However, the authors report that people's attitudes on key areas such as requirement for informed consent, developed as they talked through the practical implications of scenarios. They note that "views may well have continued to develop further once participants departed from the groups and had the opportunity for a longer period of consideration" (Shickle et al., 2002: p.94).

1.5 Questions explored

A key strategy employed in this research was therefore to explore in greater depth how, and in what ways, people deliberate on issues of research governance. In the domain of biomedical research, we examined people's engagement with, and responses to, a range of stimulus material on key issues and principles associated with governance. By studying the process through which people encountered and assimilated such material, we were able to shed light on how public perceptions are formed and maintained, in particular the reasoning that people used to make sense of systems of regulation and control in this area of research.

Our deliberative method enabled us to address three specific objectives:

1. *To situate the role governance plays in shaping attitudes towards biomedical research.* We consider how important it is that people feel they are aware of regulations and controls or that they have confidence that such matters are taken care of. We investigate the extent to which people view human biomedical research as having an intrinsic value for the good of society and our future health and how far this may outweigh perceived costs to the individual in terms of their privacy and confidentiality.

2. *To explore public responses to the principles and processes associated with different models of governance.* Here we focused on how members of the public appraise systems of legislation, of oversight bodies and self-regulatory processes along parameters including their efficacy, transparency and trustworthiness.

3. *To investigate the processes that function to reassure the public and give them confidence in the way biomedical research is governed.* Equally, we discerned boundaries of people's 'comfort zones' where public anxieties are not easily allayed by existing systems of governance.

CHAPTER 2: RE-EXAMINING PUBLIC AND EXPERT UNDERSTANDINGS OF GOVERNANCE

2.1 Overview

While not the focus of the original data set on which this analysis is based, the theme of research governance was spontaneously raised within both the interviews and focus groups. The general public cohort exhibited quite a sophisticated understanding of the rationale for and processes underlying research governance, and invested faith in the UK as a state which takes regulation and safety seriously in comparison to other countries. However, confidence in governance through legislative regulation is threatened by participants' constructions of the agendas of individual scientists, their lack of trust in government, and concerns about transparency and the independence of research organisations.

2.2 Introduction

The secondary data analysis presented in this chapter constitutes the first phase of this three-phase research design using qualitative data generated from an ESRC-funded research project entitled Attitudes to Genomics carried out between 2002 and 2005. The aim of this ESRC project was to provide a basic understanding of current attitudes among the public towards genomics and the formation of, and changes in, attitudes over time. It investigated the relationship between attitudes towards genomics and other more general sociopolitical attitudes, and attitudes towards other new technologies.

The Genomics project did not set out to examine specifically attitudes to research governance but issues regarding the regulation of research did arise. The limitation here, for the purpose of this current project, is that the concept of genetics carries it own associated meanings, and those meanings may not be salient for other sorts of biomedical research. Nevertheless, the secondary data analysis provided a helpful starting base by enabling us to see how governance does or does not figure when people are invited under different conditions and contexts to think about genomics in a broader framing. The overall aims of using the secondary data were to:

i) sensitise us to the range and content of the publics' views on biomedical governance;
ii) help inform our decisions about the content of the films to be used in the reconvened discussion groups;
iii) enable us to make further decisions regarding appropriate stimulus material for our deliberative method with the reconvened discussion groups.

Consequently, this provided a useful foundation from which we were able to move on from in order to take a more detailed look at the specific processes of governance as they relate to biomedical research.

2.3 Methods

Forty interviews were carried out with the general public, 20 of which were with individuals who had been affected by genetic illness. Interviews were carried out after participants had watched a short factual film about genomics. Eight focus groups were carried out with the general public, of which four comprised participants who had been affected by genetic illness. Participants did not watch the film first and discussion was on genetic technologies more generally. Similarly, an open-ended approach was taken in the 30 interviews that were carried out with experts from industry and research.

Full details of the sample of both the general public and expert groups and of the analysis can be found in Appendix 2.

Although issues around research governance mechanisms was a significant theme within the expert interviews, as the focus in this report is about public attitudes, the findings from the expert data can be found in Appendix 3.

2.4 Findings from the general public data

The following four themes were identified for their relevance to the expressed aims outlined above, and associated topics relevant to the objectives of the secondary data analysis were explored:

- attitude to research governance mechanisms
- regulating new research
- trust and regulation
- public participation.

2.4.1 Research governance mechanisms

Among participants, research governance is understood as both a practice concerned with protection of the public, and safety with respect to the processes and outcomes of research, and was deemed necessary by all participants. While participants believed UK regulation was more stringent compared to that in some other European countries and the USA, there were still concerns regarding the current measures in place to protect the public. This led to a lack of reassurance in governance mechanisms, and a range of factors were cited.

Lack of international regulation

Without international regulation, banned research in the UK could just as easily be carried out in less well-regulated countries. New research would be impossible to control, which could lead to abuse and exploitation:

> And they'll pick on some poor third world country desperate for dollars who'll allow them to do research in there.
>
> (Female: General Public Focus Group 5)

Fighting a losing battle

Regulation is unable to keep up with the ever-changing face of new technologies, and there is a sense of inevitability about scientists' pursuit of new research possibilities.

Unethical scientists
Confidence in governance is threatened by participants' constructions of the agendas of individual scientists who are seen to place themselves 'above' moral and ethical concerns, and which legislation could not account for:

> We're just going ahead without asking the questions whether we should be going further or whether ethically this is the right thing to do.
> (Female: Genetic Illness Focus Group 2)

2.4.2 Over-regulation and inhibiting research

There was a concern that overly extensive governance could inhibit new research to the detriment of those directly affected by conditions that might benefit from this work.

Stakeholder perspectives
Participants affected by genetic illness were likely to express irritation with those trying to limit new research arguing that they would take a different view if they had personal experience of the distress and pain caused by genetic illness.

Furthermore, the public have a role to play here, and need to 'move with the times' and not hold on to values of previous eras that are inconsistent with the modern world.

Need to move with the times
There was a suggestion that public attitudes were lagging behind new technologies and that as new problems arise it becomes necessary to develop new ways of thinking:

> I think people are kind of, tend to be resistant to change. You know, we're all creatures of habit and something like this, or somebody tries to change it, I think immediately, you kind of think the worst: 'Oh, this can't be good', because I think there's a certain degree of resistance there.
> (Female: General Public Focus Group 6)

2.4.3 Trust and regulation

There is widespread mistrust of almost all oversight bodies charged with regulation, including government, pharmaceutical companies and scientists, none of whom are perceived as sufficiently independent or demonstrate the necessary openness to encourage public confidence. Lack of trust manifested itself in a range of contexts.

Government secrets and lies
The public are increasingly disenchanted with what they see as the lies and inconsistencies fed to them by government, citing numerous examples of health scares associated with drugs and food that government had given assurances of their safety, such as the BSE crisis. Consequently, government is seen as untrustworthy:

> I think too the public has lost a lot of trust in government since mad cow because we were all so assured that it wasn't an issue and I was reassured, really, and I had children at an age where I absolutely wouldn't have given them beef if I'd known that it was as dangerous as it turned out to be.
> (Female: General Public Focus Group 6)

Burying bad news
Participants felt they were rarely informed about negative research outcomes, and that large pharmaceutical companies withheld the results of 'bad research' whereby the public were unwitting guinea-pigs for potentially harmful drugs.

Lack of transparency
Participants expressed a desire for greater transparency regarding the commissioning and funding of research, wanting more information about the sponsoring body's intentions and uses of the research.

Lack of independence
There is a strong sense that most research is "more corporate-led than scientific-led… the profits first and the effects are later" (Male, Focus Group 6). For this reason, although recognising the positive contribution made by scientists, their perceived lack of independence was problematic.

2.4.4 Public participation in research governance

Although in recent times a more participatory model of public engagement has been advocated, the public express scepticism about the extent to which they believe their views can make a difference. This is exacerbated by the fact that the public are often granted access to deliberations after they are complete, rendering public opinion irrelevant.

In light of the public's concerns about their perceived lack of influence, there was significant discussion among participants about taking of responsibility both personally and collectively.

Personal political activism
There was a strong sense that taking responsibility was almost a civic duty. Participants said that issues should not be avoided by stating that it was someone else's problem rather that it was important to rise above apathy and take a stand:

> If enough got together and said 'Look, we're not standing for this, you know, we're not' […] but these days everybody's too busy or someone's watching telly […] But if enough people have the guts to get up and say 'Yes, I'm not putting up with it…'
> (Female: General Public Focus Group 8)

The boycotting of unscrupulous companies was a significant way in which the public made their feelings felt. While recognising that their contribution was small, this gave them a degree of power to exercise their rights and choices about things they felt were beyond their control:

> I won't buy Nestlé products because they've campaigned to sell baby milk to third world countries when they haven't got fresh water.
> (Female: Genetic Illness Focus Group 1)

Collective political activism
The public cited a range of ways in which they could be achieved, from lobbying MPs, joining activist groups such as Greenpeace, to mounting their own campaigns, and attending public marches.

2.4.5 Conclusions

Ultimately, in order to restore the public's faith in governments and research communities, there must be greater levels of transparency and openness about research agendas, sources of funding, and honesty about particular health hazards. Not only would this offer the necessary assurances the public desire, but it would also enable the public to make considered and informed choices about what to consume, and what research agendas and organisations they wish to support. This would help counteract their perception and concerns about the 'inevitability' of technology and new research that legislation seems incapable of challenging or preventing. Furthermore, the public will find ways of taking action and getting involved if they feel their views are being sidelined. From the smallest personal gesture to larger, collective forms of activism, the public are willing and able to make themselves heard.

CHAPTER 3: METHOD

This chapter outlines the research design of the reconvened discussion groups. Full details can be found in Appendix 2.

3.1 The sample

A total of 89 people took part in the study:

- 60 general public participants divided into eight groups: 'Public' participants
- 15 participants had specific experience of participating in some sort of biomedical research divided into two groups: 'Biomedical' participants
- 14 participants who self-identified as having a long-term illness divided into in two groups: 'Patient' participants.

All participants in the biomedical and patient groups were recruited on the basis of fulfilling the following criteria:

Patient: reported having a long-term medical illness or health problem AND no prior experience of participating in biomedical research

Biomedical: reported having prior participation in biomedical research either as a healthy volunteer or a patient.

The public participant groups included four main general public groups and four mixed groups: two included a minority that had experience of long-term illness and two included a minority that had some experience of participating in biomedical research. In addition, recruitment of participants to the public groups took account of achieving a range of ages and a gender balance across the sample. In addition, to facilitate discussion participants were allocated to specific groups on the basis of the level of their highest educational attainment (A-level and above or GCE/GCSE or below). Overall, 12 per cent of participants were from non-white British ethnic groups. All participants were recruited by a market research company briefed by the research team.

Characteristics (N=89)		Biomedical participants (numbers)	Patient participants (numbers)	Public participants (numbers)
Age range	18–30 yrs	2	2	17
	31–40 yrs	7	1	17
	41–50 yrs	2	4	11
	51–60 yrs	4	6	11
	60+ yrs	0	1	4
Gender	Female	8	8	35
	Male	7	6	25
Totals		15	14	60

Each group consisted of a maximum of eight participants and the fieldwork took place in city locations in the Midlands (Birmingham) and in Southern England (Guildford and Woking). All general public groups were held in July 2006. The Biomedical and Patient discussion groups were held in October and November 2006.

Participants were paid an incentive totalling £100 for taking part in the reconvened discussion groups; £30 was paid on completion of the first session and the remainder at the end of the final session. All participants took part in both parts of the fieldwork.

3.2 Deliberative method design

A qualitative deliberative research method was used. This consisted of groups of seven to eight participants attending a full day of discussion built around the provision of relevant stimulus material. Participants were also given material that related to the discussions to take away with them so they could reflect further on the research issues before returning one week later for a further 1.5-hour discussion. A strong emphasis was placed on making the information provided as accessible as possible, keeping technical or legal terminology to a minimum and wherever possible relating the more abstract principles of governance to situations or structures that people would be familiar with in their everyday life.

The stimulus material for the full day of discussion consisted of:

- four short films that dealt with key topic and debates concerning research governance
- written information handed out during discussions about different topics
- posters on mechanisms of governance displayed in the room where the group discussions were held
- written information to take home between the full day and the reconvened session.

The shorter reconvened group discussion involved the provision of three research scenarios, plus baseline activity tasks (see below).

The reconvened group discussion approach has several advantages. First, for a topic such as biomedical research governance where prior public awareness and factual knowledge is likely to be low, it allows people to engage with a range of material over a relatively short time period. Second, the discussion groups are facilitated by moderators

to enable participants to express and develop their views and ideas about the issues they feel are important, interesting or puzzling. Third, it provides an opportunity to examine how participants' views change and develop at an individual or group level over the course of two discussion groups, with time to reflect, and with the provision of information. This means the research can 'get underneath' participants' initial reactions to explore their perspectives in more depth.

3.3 The films

Four short information films were developed to enable participants to explore issues in research concerning provision of personal information, informed consent, the use of databases for research, and governance committees. The films lasted approximately two minutes, and each had a 'talking heads' approach whereby a male and/or female actor voiced opinions that were often at odds with each other, were at times exaggerated or deliberately misunderstood. Humour was used to engage the audience, and the opinions presented in the dialogue reflected the arguments generally available in the media about research governance issues. Further detail on the film content is available in Appendix 2.

3.4 Tasks

Before the group discussions started, participants were divided into sub-groups of three or four and asked to take part in three short tasks. The tasks were designed to elicit participants' 'baseline' views at the start of the day, and to also to help them 'warm up' for the group discussions. The qualitative data generated from these tasks are reported in Chapter 4.

Task 1: What is biomedical research?
A definition of biomedical research was provided. Each sub-group then worked together to identify what sorts of things they thought might be included in this definition. These ideas were written on a flipchart sheet. A handout was then given out which gave specific examples of biomedical research (see Appendix 2), and further comments were noted by the facilitators.

Task 2: The H-form
The second task consisted of an approximate scale which ranged from 'not important' to 'very important', portrayed as a line. Participants were asked to indicate with an X their position on the scale in relation to the question: *How important is it that people participate in biomedical research?* Each participant was then asked to write down a reason why they a) had not marked a higher score, and b) had not marked a lower score. That is, they were asked to indicate why a) they did not think it was *more* important that people took part in biomedical research, and b) why they had thought it was *as* important as they had indicated it was.

Task 3: Reasons why people might not want to take part in biomedical research
The final task involved participants being asked to identify reasons why people might not want to take part in biomedical research. These reasons were recorded on a flipchart sheet by the facilitator.

3.5 Group discussions

Participants then moved on to the full group discussions. Over the course of the day participants were taken through material in the following areas: personal information; informed consent; databases; and committees involved in governing research. All groups encountered the material in the same order. Discussion was structured using a detailed topic guide that probed responses to the film and other stimulus information and allowed for respondent-led discussion.

Approximately one week later, a shorter session of 1.5 hours was held. This session encouraged people to reflect on the material they encountered last time, in particular to share with others their deliberations and any exchanges on the topic they had had with others outside the discussion group. In this reconvened session, people were also introduced to three research scenarios built around issues concerning informed consent, anonymity and confidentiality covered previously. Drawing on the material they had already encountered, participants were asked to make judgements about how comfortable they would feel taking part in different types of research outlined in the scenarios and to outline their reasoning in each case.

Copies of the topic guides used in the reconvened discussion groups can be found in Appendices 4 and 5.

All group discussions were recorded using digital audio recording equipment with the consent of all participants.

3.6 Data analysis

The group discussions were coded to capture the key points, positions and opinions that were expressed using qualitative analysis software (Atlas-ti). Comparisons were drawn between the public groups and the biomedical and patient groups to identify whether there were any systematic differences in views or concerns. In the following chapters reporting the findings, we use quotes from the discussion to illustrate the analytic points, drawing on longer quotes where necessary. Quotes are identified by type of group in the ID number: PAT for a patient group; BIO for a biomedical group; PUB for a group consisting of the general public. Where longer quotes involving discussion between group members are cited, changes in speaker are indicated as P1 (first speaker in the extract), P2 (second speaker), etc. These do not identify individual speakers between different extracts, i.e. P1 in one extract is not necessarily the same person as a P1 in another extract. This maintains anonymity at the highest level requested by the some of the participants themselves.

CHAPTER 4: INITIAL UNDERSTANDINGS OF BIOMEDICAL RESEARCH

4.1 Overview

An analysis of the tasks carried out at the outset of the reconvened discussion groups suggested that participants from all groups categorised a wide range of activities and scenarios as being exemplars of biomedical research, ranging from stem cell research and cryogenics to drug trials, and audits of health records. Medical procedures were also included within this category on occasions.

The tasks indicated strong support in principle for biomedical research, valued for the possibilities it held out for the eradication of disease, alleviation of suffering, cures, and improved treatments. However, this support was not given unquestioningly and at this early stage in the discussion groups participants identified a range of factors that they said hindered unequivocal acceptance of research of this kind. Participants suggested that they did not know enough about what was involved in participating in research. They noted the potential for things going wrong in a drug trial and the salience of media reporting of such incidents.

4.2 Introduction

We were aware that the concept of biomedical research might be a new and somewhat unfamiliar topic to the research participants, and participants' understandings of what it entailed were likely to be diverse given the stratification of our sample as public, patient and biomedical groups. To this end, we developed three short preliminary tasks to carry out with participants at the outset of the discussion groups to elicit their baseline views of what constituted biomedical research, to ascertain where they positioned themselves when considering whether it was important to participate in research and their reasons for this. Chapter 3 described the nature of these tasks.

As well as broadly aligning participants to the subject matter of the day and providing a useful starting point from which to open up discussion, the data from these tasks give us insight into participants' initial positions and opinions on the acceptability of biomedical research.

This chapter reports a summary of the views expressed. While it was evident that there was widespread support for biomedical research by participants across all the groups, some aspects caused concern. We highlight the reasons why participants were so favourably disposed towards research, and highlight the potential barriers to acceptability that they identified.

4.3 Discussion of tasks

4.3.1 What types of things constituted biomedical research?

This task elicited a vast array of examples of biomedical research, and across all three groups there was considerable consensus about the nature of these with only minor variation between groups.

Four areas were mentioned by all groups: stem cell research, clinical trials (diseases such as diabetes, cancer, and Alzheimer's being most frequently mentioned), epidemiological studies (e.g. researching the link between health and poverty), and use of personal data (including blood donations, health records, leaving one's body to medical science, lifestyle and dietary information). The majority of the examples given by participants related to finding cures and the eradication and prevention of disease. In addition, across all groups, biomedical research was largely understood as something one was paid to participate in.

It was also noticeable that several examples, mentioned in all groups, referred to unsuccessful or unethical research or medical treatment that had received significant media coverage in recent times. This included 'babies in jars' (a reference to the Alder Hey Hospital in Liverpool where organs of dead babies were removed without the parents' permission), 'face transplants' (pertaining to the first procedure of its kind in France in 2005), and the 'elephant man' (a reference to the failed trial of the experimental drug TGN1412 at Northwick Park Hospital).

There was little variation across the groups except for the following two examples. Firstly, among the public groups, there was a tendency also to include activities that might be considered to be medical procedures rather that research, such as autopsies, transplants, plastic surgery, choosing the sex of a child and selecting 'designer' babies. Secondly, only participants from the biomedical group mentioned longitudinal research which might reflect their own experience of participating in trials, of which public and patient groups were less likely to have direct experience.

4.3.2 How important is it that people take part in biomedical research?

It was particularly noticeable that the majority of participants placed themselves at the far right-hand side of the scale in the H-form task, indicating that they believed it was very important that people participate in biomedical research. Although it might be expected that participants from the patient groups might score more highly (due to personal investment in the development of new research), this was not the case as obvious support for biomedical research was expressed across all three types of groups.

The most frequently cited reason for supporting biomedical research was the fact that the issue of health and wellbeing is everyone's concern. As several participants in the public groups commented, 'nothing is more important than your family's health' and you never know when you might be personally affected by disease. This was a strong theme suggesting that, whether or not participants or their families were in immediate medical need, anyone could be personally affected in the future. Consequently, they wished to have the best medical help available which was not possible without research – 'without research, medicine can't move forward'.

In addition to the potential personal benefits accrued from medical research, reasons given for not scoring lower often pertained to the health of future generations, and the notion of social responsibility: to reduce suffering, prolong life, save lives and to provide a better future for all.

In addition, there was significant support for the idea that in order to test drugs properly, their effectiveness needed to be tested on human subjects. Furthermore, not to do so increased the possibility of risking human health if treatments were 'untested'. In this

sense, animal testing was seen as having limited use in monitoring the effects on humans, although several participants framed this in a positive light in that they believed this removed the need for animal testing, which they objected to on moral grounds. It should be noted that animal testing was not included as a topic in this study but participants alluded to it spontaneously in the context of the preliminary tasks.

While there was, however, generally widespread support for research, participants had some reservations that led them to question the wisdom of unequivocally accepting that participation in biomedical research was a good thing.

Participants from all groups voiced many of the same concerns. The most commonly expressed of these were:

- negative press coverage, e.g. 'elephant man' case, and fear of trials going wrong
- not wanting to be a 'guinea pig' or 'lab rat': associated with safety, risk and fear of death or pain
- information and transparency (reason for research, who is overseeing it, what is it being used for)
- lack of time/family commitments.

In addition, biomedical participants were at pains to protect their privacy, not wanting others to know of their involvement in a study. Participants from this group were the only ones to mention anxiety about the use of their information for secondary data purposes without their permission, and the importance of compensation should something go wrong. Public participants also mentioned monetary recompense but this was framed as receiving sufficient monies to cover loss of earnings while participating. Among the patient group, some had also participated in biomedical research. It was only among this group that participants stated they had not scored more highly because biomedical research might be too stressful, there was a lack of time, or people might not be happy with the recruitment process (i.e. people do not like the idea of being randomly contacted). These reasons suggest that personal experience plays a part in the concerns people raise regarding participating in research.

Some specific concerns were only raised by the public groups. It was felt that widespread participation in biomedical research might lead to a form of 'compulsory' participation, that it might become an expectation that people would and should participate, and proper consent would not be sought. The issue of trust in governance measures was also suggested as a reason why public participants did not score more highly. Although they felt it was important to participate, support depended on whether they thought sufficient ethical and legal controls were in place.

4.3.3 Why not take part in biomedical research?

Many of the reasons given for not scoring more highly on the H-form scale were reiterated in relation to the question 'Why not take part in biomedical research?' for the final task.

Across all three groups, these could be specifically identified as:

- *Risk and safety*: this was raised time and again by participants suggesting that concerns about long-term side effects, or negative health outcomes was a significant reason for not taking part.
- *Negative press coverage*: bad publicity about failed drug trials and unethical practices were cited as having implications for people's reluctance to participate.
- *Pushing the boundaries*: fears that research can be taken too far.
- *Lack of information*: there was considerable strength of opinion here with participants stating that they would not consent to taking part in research where they felt they had had too little information. In particular, they wanted information about possible side-effects, what the research would be used for, what research had already been carried out and who was backing it.
- *On ethical/religious/cultural grounds*: this included objections to animal testing, not wishing to participate in research that might be used for biological warfare, and testing on prisoners or those whose state of mind might be impaired, i.e. the inability to either have the choice or ability to provide informed consent.

The patient group made no mention of issues about privacy, confidentiality or anonymity in relation to why people might not wish to participate but these issues were raised by both the biomedical and public groups.

4.5 Improving awareness of biomedical research

Across the three tasks, an additional theme raised by all groups drew attention to a perceived need for improved awareness and understanding of what biomedical research entailed both to participants personally and to the general public more widely.

Despite the fact that the tasks elicited a wide range of responses as to what constituted biomedical research (suggesting that participants had a reasonable understanding of the term, and were able to articulate their position in relation to biomedical research as part of the task questions), participants in all groups reported a desire for more information for themselves. They also suggested that there was a need for greater understanding among the general public at large.

Participants felt that where they (and others) were unaware of the purpose of biomedical research and what participation entailed, that this was likely to lead to confusion, hostility and fear. This in turn meant one was less likely to participate, especially if no direct benefits were perceived to self or family:

> Some people are frightened by it [biomedical research], they don't understand... is that animal research, is that going to be prodded and poked, are they gonna call me up because I've got to be part of their study? […] I think there is a lot of confusion where people might just go on to the selfish point of 'Well, I don't need any research done about me, I'm doing alright. My family's doing alright. I'm gonna click out of that'.
> PAT2-dw15

There was significant support even at this early stage in the discussion groups for raised public awareness of the issues. This was so even in biomedical participant groups who, despite having themselves participated in research, still felt their personal information needs had not been wholly met. In fact, no participants in any group felt that they were sufficiently well informed, which had made them somewhat fearful, as the following comment illustrates:

> I think if you want to do more biomedical research you've got to have awareness sessions for the general public explaining what it entails – taking away the fear factor – including myself. I didn't know too much about biomedical research; it sounds a bit scary.
> BIO2-dw19

4.6 Conclusions

Participants' initial understandings of biomedical research show a strong support in principle for the value of such research and the importance of people participating in it. Alongside this, however, people were able to identify concerns that that might deter them from taking part, or impede whole-hearted acceptance of biomedical research. Fears about personal safety and level of risk, negative press coverage, lack of appropriate information, ethical concerns and exploitation of research were cited. To a lesser extent other factors influencing why they might not wish to participate included lack of faith in governance mechanisms, assurances about confidentiality, time constraints and personal commitments, issues around consent, and religious/moral beliefs.

Furthermore, participants stated that there was a need to raise public awareness about biomedical research, not only with regard to what it was, but also to demonstrate to the general public the benefits of this type of research. Participants stated that there was a 'fear factor' surrounding biomedical research both in relation to terminology ('biomedical' conjuring up images of 'babies in jars' or the 'elephant man' drug trial) and to potential negative outcomes.

CHAPTER 5: PERSONAL DATA, ANONYMITY AND CONFIDENTIALITY

5.1 Overview

In this chapter we explore what kinds of data participants consider to be 'personal data' and the implications of this for the governance of biomedical research. We found that sensitive information about the individual was always considered to be personal data. At the same time, participants felt that all information that was unique to them as individuals, or a potential route to identifying them, also constituted personal data in the sense that it was individualised. When data were thought to be personal, concerns about why they were wanted, who would access them, and how they would be protected came to the fore. However, this did not mean that participants would be unwilling to provide such data, sensitive or individualising, as part of a biomedical research project providing the reason for their requirement in the research was understood, and as long as the participant had confidence that their personal data would be protected via processes of anonymity and secure data storage. There were no discernible patterns of difference in views between participants who were in the general public groups, and those in the patient or biomedical groups.

5.2 Introduction

A key question addressed in this study was how the 'status' of the data participants could be asked to provide in biomedical research would impact on their views about the governance of the handling of that data. Specifically, the Wellcome Trust was keen to understand the relationship between the individual participant and their data. Here data can be understood to be the material gathered by the researchers for the purpose of the research, and in this respect it ranges from information about the individual (such as name, age, gender and ethnicity, location), information about an aspect of the individual's life (such as health/illness details, whether or not they smoke, take certain medications), through to bodily tissues and materials (such as blood samples, 'waste' tissue removed during surgery, and other bodily parts).

In order to enable participants to talk about what might count for them as personal data, we started this section of the first research day with a film featuring an elderly woman being asked to provide information about herself when enrolling at a new health centre (see Appendix 1 for an outline of the film). The film raised issues concerning the nature of personal information (including sensitivity), assurances of confidentiality, the notion of opting in or opting out of allowing routinely collected data to be used for research, and anonymisation.

As we have shown in our analysis of the H-forms (Chapter 4), not unsurprisingly given that these were people who had agreed to take part in our own research, participants were very positive about the role of research in improving health and generating knowledge which would be of benefit to society as a whole. In discussion this support for the enterprise of research extended to support for the collection of personal data as part of the research process. However, this support was not unqualified: concerns were often raised about the security of the data, and potential breaches of anonymity and confidentiality. However, before examining these reservations we will start by looking at

the ways in which participants thought about data, and in particular what they felt made data 'personal'.

5.3 What is personal about personal data?

The concept of 'personal data' was broad for all the participants. It could cover general information about your life and more sensitive information about people's behaviour, health status or identity. In one of the general public groups this breadth was illustrated very clearly:

> R So what do you actually think of as personal data? When you think about it what kinds of things come to mind?
> P1 Lifestyle and medical history.
> P2 Ok, any other
> P3 There's loads. Age, gender, nationality…there're all elements of your personal information…how many kids you've got, how many sexual partners, whatever number that happens to be.
> PUB4-db11 (185-199)

This was echoed in a biomedical group:

> P1 …everything is personal…I'm a person and everything from my name, height and everything else is personal to me…
> […]
> P2 But then it's different for each person, some people might not want to share about sexually transmitted diseases or whatever, reproduction, then other people might be very sensitive about mental health and so it's, I think it's unique for each person, I don't believe you can generalise.

Within the broad category of 'everything that is about me', distinctions were made between different types of personal data. These distinctions were important in influencing how comfortable participants were with the idea that they first of all might be asked to provide certain sorts of personal data as part of the research process, and secondly what concerns they might have about providing this data.

5.3.1 Sensitive data as personal

There was strong agreement that data that were sensitive were automatically 'personal'. Sensitivity was primarily related by participants to information concerning a person's sexual behaviour and their sexuality. This did not mean participants would necessarily be reluctant to provide such information about themselves, rather that issues concerning security of data, anonymity, and confidentiality came to the fore alongside concerns about the consequences of sensitive information becoming known outside the research context:

> P …if you've got a guy whose track record is as a married man, he'd have to answer that question [in the film] about sexual partners honestly and his wife had a chance of finding out the results of that, then he'd be very reluctant to give it, wouldn't he? So things like that you'd want to know, but general things about cross-referencing whatever drugs I'm taking, whatever side effects they may be giving, I think we should assume that's going to be used for general accumulation of information.
> PUB1-dg01 (122-122)

However, sensitivity was not just confined to information concerning sexual health and/or behaviour. Other 'facts' about oneself which were considered by participants to be

stigmatising or negative were also seen to be sensitive and as such to constitute personal data:

R …what else do you think of as being personal data, for research?
P1 Your background history, […] such as […] some people were brought up, you know without their mums and dads […]
P3 Yeah like, maybe in care for a while?
[…]
P4 If there's been any alcoholism in your family, drug issues or abuse, or …
P1 Abuse. That's very personal.
PUB3-db09 (904-922)

Sensitivity also emerged as encompassing information about a person which, if known, has possible serious consequences including the potential for stigma and discrimination. This widened the range of situations which were potentially sensitive, and related again to what might happen if data were to 'escape' out of the research context into other aspects of people's lives:

P1 Things that you could be discriminated against, so HIV status, sexuality, sexual history, erm …
P2 Health history.
R Right.
P2 Generally with that. You might have had something, you know …
P3 Like mental health.
P2 Yeah.
R Right, so could be considered forms of sensitive data that you wouldn't be…
P1 Drugs and alcohol, because that can be a stigma, with people being afraid that if they've had a bout of depression that a potential employer would not want to employ them.
P2 Or like you …
P3 And like implications for insurance, like with [unclear] and HIV.
P2 And family history of certain things.
R Any examples?
P4 Well, if you've got a family history of heart disease presumably that might affect what an employer might think about you, if your family has a history of certain conditions.
PUB4-db11 (237-267)

For some respondents the consequences of personal information 'coming out about you' extended beyond the self to include their family, thus the significance of providing some kinds of data would be quite high if confidentiality were not maintained. We return to this later in the chapter.

> You've got to look at your family. You wouldn't want your children, something coming out about you that was personal, and your children being teased or… It's the hurt it could cause to your family, isn't it? See, I'm not bothered about what anyone says about me, or does...
>
> PUB3-db09 (1832-1834)

Sensitivity was also contextual and not necessarily clear cut. As the following exchanges illustrate, participants were keenly aware that something could be sensitive for one person and not for another, that it might be sensitive in one context and not another, or that the sensitive nature of some information could be created through one fact about a person having a different, more sensitive meaning, when taken together with another fact.

P1 Where do you draw the line as to what's sensitive and what's not?
P2 I guess we are saying what is sensitive to one may not be
P1 necessarily to another?
P3 It's a grey area, isn't it?
P4 Sensitive data may not be in context without the other data, so if you're doing a study and you don't know, say you've done sexual partners but you don't know the gender then it may not work without the other.

R So a perfectly ordinary piece of information can make something sensitive when they're put together.
PUB2-dg03 (399-405)

Yeah, it's funny how you'll accept the, you know if you are a blood donor, you will accept if you're asked, you know "have you ever slept with anyone with HIV, have you ever shared a needle?" and all that, you'll tick all those quite happily, your name and address is on the bottom of it […] And all your full details, but when the doctor's receptionist is asking somehow it doesn't feel er, quite the same…
PAT2-dw15 (58-72)

Other examples given included how one's ethnicity, religious identity, or other contexts could heighten the sensitivity of certain facts or create new sensitivities. Ethnicity was felt to be important in terms not only of cultural or religious beliefs but also because of the perception that people from minority ethnic backgrounds might be subject to particular stigmatisation by their community if they transgress. A very strong link was made in this case between sensitive personal data and questions of security of data, reliability of guarantees of anonymity and confidentiality:

.

P1 …I think that one of the reasons that I'd want to go, or have the option to opt in or opt out [of agreeing personal information could be used for research] is you're doing your own risk assessment, that if this went elsewhere, I think you are, you have the best judgement about what the implications are for you. So, for example if I had had an abortion, as a Pakistani Muslim woman, if that was known to the wider community, that would have, and this is all theoretical of course, [laughter] but that would have a serious implication on me.
P2 Yeah.
P1 That would not necessarily be the same for a non-Muslim woman.
P3 Yes.
P2 Even though it's private, but the implication for me would be much more serious, and a researcher would not necessarily be aware of that. And that's the whole … you have to weigh that up.
PUB4-db11 (608-161)

Other contexts that were identified as significant in terms of data sensitivity were those where the individual themselves might be reluctant to be visible to official sources or have their details on computer systems. This included refugees, women fleeing domestic violence or those who simply wanted to make a new start after difficult times such as a severe mental illness.

From the perspective of doing biomedical research the importance of some data being sensitive lies in the perceived consequences of that information becoming known outside of the research relationship. While biomedical research does not necessarily include the collection of sensitive data about the individual, it may do. Where it does, concerns about being asked for particular sorts of information raise the significance of watertight anonymity and confidentiality processes. As we discuss more fully in section 5.5.1, confidence in the security and reliability of promises of anonymity and confidentiality concerning personal data was in some respects quite fragile and could be considerably undermined by personal experiences of the failure to keep such promises.

5.3.2 Private data as personal

As well as sensitive data being personal, the group discussions revealed that participants also classified data that were 'private' as personal even when they were not necessarily sensitive. For example, information about one's age, name and address. Here, appeal was made to ideas about rights to privacy about one's own life details. A short exchange in one of the groups involved this idea of privacy:

P1 or you might have within the family, adoptions and things like that
P2 that's private, isn't it?
PUB4-db11 (237-267)

The idea of privacy was hard to pin down conceptually but it seemed to relate primarily to the right to keep some information about oneself to oneself. There are some obvious links here to the use of confidentiality in healthcare, where a patient can expect that information about their health will not be shared outside the health profession without their permission:

> Well, you might not want the other person in your household to know that you've got diabetes at all. Even if it's something that's not got any stigma to it, you might just not want it.
> PUB4-rb12 (261-267)

In one group a lively discussion occurred concerning why certain sorts of 'private' information were sometimes required from people in some research, such as their marital status. The key issue was that participants perceived some personal questions to be irrelevant to the research, and as such to be intrusive into their privacy. Through this discussion and other exchanges, it became clear that participants actively engage with the idea of research as requiring data and evaluate what they are being asked to provide in terms of how they understand it to be of use for the research being conducted. This has implications for biomedical research that seeks to gather general demographic and 'background' data in order to contextualise other data being collected, since problems of non-response or refusal may arise if participants do not see the relevance of the questions being asked and may feel the questions are overly intrusive.

5.3.3 Material data

In the group discussions we also explored whether data other than information were considered to be 'personal' data. We specifically introduced the idea of blood samples and waste tissue resulting from surgical procedures being a source of data in some types of biomedical research. Initially most participants did not categorise this material data as personal, particularly in respect of 'waste' tissue that has been removed for another purpose:

> Quite honestly with me I didn't think about it when they removed it [some tissue in surgery], what they removed from me, they didn't ask me if they wanted to go and do tests on it but if they did, I would think, go on, go for it because maybe you are going to save someone else…
> BIO1-dw17 (181:190)

In one part of the discussion we focused in on what participants thought about blood samples that had been given for one purpose (such as individual testing for anaemia) being used for research on something else, and whether they thought their blood sample constituted personal data. Most of the participants were clear that this type of material did not constitute 'personal' data, seeing it as either a waste product, or its re-use for research being acceptable as a benefit to society. However, this clarity was undone somewhat when participants discussed the possibility that research might involve the identification of some disease or pathological process in an individual's sample. In this participant-generated scenario, the waste material from an individual was transformed conceptually into personal data, since it holds 'information' about the individual as an individual rather than representing a sample of human blood which is de-individualised. The implication of this was that participants then wanted there to be the possibility that they could be linked again to their own sample in order to be given the information about them as an individual that has emerged out of the research:

P1 Well, I think the thing with that, what we said about epidemiology sort of stuff is that, in terms of research, is I'd want to track you back.
P2 Right.
P3 If they do find there's clusters of cancer, because of some environmental issue, or whatever else, you know, contaminated land, whatever. They've done as study and identified this and I'm now at risk, then come early, please. [laughter] I don't want to go through that sort of discomfort.
PUB4-db11 (378-392)

If it's concerning a health problem you have and they're doing all this research, it would be nice to be informed about what the results are.
PAT1-dw13 (272:280)

The participants sometimes expressed this as a right to know information about themselves. While this can be understood in this way, the significant point here is that the possibility of research generating knowledge specific to an individual (e.g. that they carry a pathological gene or detecting the presence of an abnormality) appeared to confer a personal dimension onto the data that is absent otherwise. In this context, participants effectively wanted to resume 'ownership' of this type of material data although they were happy to relinquish the material if the research would not generate information about them as an individual. When we explored this further, it became clear that this had implications less for whether people would consent to their waste tissue and material being used for research, and more for how consent and anonymity were handled. We discuss the latter in section 5.5, and issues for consent in the next chapter, in section 6.5.

5.4 The role of personal data in research

As we indicated earlier in this chapter, participants demonstrated an active engagement with the research process itself, thinking about different aspects of research, different types of research, and what it is researchers aim to do. Participants understood that what are personal data at the individual level in their terms, information about an individual's lifestyle, health status, geographical location, age, etc., could be aggregated with that of other participants to generate a bigger picture. For this reason, participants did not see the collection of personal data, even when they were sensitive, to be a problem *per se*. The key issues were the protection of anonymity and confidentiality and data sought by researchers being relevant for the purposes of the research.

R ...what [do] you think of as personal biomedical data?
P I think they want to find things out like is asthma more prevalent and the only way they can get that is by all this data from the doctors I suppose. Has a certain pattern increased in an area?
PUB2-dg03 (282-288)

Suspicions that researchers were simply being 'nosy' in wanting certain sorts of information about an individual were amplified where the information sought also had potential for breaching anonymity. Discussions about these issues stood independently of the question of whether the data were sensitive. Two participants, for example, agreed that there were limits to what ought to be asked for in terms of personal data, particularly if the nature of the personal data was such that you could potentially be identified from it as an individual:

P1 Apart from circumstances where you've got to deal with anyone, I don't see how your name or your actual address could help [research], so if you're researching, knowing someone's actual name or their actual address, location obviously we talked about asthmas but those pieces of information shouldn't be transferred, there's no need for them to go out.
P2 There's not a need for your name. If your name's Smith and there's a 25 per cent chance of [getting asthma] but if you live within half a mile of the M25, which I do, I have a greater risk of catching asthma than someone who lives [further away].
P1 The postcode would be enough. Actual name and address, there's no benefit.
PUB2-dg03 (296-300)

Here both are thinking about the personal data in terms of how they would be useful for the research question. In this case, if the statistics are being gathered about asthma and pollution, then in which area you live is relevant, but the specificity of where you live or who you are is not seen to be relevant. This was often linked to puzzlement over how participation can be anonymous if names and other identifying data are recorded unless it is linked directly to the research question:

P1 Isn't that supposed to be, it's all supposed to be anonymous? So, why would you need all that?
P2 Yes. Exactly.
P3 I wouldn't give my NHS number.
P1 No.
P4 It, it wouldn't bother me to give my name and the area that I lived in, 'cos I think they could do the research then, possibly.
P1 Yeah.
P4 But then I don't see why they need your full address.
R Yeah.
P1 And your number.
P4 But that's it, they could say, this person lives in this area, we could link in this sort of disease.
P1 Unless they were going to point out that, the, the statistics show that you are at risk of something, or, you know, I suppose …
P5 Because of the area that you live in.
P3 Yeah.
P1 Yeah.
P4 That's what I mean, so they could just have your area and your name. I think they don't need to have your full address. I don't see the reason for that.
PUB3-db09 (928-936)

Participants drew strong parallels between being asked for personal data such as name, address, date of birth, for research purposes and such information already being held on commercial databases in the public domain. This parallel appeared to both undermine confidence in the security of how identifying data are handled on the one hand and to engender a certain sense of resignation in the face of the ubiquitous presence of personal data on company files and computer systems which rendered hesitations about providing identifying personal data to researchers somewhat pointless.

P1 But would you have reservations about providing any, taking the point that it's just there anyway, do you have any reservations, personal reservations, about providing that kind of basic identifiable data [e.g. names or addresses]?
P2 Well, like [P3] says, they've got our names already and our addresses and our ages and how much we earn, so that's already there.
PUB1-dg01 (224-236)

The assessment of the relevance of the data to the research for which they are being collected became more acute when sensitive data were sought. In the film, Mrs Barker complains that the form she is filling in for her new GP registration asks her about the

number of sexual partners she has had over a period of time. In the ensuing discussion, participants drew attention to the seeming irrelevance of this data:

> And also…what is the relevance of that [number of sexual partners] to what she was completing? Was she going for an STD test, in which case it's relevant, but if she wasn't , why, then?
>
> PUB4-db11 (107-111)

Referencing the film, the question of whether Mrs Barker was in a position to deal with requests for personal data adequately revolved around her age (or in other respects, her generation) and the amount of information she was given about why the data were needed. In the film Mrs Barker indicates that she decided against providing personal data because she was unsure about why they wanted it and she did not trust the receptionists not to laugh at her answers (an issue to which we will return later). In the discussion groups, many participants felt that her refusal was not a good decision in that they favoured supporting research, but they felt sympathy for why she had refused. There was a shared view that older people in general were more vulnerable with respect to being asked for personal data:

> I think a lot of older people are completely bamboozled by the amount of information that, you know, a doctor or someone requires off you these days. I can't speak too much for myself but I imagine before it would have been name and address and just this, but I mean you start talking about it, your ethnicity, you know you background, this, that and the other and I think a lot of people think what relevance does that have to my health, do you know what I mean, why do you want to know all these other things? You know, is that really gonna aid your records? You know, so I think a lot of people may think that they're actually prodding in too far to their personal, well they just get this form and they just get confused by the amount of columns and stuff that they have to fill in really…
>
> BIO1-dw17 (101-101)

This generational issue was amplified in another group where they expressed concern about the process by which personal data are requested. Agreement to participate is predicated on certain understandings of what is being asked of the participant and, when these understandings are compromised, then participants may decide not to continue with the research. However, this option of refusal was seen as less available to older participants without support from, for example, a family member who could advise them not to answer questions that were too personal and/or irrelevant.

5.5 Personal data, anonymity and confidentiality

Much of the discussion about personal data led on to considerations of anonymity and confidentiality.[1] Indeed, the security of data was central to concerns about being asked for all types of personal information, but particularly so for sensitive data. The assurance and maintenance of anonymity and confidentiality was seen to be essential but was also viewed both as something hard to achieve in reality, and as something of a conundrum in certain situations.

5.5.1 Breaches of anonymity: identifying data

Most participants expressed concern or reservation about assurances concerning anonymity and confidentiality. Firstly, the provision of personal data in itself was considered to be a potential source of breach of anonymity as what is personal is what is individualised:

[1] Typically in research we distinguish between anonymity and confidentiality but in this study participants used this interchangeably as they saw the two concepts bound up with each other. In respect of this the chapter treats these as a 'unit' rather than drawing out the differences as researchers would understand them

[Participants watch Personal Information film]

R That was just a brief film there about personal data and Mrs Barker going to the doctors. What kind of struck you or caught your attention in that film? [...] What were your initial thoughts about the issues being looked at there?
P1 The confidentiality.
R The confidentiality. In what respect?
P1 That you're anonymous.
P2 Exactly, you're supposed to be anonymous, but I think we've all filled in questionnaires and at the end you think, right, what age are you, where do you live, how old are you, what group, what ethnic colouring are you? In the end you think sometimes it could lead back to you, especially if you're doing it for a work group.
PUB1-dg01 (34-34)

Secondly, concerns about breaches of anonymity stemmed from cynicism about the status of guarantees and promises of confidentiality and anonymity. People provided examples from their own lives that these promises did not hold firm and thus could not be relied upon:

> Numbers can be traced back to individuals. All of this whole data issue seems reactive. You read stories in the paper that now your data can actually, can harm you, I saw a thing about someone's plane ticket, just the end that they ripped off, was traced back and their identity was stolen from that. So all things like this are now reactive and now suddenly medical records, everyone is thinking well, from the stub of your plane ticket, they can get financial information, what can they do with all this?
> PUB2-dg03 (373-387)

Almost all the talk about anonymity and confidentiality processes was illustrated with examples from everyday life where provisions such as private ID numbers, secure storage of data, control of access to data had been undermined through human action. This included identity theft, obtaining of credit card ID numbers, files containing confidential information being found in public rubbish bins, and information simply being shared with the wrong people. These examples were largely drawn from media reports of these matters, but in the latter case participants cited direct or indirect experiences, as in the case below.

> … I remember going to the doctors and being given, this was a long time ago, and being given my sister's records by accident., and I was sitting outside the doctor's office going, reading it, ooh, potentially [name of particular illness]. Ooh, what's happened? And you know, it's just… So now I know and it's the unspoken, kind of, secret that goes round our family.
> PUB4-db11 (1304-1312)

Participants also understood anonymity as not only relating to name, but also to distinguishing features about an individual.

5.5.2 Breaches of anonymity: data processing

Another potential point of breach of anonymity or indeed confidentiality concerned the processes used in research to generate data. In regard to this, participants focused on how the information they might provide in a questionnaire administered in a GP surgery is 'turned into' data via it being 'entered' into a computer. This process of data entry constituted a 'gateway' to the potential compromise of anonymity.

> My biggest concern is information can be traced back to you and if the doctor acquires the information or the nurse does, or anybody else acquires that information and it goes into a central computer and it's traceable back to you, then the confidentiality's broken. I'm quite

> happy for all the boxes that I've ticked to be passed on, as long as there's no way it's traced back to exactly me who provided the information. I think we need to be reassured of that, but no one actually contacts us at all or tells us what's going on at the moment, do they?
> PUB1-dg01 (174-176)

This also linked to general concerns about new technologies coupled with the experience of the extent to which personal information is held extensively:

> R I mean, around the issue of confidentiality do you, when you're assured that your information is confidential, do you actually feel 100 per cent reassured that it is?
> P1 No.
> P2 No way.
> P3 I don't think anything is any more. I mean, in order to do banking over the phone now… and there's a lot of things that are supposed to be confidential, but they're able to read into so much so quickly now. If you are ringing up for a mortgage, er, within seconds your whole data is in front of them, your whole past is in front of them, you know, and I just feel where is your privacy? I mean, they seem to know all my personal business, within minutes on the computer, and I think that's quite frightening. Where, I'd like my business to be my business and private, and if I want to tell you, I'll tell you, but I don't want it all just up on a screen. And it seems to be with medical, everything, within seconds now, with modern technology, which in some ways is good, but I don't think it's always good with regard to your personal, private matters. I, I think it's all a bit too much.
> R Any other thoughts on that?
> P4 It's to do with people too, as well, that the data has to go through.
> PUB4-db11 (396-398)

While participants showed great confidence in their GP in terms of confidentiality and anonymity, this was somewhat less the case concerning the person who they thought most likely to be inputting the data: the GP receptionist. The problem of there being some sort of local connection between the potential research participant and the GP receptionist tended to lie at the heart of these reservations, alongside a sense that they were an occupational group which lacked the professionalism of doctors and nurses with respect to confidentiality. Thus, for many participants the idea of the receptionist reading forms containing personal data provided by the individual was very problematic because the receptionist is someone they might know personally, someone they might see while they were going about their everyday lives, and someone who might just gossip about the sensitive information to which they have access.

One participant talked about how she personally knew the receptionist at her GP practice as they had been at school together. This was contrasted by someone who was registered at a large practice and felt that they were unlikely to encounter any of those workers in settings outside the health context. For that respondent there was little concern about anonymity being breached in the process of generating personal data. This was the case too for another participant who frequently donated blood, a process which is covered by guarantees of anonymity and confidentiality. There was then a strong shared sense that the 'localness' to the situation of being asked for data at the GP practice which could (or did) cause problems with anonymity and confidentiality. All of these concerns heightened the sensitivity of the personal data provided and increased the risk that sensitive information might leak out with all sorts of negative consequences.

> But humans are involved [in data input]… humans are the sniggering receptionists…
> PUB4-dg11 (600-608)

This problem of the person reading the forms you have filled in being either unreliable, unprofessional or simply someone you know or who knows you occurred repeatedly

throughout the groups. In discussing the problem as the participants saw it, a solution was offered that underlined the problem of localness and perceived professionalism:

P1 But I think one of the things that the lady was talking about [in the film] was she fills out the form, she gives it to Meredith, or whoever she is, behind the desk, and then she said that it's only the doctor that can access it. But of course the lady behind the desk is probably the one that's inputting it. So, she's gonna, especially if it's was a local doctor's surgery she's gonna know things and ...
P2 The way I see it, if it's gonna be anonymous then it has to be done
P1 Elsewhere.
P2 … no names, elsewhere.
P1 Send it to Bangalore or somewhere.
P2 And send it to somewhere else, you know.
P3 But they must do so many of them a day,
P2 Oh, yeah.
P3 … that do you really care?
P1 If it's somebody that you don't know that's processing it, that's probably not a bother,
P2 I think it's the …
P2 … but if it is somebody you're gonna pass in the supermarket everyday, or in the local corner shop.
P3 Yeah but do you really, we see so many, there's so many, we see so many people. Yeah, going to the doctor is always private and you're always sitting there thinking, 'Oh God, I wonder what's wrong with them', 'I wonder if they know what's wrong with me', but at the end of the day you walk out of there and you're never gonna see them again really.
PUB2-dg03 (78-102)

However, in other discussions about the security of data provided, sending forms off to be processed elsewhere (particularly abroad) was seen as increasing the points at which anonymity or confidentiality could be breached.

In contrast to the poor reputation of GP receptionists, GPs themselves were felt to be highly trustworthy and not to present any threat or point of compromise to anonymity despite the fact that they would know their patients as individuals:

> The doctor usually knows you quite well so you don't mind your doctor knowing that personal information, if you've given it verbally or handed a piece of paper directly to the doctor, you've got more of a trust, but if you're handing it to somebody that you don't know, then you're not going to have that kind of relationship.
> PUB2-dg03 (198-204)

Interestingly, there was also a view that drug companies were the best organisations to be doing research, better than the NHS, because they were professional, focused only on research and well resourced:

P1 You see the thing with the health service is, the drug company would be a private company, whereas the, the doctor's surgery, they're all, you know, overworked, and they're all, well I suppose they still have their cups of tea and their … they're just, I would see the doctors as more everyday people, whereas I would see the drug people as sort of, professional, like doing it day in, day out. Whereas the receptionists have to deal with something other than that. So, they don't just concentrate on that, whereas the drug people probably would be concentrating on that more.
R Yeah. So, would, do you feel that, if a drug company was running a research into some clinical trial of a drug, and gave you assurances of…confidentiality and anonymity, that you'd, you'd be more ready to trust that they would stay within that?
P1 Yeah, yeah.
P2 And they've got too much to lose, as well, if you sued them.
P1 Yeah.

P2 If they breached the confidentiality.

P1 Whereas, you go in your doctor's, and you're just, you become friends with them, don't you and, you know, and you're really anonymous to the drug company, 'cos you're just a name to them. Whether you're a number, a name, whatever. Whereas, at the doctor's you're a person. That'd be my, sort of, take on it.
PUB4-db11 (139-154)

Surprisingly, then, the 'drug company' doing research was seen as more reliable and professional with respect to being able to honour and secure confidentiality than the NHS. This was related to the focus of the drug/research company being only on research, coupled with greater power of the participant in respect of being able to sue a private company should assurances prove to have been false. There were few references to academic researchers but those that did arise were discussed in the context of carrying out this study. Participants stated that it was the fact that it was university-led research that gave it credibility, and the belief that the university was bound by a strong code of ethics provided a further degree of reassurance about the security and appropriate use of personal data.

Alongside concerns that there were 'weak links' in the research chain which could lead to anonymity or confidentiality being breached, and thus to stigmatisation and embarrassment, there were also concerns about information being sold on for commercial purposes. Whether this could be the case for data provided to the NHS was a moot point. Some participants felt that any system was fallible, others were not confident that lists and information would not be sold on, while others indicated they had more trust in the integrity of both the health system and researchers.

5.5.3 Breaches of anonymity: data storage and security

Discussion about personal data and anonymity also included reflections on how data are stored and accessed, and the potential points that created for anonymity and confidentiality to be breached. These discussions were frequently couched in terms of people's own experiences of operating allegedly secure data storage systems in their work life. Reassurances such as password protection on computers, storage of personal data in secure locked facilities, and the operation of laws such as the Data Protection Act did not instil great confidence since many people could provide accounts of the failures of these systems. Thus while one participant who was a police officer could set out in detail how information about individuals was protected through passwords and systems that monitored who accessed the information, another participant who worked in a different setting volunteered that people 'borrowed' each other's passwords when they had forgotten their own. On the other hand a participant recounted how she had been reprimanded under the terms of the Data Protection Act when she commented out loud in her office that she had just received her own mother's file to process.

The question of whether or not computer systems were secure from hacking occasioned little debate since there was a general view that no system was secure in this respect. Rather, the point of debate was more the question of who would want to hack into research data.

P1 The thing is though, at the end of the day, we're all human beings, we all have like physiological functions, we all have things which go right and go wrong with our body, what is it that we're all so worried about protecting? What is it that…

P2 Yeah, and I was thinking, because I was thinking, what does it matter if they want to know how many people have got lupus, MS or cancer or you know? We're not gonna be affected by that, if they take any data off any of our records.

BIO2-dw19 (1097:1101)

However, companies with a commercial interest in that information, such as insurance companies, were felt to be potential culprits along with people intent on opposing certain sorts of research such as anti-vivisectionists or other protest groups.

P1 But also, the other thing is you can go to your doctor and you can see your medical notes, so there is that option, but I think the majority of people would feel it's open to abuse if it got into the wrong hands. And all these computers linked up, there are computers linked up that we don't know about, governments, they could know every single thing about us, the only thing they can't get is, is what you've got here. There are forms for every single facet of your life.
R Can I just kind of probe you a bit about that? Who are the wrong people in your mind?
P2 Someone who's tapped into MI5, isn't there someone who's gone to court recently?
P3 Yes, he was extradited to America.
R So you're concerned about hackers getting hold of your data? Are there other more organised groups of people you'd be concerned about getting access to it?
P2 Yeah, non-medical companies.
R Okay, non-medical companies.
P4 And also the groups who are against certain things, the anti-abortion people, political people, fanatical people.
R So you might be concerned about them getting hold of it and then targeting people?
PUB1-dg01 (785-790)

This latter concern that personal data which identified the individual were vulnerable to use by groups with violent aims was expressed across the groups. The issue here related really to more general anxieties in contemporary times about risk and identity. At the same time, while people had reservations about how secure a system could be, they also had reservations about how important that was in reality. This was summed up well by this interchange:

P1 … I don't find computer, like, computer information any more secure than physically stored information. Because, well, physically, obviously you can just break in and get it, type thing, if you really, if that's what you wanted to do, but I think there's people who can hack into police databases and military databases, do you know what I mean? There's people who, if they wanted to do it, they could. So, it's not that you'd really want to… I don't know man, because, to me, I don't care if anybody looks at my medical records, even if I had AIDS or HIV or ought. Like, I don't… like, it depends on the actual person. If you're not actually bothered, then it doesn't matter, but then…
P2 If you don't know that person anyway.
P1 But, no one's going to know who I am, do you know, I'm just a number, to you. Well you might even know my name, but it's not gonna make it, nine times out of ten you're not.
P3 We all know you.
P4 [name]!
P5 It depends, like you were saying, you touched on at the end. Who would want to hack into medical records? Who would want to go to the effort of hacking in to your medical records?
P1 I think the only people is kind of like, marketing people, who kind of want to like make money off people.
PUB3-db09 (567-587)

Thus, concern about security did not necessarily relate directly to concern about the consequences. These were perceived to be two separate issues.

5.6 Personal data and reversible anonymity

The matter of reversible anonymity and re-consent emerged in discussions about how important it was that personal data were protected. The ultimate protection of personal data (in its various constructions) was through the assignment of only a number to identify the data file. However, as we showed earlier, participants felt that data *became* personal when it held information that was pertinent to their own circumstances. In this case most participants were very sure that they would like this information, indeed that they *should* have this information given back to them on moral or rights grounds. This was seen to pose a problem though for anonymity and confidentiality since if data were highly secure following all personal identification being removed from them, then they would not be possible to trace back to the individual. Recognising this conundrum, participants identified the GP as the key agent in a process that would amount to a breach of anonymity. The view expressed by many participants a number of times was that research could be 'funnelled' through their GP. This person would have no interest in breaking confidentiality and so was completely trustworthy. This also tied up with questions of re-consent for further research on data already provided, where participants saw the GP again as the proper conduit for them to be re-contacted by researchers (see Section 6.4.4). In this respect, complete anonymity and protection of personal data was seen as a problem if it meant that personal health information about an individual would be known (or could be known) by the researchers but not provided back to the individual.

5.7 Conclusion

The concept of personal data was quite complex. It was most often thought about in terms of information about the self that was unique to that person. Additionally, personal data also included sensitive information relating to sexuality and sexual behaviour and certain potentially stigmatising health conditions. Sensitivity of personal data was seen to vary by other aspects of people's lives such as their ethnicity, marital status, age, etc.

Waste tissue and other material data were generally not seen as 'personal' data unless/until they contained information relevant to the health of the individual who had provided them in the first instance. In these circumstances, participants felt that the material data were personal to them and as such they had rights to the individual information generated out of the research. At the same time participants recognised the difficulty of doing this, but nonetheless felt that practical solutions could be found. This posed a challenge to the value of irreversible anonymity as a means of stopping data being personal (i.e. identifying the individual) since almost all participants expressed a desire to be contacted with the findings about their own data contribution. The resolution to this was seen to be the GP who was felt to occupy a protective intermediary role between the individual and the researchers.

Views about the acceptability of requiring personal data in biomedical research depended on questions of the purpose for which such personal data were being gathered, how they would be gathered, and how anonymity and confidentiality would be maintained. Participants were reluctant to provide personal data if they could not see how they related to the research question or topic. There was also an expressed reluctance to provide such information to intermediaries such as GP receptionists who were thought to be unreliable with regard to maintaining confidentiality, whereas drug companies, the GP, and professional researchers were seen to be highly reliable. The ability to protect data (and in effect stop them becoming personalised) was seen to be

better handled by drug companies because of their professional practices, experience and interests, and by GPs because of their relationship with individual patients. In general, though, considerable doubt was expressed as to whether promises of anonymity and confidentiality could ever be fully relied on, both because of the people who might be involved in the chain of processing data, and because other experiences in everyday life led participants to reserve their judgement concerning the security of systems, particularly those that involved computers.

CHAPTER 6: INFORMED CONSENT

6.1 Overview

The adequacy of research governance was more strongly anchored around concrete concepts like consent than in the much less tangible concepts of legislation, self-governance or external regulation (see Chapter 8 for full discussion). There was much discussion of the consent procedure itself: the form, opt-in/opt-out boxes and who is best placed to broker consent. Although the notion of consent was fundamental to participation in research there was some variation in the centrality of the consent process. This was a function of the type of research and the role of anonymity. The groups saw that practical considerations made the notion of one-off consent the most workable one. In order to take account of understandable differences in individual perspectives, the notion of 'levels of consent' was developed.

6.2 Introduction

One of the key aims of this research was to consider how people made sense of the notion of consent. We set out to explore the meaning of consent: how, why and when it might be important for people and to identify the characteristics of the consent process that signalled to people that they were part of a professional and safe framework of research governance.

We introduced the issues of consent to people in a short film (see Appendix 1). The film showed a professor being interviewed. The interviewer challenges the professor about his view of situations where consent might be of more or less importance and about the misuse of data. The film introduces the issues of re-consent and implied consent and whether the guarantees the consent procedure provides can be changed. As a further focus for discussion participants were also given a handout of types of consent and a copy of the NHS consent form itself.

6.3 The meaning of consent

There was strong agreement across the groups about the meaning of consent. The essence of consenting was seen to be the formal and explicit indication of understanding and agreement. It was about granting permission, entering into a contract and to some extent signified a willingness to waive personal rights. Although at one level it was very important to understand what was being consented to, it was generally accepted that it is not possible, or necessary, to know *all* the details of how the provided tissue or data will be used. Participants acknowledged that trust is required.

Across all the groups, being given choice and explicitly being asked for consent was invariably seen in principle to be desirable. Consent being sought was the foundation stone of participating in biomedical research in a democratic society. Once this premise was established it was then acceptable to specify areas where – in practice – exceptions could be made and explicit consent could become less important. The areas where the importance of formal and explicit provision of consent became less important were related to the role of the GP and to the type of research and will be dealt with in more

detail in sections 6.4.2 and 6.5.2 below. Although there were circumstances where explicit consent was less important, there was little leeway or 'wriggle room' within a consent contract that had been agreed.

The right and the desire to be asked was the dominant framing around consent, independent of willingness to participate in biomedical research: that is, those who expressed great willingness to participate also wanted to be explicitly asked. This was even the case for those that had previously taken part in biomedical research.

> P1 So are you saying that explicit consent should be the basic principle in most cases for use of your data?
> P2 See, I would have probably ticked that box anyway, I would say, 'if you need it for whatever', that wouldn't worry me but I think it would be nice to be asked at the beginning.
> BIO2-dw19 (124:137)

Participants generally agreed that the provision of choice inherent in explicit consent procedures was more likely to predispose people to greater willingness to acceptance, rather than refusal, of the opportunity to participate.

The strongest pro-consent position, most often expressed in the public groups near the start of the discussions, was that biomedical research proceeding without the consent of those providing data or tissues could be classified as abuse.

> I mean really its abuse really isn't it if they're using something of yours? It can be classed as abuse can't it, without your consent?
> PUB1-dg01 (946:956)

Participants referred to both past high-profile media stories and unwanted futuristic scenarios when providing examples of the dangers of proceeding without consent and of the way in which this could constitute abuse:

> P1 One of the things that was in the news that caught my eye was how they've grown a liver from stem cells, in a laboratory, and my immediate thought was, all those umbilical cords that have all those stem cells in them, when every woman gives birth, what happens to them? We don't know where they go. Have they already taken those, from, you know, which they should have just destroyed, we're never given the choice, and that's what, you know, when you start going down the road of ethics, isn't it? Because it should have been destroyed, but maybe they haven't been, and that has so much, you know, that's the way the science is going at the moment.
> P2 I think we all, basically, want to be asked, not just assume that it's okay.
> BIO1-rw18 (637:645)
>
> R What do you think of as being misuse?
> P1 Okay, misused to be used to [laughs], this is going to sound crazy, make things that are not used to, I don't know…
> R Make a mini-P1 [*name removed]*
> P1 Yes! [laughter] Do you understand what I'm trying to say, no you don't!
> R Help her out here, group.
> P2 It's like cloning…
> P3 The harm side of things, the negative side [rather] than positive, than looking for cures and things…
> BIO-dw17 (399:409)

Although there was strong agreement across all the groups of the importance of explicit consent, there was also recognition that prioritising personal choice around consent may work against the greater good: being able to choose not to participate carried a risk that medical progress could be thwarted or that important information could be missing about particular groups of people. Participants also had a clear awareness of the way in which the practicalities of eliciting consent are time consuming and they could envisage that there might be urgent public health issues where the consent process may militate against speedy and effective research on these issues.

In all the groups participants recognised that there was considerable variation in individual positions around the necessity of consent. People appreciated that where they themselves took a relatively permissive stance, this might contravene more basic values for others. They pointed out the difficulties in any system being able to successfully contain such a range of preferences and values.

> I'm thinking about the anarchists, the Buddhists, the Jehovah's Witnesses, and the complexity of it. I'm not disagreeing with you at all, but I'm just thinking about the complexity of one size fits all.
> PUB4-db11 (1109:1111)

As well as recognising that it was a challenge for systems of governance and the structure of the consent procedure to contain variations *between* people, participants also acknowledged the range of their own views and how these varied at different times and in different contexts. (Section 6.5.1 explores how people resolved some of these issues.)

6.4 Process of asking for and providing consent

6.4.1 Providing consent

Invariably participants stressed the need, in principle, for consent to be solicited in a situation where time and thought could be given to the information. Referring back to the Personal Information film, participants felt that Mrs Barker should not have been asked for her consent to have her data used in research while she was in the doctor's waiting room. This was linked with undue pressure and possibly embarrassment.

At the same time, however, participants noted that even when time *is* available, forms that are long and difficult to understand mean that there is a certain amount of 'hoping for the best' when boxes are ticked and forms are signed. Alongside this, consent, and providing a signature in order to signify this agreement was seen to be an increasingly routine event. Participants thus thought it understandable and even legitimate that people often did not give much attention to all aspects of the consent process.

> P1 We're a nation of signers, really, aren't we. Sign here. If you've got a nice face, we just do it.
> P2 You're right. You're right. You just trust people. You've signed your house away.
> P3 One of two things. I think it's laziness as well. As you say, two or three pages long, and you think I can't be bothered reading all that.
> P2 Just sign it.
> P3 You know what I mean.
> P4 And because everyone else was signing it as well. Everybody else was doing it. A lot of people would go, right, where do I sign?

P2 Yeah, I'm sure.
PUB3-db09 (1446:1458)

In the light of these barriers to some extent the decision to consent or not is based on heuristics or 'rules of thumb'. In the following excerpts from the public and patient groups, the approach of imagining a worst-case scenario is taken as a way of deciding whether to sign the form or not.

> A lot of these consent things can be quite lengthy in wording as, well, it's a contract isn't it? A lot of people aren't going to sit there and read through five pages of consent. A lot of the time I look at stuff and think what sort of damage is going to happen to me if I sign it without properly reading through it, depends what the risk is.
> PUB2-dg03 (776:776)

> And it's normally if you can foresee that there's gonna be a lot of problems in whatever you might be signing, you go 'mmmm', then you read it more but with a lot of these things we accept that we're gonna be signing these things, we know that they're going to be put in a drawer and nobody's even gonna look at it, I may have signed Joe Bloggs on here, maybe nobody's actually even going to acknowledge it whereas I think if it's something that's very important to you, or you could imagine 'right, I'd better do this, 'cos like, whether it be a solicitor, or maybe even when you're buying and selling a house, if suddenly there's something that you haven't read and you think, okay, if I sign my consent here and this goes wrong then that could be thousands of pounds, or, you know, or I could go to prison, something like that you're gonna read it whereas often quite a lot of these, maybe stuff that you don't understand …
> PAT2-dw15 (511:518)

In making sense of the process of consent for biomedical research people drew upon their life experiences in other areas such as solicitors' forms, having appliances serviced and going to the dentist. The most immediately relevant area of experience was consenting to medical treatment where the process of consenting tended to be associated with a sense of being under duress (for example, being in pain). There was also a sense of the 'consent seeker' seeking to limit their accountability for subsequent events.

P1 When you are in hospital you have to sign consent if they're going to do something, but you're in so much pain, you're literally not concentrating just hoping that what they're doing is for the best. What they're really saying is that if it screws up…
P2 You can't sue us.
P1 Yes, exactly, so I think it depends on where you are.
PUB1-dg01 (721:741)

6.4.2 Consent forms

Clarity of background information and of the presentation of options on the consent form is paramount. This is the case even where the most liberal attitudes to consent prevail.

There was considerable consensus among participants that they knew very little about what was involved in taking part in biomedical research and that more information was needed as part of the consent process. The point was also made that there needs to be a balance in the amount and presentation of information.

> I don't want too much information because I think that can sometimes put people off but you need almost a bullet point, like you say what the end result is, why you need extra people, whether you need their actual bodies or you need their mind or what you need or whether you need their blood, that sort of thing and that's it rather than reams and pages to read 'cos it

does just go over your head, you can't I don't think anybody can digest half the information that they give, I mean probably on half of these things, you'd have to take them home .
PAT2-dw15 (539:544)

NHS consent form

As part of the process of discussion around consent, participants were given a copy of the NHS consent form to look at. For some participants this proved a good example of where less information would be better. Others though thought the form was set out in a way that was clear and that encouraged understanding. Both the patient and the biomedical group highlighted the value of such a form not just being left for the patient to read and sign but strongly preferred the option of the doctor going through it with the patient. This preference illustrated the preference for receiving this information in the context of a relationship and is also indicative of the way that the need for reassurance may be indivisible from the desire for information.

In the patient group, there were several participants that had experienced completing the form prior to having surgery. There was a mix of accounts around this: some said that they had seen it and had it explained before signing and others either could not remember it or said that they had signed without reading it. In the biomedical group participants reflected on the fact that they had been less vigilant about reading the consent form for a medical procedure than had been the case around their participation in a biomedical research project; in hospital they felt that they would definitely be looked after. They were less sure about the care that would be taken around them as participants.

Research consent form

Another approach to encouraging the groups to explore the issue of consent was to invite their reflections on the consent form that they were invited to sign prior to participating in the discussion group itself (see Appendix 6).

Participants were well able to reflect on the process they went through in relation to signing the research consent form. There was considerable consensus across all the groups that the research being conducted under the auspices of a university gave them cause to trust that the process was official and would be conducted professionally. Other factors that communicated the credibility of the research were that participants were given some details ahead of time as to what the research was about and what would be involved. The fact that the option to opt out was also provided was also seen as indicative of a professional approach.

R Would it, does it reassure you, if, if, to have something like this to sign? How would you have felt about this research if, if we'd just, you know, brought you in, sat you down and got started?

P1 I think it shows that you're a professional in pointing out that is what's going to be happening. And that's sharing. It's sharing the information with each other, isn't it? This is what you're going to do, which is what we've all come to do, isn't it?
PUB3-db09 (1478:1480)

At the same time though other participants admitted they had not read the form before they signed it, said that it went over their head or that a brief scan of the form would have revealed anything untoward. It was also clear that others considered that signing was simply a formality given the innocuous nature of the personal information they had supplied and the fact that it was 'only' a discussion group.

> I have not given you my blood sample, you know, anything too personal. Okay, you have got my name and address but in this day and age what can you do with just a name and address? It's limited. So it is just a formality, things like today.
> PAT1-dw13 (422:442)

The heuristics that helped people make decisions around this consent form were primarily that the university was trusted and that there was likely to be no cost of participation.

6.4.3 Opt-in/opt-out boxes on consent forms

Some of the discussion around the process of consent focused specifically on the provision of an opt-in (or opt-out) box that would be ticked as a way of indicating whether or not consent had been given. Dealing with the opt-in/opt-out box was something people were familiar with negotiating in many other domains where form filling was routinely involved, for example around whether or not you wished your data to be shared with other companies.

Participants drew on their experience of 'ticking boxes' in other areas of life and noted the way in which this seems to have unwanted repercussions and that ticking a box did not always lead to the intended outcome. They were thus sceptical, if not cynical, about the guarantees that these boxes ostensibly embody.

> Do you know what I think undermines my trust in giving consent to people? It's when you get all these kind of telemarketing people phoning you up trying to sell you garage doors and all these sorts of people and they get really shirty when you can't get them off the phone, and they're saying, 'You've given us your consent', and what they mean is that at some point you bought a Kenwood toaster and when you sent the guarantee back, you haven't ticked the teeny weeny box, and I think that makes me cynical when considering the issue of consent in terms of this, which is a far more important, significant area, but it's kind of breached my trust in people.
> BIO2-dw19 (571:579)

The need for great clarity around the tick box was stressed. In one of the patient groups it was suggested that the format of this should be standardised so that medical research forms were always the same format. Some said that ticking the box should signal opting in. Here ticking to opt in is an active act that would protect those that omitted to tick the box, perhaps because they were unsure or forgot.

> R It should always be your choice and should it be an opt-in choice?
> P1 Yeah, opt in, I am going in rather than, unfortunately, not understanding it.
> P2 If you don't want to do it you just say no and don't fill in the form.
> P3 It's there for a useful reason, all this information that the patients put on the form, it's got valid uses for it. I think if it was an opt out but also they've got to outline exactly what the data is going to be used for and say this information won't be used for insurance purposes, just purely for medical research, tick this box if you don't want to be part of it, I think that would be clear?
> P4 It's better to opt in because that's going to take out all the element of I didn't really look at it, I was in a rush, I just left it, because then you're in and you might not want to be. If you do forget to look at it and opt in, it's not because you're still out, it should be an opt in because then that's all going to take out all of the risk of accidentally being in. If you've got to read it and you've got to opt in, you've done something to put yourself in, you've made the decision. If you didn't look over it or didn't do anything and you were still in, then that could become a problem. You've got to do something to be in.
> R Be active to get in?

P4 Yeah.
PUB2-dg03 (244:264)

The opposite view was also expressed, that the box should be ticked to opt out, with the justification that this would maximise the participants for medical research. In the quote below the view was expressed that the ideal situation would be one where the societal norm was that the default was that everyone was in unless they opted out. This would increase the likelihood that research pertinent to wellbeing and the greater good could take place. Another participant proposed that the emphasis should be helping people develop a better understanding of the implications of opting out.

P1 I think there's nothing lost with asking it more than once, or repeating what you're asking, because you've got the right to say yes or no.
P2 I think there could be societal norms, and I actually think, with things like transplant opportunities, and things like that, people shouldn't opt in, they should opt out.
P3 Yeah.
P2 Because there is the issue of time, and opportunity, and all the rest, for the greater good and well-being. And I think, I think if it's a societal norm, if it's understood, well informed, so in other words the education stuff has been done upfront, then I think there's no reason why every time you should have to opt into a consent. I think it should be the other way round, that if you choose to opt out, because you have other beliefs, or other feelings, or whatever, you have every right to opt out, and that should be enshrined. But I think it should be the other way round.
P3 I agree with that.
P4 You should have the option. You should have the option, though.
P2 Yeah, there should be the option. So the understanding should be about the fact that you're opting out.
PUB4-db11 (159:171)

It was felt that the tick box on the NHS form signalling that consent could be withdrawn was not early or prominent enough. This consideration of tick boxes and how the consent form was structured led to participants talking through how consent forms could better reflect a range of options around participating in biomedical research. At a basic level it was suggested that there could be two boxes in order that both opting in *and* opting out were made an active choice. This point is further developed in relation to 'levels of consent' in Section 6.5.1.

People recognised that where the consent-giving process was embodied in completing a form this might systematically disadvantage some groups of people. This point was partially made around the importance of guarding people with particular vulnerabilities but more around the seemingly practical impossibility of appropriate information provision necessitated by, for example, those with learning disabilities or those who speak other languages.

6.4.4 Personal asking preferred

Being asked in person was the preferable context for eliciting consent. More specifically, the GP is generally seen as the most desired access point for consent; the GP offers a pivotal role for maximising reassurance to potential research participants.

To some extent participation in biomedical research was linked to health and illness status and thus the GP was seen as an appropriate mediator of requests for consent that emanated from elsewhere.

R Okay, so just to go back to one of the points we made early on, do you think it's acceptable or not for the NHS database to be used by medical researchers to select people for a research study? So for example, searching the whole of the database for people with a history of say, cardiovascular disease.
P1 Yes I was just wondering about that.
P2 Surely they should go to the NHS and then the NHS does that.
P3 They should work with the doctors.
P1 Because anonymity should be there somewhere.
P4 Yes, we're trusting the NHS with our details, they should approach the NHS I think, and somebody in the NHS should then find out how many people, and then go back to them and suggest, there are some people… contact a certain amount of people that have that, but the NHS actually contact you.
P3 That could be done through your actual doctor.
P4 Otherwise you would worry that it would be going somewhere else.
PUB1-dg01 (1340:1353)

A personal conversation with the GP is all important both in terms of the initial consent process and where the possibility of needing to re-approach research participants was envisaged. A personal approach seems to predispose people to consider participation more favourably. It is, however, not just *any* personal approach that is valued. As suggested in Section 5.5.2 participants did not believe that the qualities attributed to doctors' receptionists and the way they worked matched the requirements of those mediating the provision of personal data. It was thus not credible or desirable that receptionists played a role in eliciting consent.

> What you don't want to do is fill out a form in front of the receptionist and then there's four or five receptionists laughing and giggling behind the counter, you're thinking, are they reading what I've just written on there or…?, that's why if you're just in a room with a doctor, it's just one to one and it's so much better.
> BIO2-dw19 (81:95)

The reassurance afforded by personal contact with the GP in the consent process in seeking consent (and re-consent) was sometimes seen as so important as to make other vital dimensions of the research process, such as anonymity, less weighty. The GP was seen by some as a gatekeeper who could be trusted to ensure that there would be no negative implications of consenting to research where anonymity was not guaranteed.

Alongside this however, all of the groups recognised the impracticality of using GPs' time in that way. Indeed in the patient group this theme was more fully developed into the idea that in reality such decision-making would be devolved to routine letter-sending orchestrated by more lowly members of surgery staff. Nevertheless, the importance of the GP surgery as part of the process of participation in biomedical research remained clear for many participants.

R So, would you think it's acceptable for researchers to be able to re-contact participants for this particular purpose? And if you do, how should they proceed? Are there any particular ways you think they should go about it? So generally, let's go back to, is it acceptable first of all in this kind of scenario, with the particular kind of disease that has had some research carried out on it?
P1 I'd say yes. I think in a case like that, yes, I think it would be acceptable and it would obviously be done through the GP. I assume it'd be done through the GP and records in the surgery, so yes I would. I'd be quite happy with that.
P2 I agree with [P1], but rather than actually through the GP, I think I would be comfortable with a letter from the GP. And then to say, if you want to discuss it further. But then hopefully sort of keep the actual process of it to a minimum as possible in terms of efficiency and time and cost involved.
R But you would be happy being contacted by somebody from a research team?

P3 No.
R Okay. Why is that?
P2 I wouldn't have enough knowledge to know whether they were bona fide or not. It would need that…
PUB4-rb12 (221:233)

The GP was not important for everyone. One participant who did not know who his GP was said that he would use the web to understand the possible implications of taking part in research. Another person in a patient group wanted to be asked by those doing the research and the GP would then only be approached if there were any remaining uncertainty.

People understood from their experience in other areas of life how understanding can be enhanced through personal contact and conversely, how just grappling with information on paper can lead to anxiety and uncertainty. Personal contact also seems to give participants a sense that the person that they are talking to is accountable for the transaction or exchange that has taken place. It was also recognised though that the recording of the transaction on paper was needed in a increasingly litigious society: a 'covering your back society' was the way this was expressed by a participant in one of the biomedical groups.

In discussing the role of the GP in mediating consent participants recognised that this was not equally necessary for all types of research. Where personal data were to be used in routine compilation and analysis of statistics, a notice in the GP surgery was seen by some to suffice.

6.5 The 'reach' of consent

There was considerable discussion in the groups of the 'reach' that the provision of explicit consent should have. Once given should it apply to other types of research or hold indefinitely across time? The baseline position across all the groups was that routinely proceeding with a variation in the agreed use of the data or tissue was not appropriate. This is not to say that such a variation in use was *necessarily* problematic. However, participants could clearly envisage that it was not 'right'. This was so even if they personally felt that, for example, once tissue had been provided that they were happy for it to be used in further research.

P1 If it was on a completely different subject, like, I don't know, Alzheimer's or asthma, or something like that, then I'd, I'd… But then I don't know, because I'm not in the situation. You'd want it to be related to the original research, I suppose… It's being respectful for people's… because when they did that original thing, that you know, it's respecting them as people, their… I'm not putting it very well, but when they did it, they; it was just going to be used for that. So to contact them again, rather than use it without their consent.
P2 So it would be important to get a second level of consent?
P1 Yes.
BIO1-rw18 (467:471)

6.5.1 Levels of consent

Participants were aware that re-use of data or tissue, in a way not envisaged at the point of consent, may be needed for important research to be done. One clear theme here was that if there were substantive changes in the agreed use of tissue or data, then, ideally,

the person should be re-contacted and re-consent given to the new use of their tissue or data. In part people justified this by saying that they may not have been happy to consent to the new use of the tissue or data in the first place. Re-consent was also seen to guard against the possibility that the data could pass from the aegis of one research body to another. On the other hand many participants felt that it was unrealistic for re-consent to be sought. They had a good appreciation of practical and resource implications that might be involved in needing re-consent and appreciated that once the data had been anonymised and the link destroyed between the data and the identity of its donor, being re-contacted was not possible. Some participants across all the groups felt that once they had given consent they were happy for this to apply to further use of the data or tissue. So, although the groups were aware that there was a wide range of individual opinions, the provision of one-off blanket consent was seen as the most viable practical system.

> The big issue is the way things change, there may, you may give your information now and be happy about it and then there may be a new disease that comes out and they're going to want to use your information for that, it can't be expected that they're going to come back to you every time. They might want a new study, they can't come back to everyone and say we're doing a new study, you said we can have the information, can it now be transferred to this, because they'd be on the phone to you all the time or whatnot and it would be costing them. But I could see how in the future something may come up and you wouldn't want your information used. So just saying once yes, you don't know what about the future.
> PUB2-dg03 (496:496)

The principles of wanting research for the greater good to be carried out and of the importance of explicit consent were balanced with recognition of the huge range of individual differences and of the practical difficulties of, where feasible, re-contacting people. Trying to negotiate and resolve the various tensions that this resulted in led to participants in the public and patient groups developing the notion of 'levels of consent'.

Particularly in the patient and public groups it was envisaged that there could be a one-off consent procedure where people could select from different levels of consent. These could range from the most permissive blanket permission for data and any collected tissue to be used for research for any medical purpose to other options that specified time limits or the nature of the research, who it was that would be conducting the research (NHS vs. private company), and/or how any re-consent process would be effected. Such a system would facilitate choice, minimise many of the practical issues necessitated by seeking re-consent and yet maintain the principle of making an explicit informed choice. It would also have the potential to take individual variations in preference into account.

The notion of one-off blanket consent was seen to be most viable when serious and credible systems are seen to be in place around the care of those data.

> R Then there's the question if that blood is going to be used for something else other than you think it is, is that okay? Or should they explicitly ask for consent, it might start off as implying it but then is there points at which point you should explicitly be asked?
> P1 It's got to be general. It's just going to get way too complicated if they're going down the route and saying yes, you consent to this and then they find something and then coming back do you, it's time-wasting, which we discussed on our board over there. If they need to just get on with the job and do it, I'd rather they just went ahead with it. If I've signed something to say they can use my blood, just go ahead and use it. I think it's highly unlikely if they come back to somebody the second time, they're going to say no.

P2 It comes back to what you were saying earlier, the proper safeguards around the information, how they collect it, what they can use it for, how it's protected and how long they can keep the information before discarding it, and the proper mechanisms for doing all of that. So when they do discard it, it's not they just erase it from their computer, they also erase all the tapes and all the rest of it.
PUB2-dg03 (746:750)

6.5.2 Types of research

There was no simple relationship between the type of research and the consent procedure. People recognised that research that might seem innocuous to one social group may have the potential to be used in ways that felt threatening to another group.

There was a strong core support across all the groups for the value of medical research. This was often juxtaposed against research that was for more superficial and (sometimes literally) cosmetic purposes. There was strong consensus across the groups that it was only medical research that was acceptable. The importance of representatives from all relevant population groups consenting to be involved in participating in research was acknowledged, as was the importance of participation over longer time scales.

P1 I think I might quite like an assurance that say tissue samples would be destroyed within 10 years or something like that, they wouldn't be floating around for years but then I'm thinking well, perhaps …
P2 Could help somebody else ….
P1 Perhaps certain research questions wouldn't come up until years and years later and it would be quite useful for them to have like a long-term back log catalogue of tissue samples, wouldn't it?
BIO2-dw19 (161:164)

Within this broad affirmation of the importance of biomedical research, it was possible to discern some ways in which the importance and the role of the consent procedure varied for different types of research. Explicit consent was particularly important around data that were considered to be sensitive and personal in a person's medical history or when it was not possible, or desirable, to anonymise the data. The type of research most acceptable with minimal levels of consent was around data being used for statistical analyses or epidemiological studies. Even here, however, there was a sense in which people wanted to know (ideally through their GP surgery) that it was being done.

It was often important for people to understand what type of research their consent was being sought for: what its aims are and what the data or tissue are going to be used for. In one of the patient groups it was suggested that uncertainty about what the research involved, through a lack of clear information, would increase a reticence to take part in research. The consequent uncertainties were seen to give a ready excuse for the non-participation of those not already committed in principle.

For some people it was important that they could see the benefits of the research and they stated that they would not want to take part in research where there was no obvious benefit or relevance or indeed where it was seen to be personally intrusive.

I think, I think it wouldn't really concern me if I had a medical issue and I was asked to take part, and I was given the, er, confirmation that it's going to be confidential, then I'd go ahead, if I was going to gain something from it. But if it was just for the sake of research, and it was how much do you smoke a day and how much chocolate do you eat, then no, I don't want to do it.
PUB4-db11 (510:510)

Although overall the patient group was most clear about the benefits that would be afforded by people taking part in medical research, it was not the case that the group thought in any way that the process of consent should be bypassed or weakened. The importance of how the nature of the research might affect the need for consent was seen in one group around the discussion of the Patient Information Advisory Group (PIAG). Overriding the consent agreement was seen to be permissible in relation to some research, such as for cancer or heart disease, but not for others.

> R My question is, does the existence of the operation of this group reassure you about patient rights and confidentiality? What do you think about the existence of this organisation?
> P1 Your interpretation made it sound quite feasible, but when you try to read this information…
> R I'm saying that there are certain cases where they can override consent. They can say consent does not have to be sought.
> P2 If it's for something really important.
> P3 People accept it if you mention cancer and heart disease. But when you say they're doing research, does that research ever include giving out drugs or treatment? And if you're going to people that are for some reason or another in a medical home and someone's giving the right to that, because they can't stand up for themselves.
> PUB1-dg01 (1989:1999)

For some participants it seemed that concerns around consent and re-consent processes were less salient in relation to research on tissues that had been removed (waste products) than they were in relation to personal information. One reason for this was that anonymity is easier to visualise around donated or waste tissue than in relation to information. Being able to visualise or imagine such anonymity distances many concerns. It also seemed that there was less interest in the purpose of the research around the donation or re-use of waste tissue; there was a sense that the tissue was no longer part of the donor (in the way that information was) and the links with the purpose of the research were therefore less relevant. (This also links with Section 5.3.3, which showed that waste material is not automatically characterised as personal data). These arguments, however, were not applicable to some types of tissue. Explicit consent procedures were vital around tissue that was considered intensely personal. Previous abuses of professional standards of research around babies and children constituted fundamental breaches of systems of governance.

Another perspective was provided by a participant in the biomedical research group who noted that in her experience it was easier to feel in control of participating in biomedical research when consent was limited to a particular project involving tissue.

> I think on the film, what came across to me was that if she ticked the box then it was all the information that was held on record that could be used for research. Whereas I think if it's just for one thing, you can control it more, it's more, it's more in your hands than the doctor's. That's how it felt, well that's how I felt when I did the research for the diabetes…said, 'yes you can have that but nothing else!'.
> BIO1-dw17 (122:122)

As noted earlier, as far as information was concerned it was the provision of information for statistics that was the least threatening as well as being seen as important and valuable, with little potential to be harmful.

> For data, for data I don't think it's quite as important 'cos they can't physically do anything with it or how I see that is more them collating, you know, numbers or figures or, you know, working out how many people have got cancer or how many people are likely to, I don't see

> that as being anything harmful to anybody else should I say, whereas if maybe it's … I don't know, blood I don't really have a problem with, I suppose it would, I don't know.
> PAT2-dw15 (546:547)

There was little consideration of the notion of withdrawing consent. This in part seemed to be because giving consent was considered such an active process and it was envisaged ideally as taking place at the beginning of the process of participation. Additionally, it seemed that this was not something that people had any experience of. Finally the question arose in one of the public groups of how one would know that the act of withdrawing consent had made any difference to the location and status of one's data or tissue. A similar point was made in one of the patient groups in relation to a blood sample: how is the act of consenting or not actually linked with the progress of a blood sample through the system? At what point for example, and how, does the withdrawal of consent stop the progress of a blood sample through the system? The notion that withdrawal of consent could effect such a change in the use of data seemed an unlikely scenario.

> I wonder what's in it stop sort of, I wouldn't say accidents but for things to go wrong, I mean you give blood, I mean how are they going to know that that blood goes into the system, you know for whatever reason to start with and then, then starts going on the research loop, how do they know that you've actually said you didn't want it to? Because I mean on the original loop it's going to find out if you've got you know, hepatitis or something like that, you know.
> PAT2-dw15 (1146:1156)

Along similar lines it was clear across the groups that participants did not know whether blood and tissue samples were routinely kept, how long they could be kept for or whether they could only be kept if consent had been given and how practice in this area related to the consent process (if at all). This was an area of considerable uncertainty that to some extent was considered illustrative of the notion of 'anything could be done and we would not know about it'.

Participants were generally able to reflect on the implications of their views well and when they recognised possible inconsistencies in them were happy to explore these. For example, when arguing for the importance of knowing exactly what their tissue or data were going to be used for, the biomedical group tried to discern the reason that they felt this.

> P1 The interesting thing though is that everyone's like, 'I don't want it to be used for this and that', but does anyone have like specific fears of what it would be used for, or is it just the fact that you wouldn't want it used for anything?
> P2 Could be the fact that it's taken out of our hands, we haven't got control over it anymore, we like to think we've got control over our lives, I suppose when you look at our lives as a whole, you haven't got the control over a lot of things, it's done for you, isn't it?
> BIO1-dw17 (382:387)

6.5.3 Implied consent

The analysis thus far has made it clear that consent was clearly seen as an explicitly active process. It is perhaps not surprising then that *implied consent* was not welcomed as a model of how the consent process might operate. People did not like the idea of implied consent even if they would have happily given consent if asked. It also appeared that the notion of implied consent was not something that people could easily relate to from their own experience.

Implied consent is seen to have no clear boundaries such as would be expected when providing explicit consent. There is also a sense in which it is seen as a slippery slope: that it might escalate further than its ostensibly harmless beginnings. It was hard for participants to conceptualise how implied consent might work in practice. Even the patient group, overall the most positive about participating in biomedical research, were suspicious as to what the notion of 'implied consent' might be used to justify; that taking blood might be taken as implied consent for any use to be made of that blood, for example:

R What about if you've given information, personal information to your GP, as you do, and there's your GP record. Some researchers would argue you've implied that you agree to that information being recorded, and therefore they would like just to have access to it, without coming back to you. What do you think about that?
P1 I don't like the idea of implied.
P2 No, neither do I.
P1 How far are they going to take it?
P3 That's it. That's right.
P4 It's insecure on both parties, I think, because, if I imply my consent to someone else, there's no proof of implied consent, basically, so you can always say, no, I didn't imply it.
P3 How do you prove it? There's no proof involved.
PUB3-db09 (1618:1634)

Overall the conclusion can be drawn that participants perceived implied consent as no consent. Although PIAG would govern research in circumstances where explicit consent could not be sought, no mention was made of this organisation because participants had no knowledge of its existence (see 8.6). While it might be thought that heightening participants' awareness of PIAG might alleviate their concerns about implied consent, there was no evidence in the data to support this; the fundamental principle of seeking consent still applied (see 10.2).

6.6 Conclusions

Consent is valued as a basic courtesy of the process of biomedical research. Qualities of the consent process and the guarantees it offers are important determinants of how comfortable people are to participate in biomedical research. They also signal the robustness of the care seen to be embodied in the governance of research. Many group members were very positive about participating in biomedical research; even so they remained strong advocates of the provision of explicit consent. The consent of implied consent was not felt to be a useful one and was considered the equivalent of no consent at all.

CHAPTER 7: DATABASES

7.1 Overview

In this chapter we consider participants' attitudes towards the idea of databases, and responses to the idea of linking different types of personal information databases. We examine why there is hostility to the linking of databases, and open this out to include a discussion about the NHS database, Connecting for Health, of which almost all participants were unaware. In exploring views about the use of the NHS database in a research context, in keeping with our earlier findings regarding the positive position participants take towards biomedical research, we observe that there is support in principle for research uses of this database but considerable resistance to its potential use in non-medical research contexts.

7.2 Introduction

To further understand processes of research governance we focused some of the discussion around databases of biomedical information. This allowed us to consider how people see the risks and benefits of such a system and what qualities of the system signal that the information is securely held. As a particular focus for the discussion people were given a handout with information about Connecting for Health, the NHS patient database (see Topic Guide in Appendix 5).

Some of the issues to be discussed around databases were first introduced with a short film (see Appendix 1). In a 'talking heads' format the two characters discussed the pros and cons of personal medical details being held on computer systems, and the potential medical benefits of GPs and hospitals having immediate cross-party access to patients' health records. In addition, the topics of linking databases and third-party access were introduced.

This chapter will consider perceptions of commercial companies vis-à-vis databases, the factors that concern or reassure people and the possible risks to individuals in pursuing public good. The final section looks specifically at reactions to Connecting for Health, and attitudes towards and acceptability of using the Connecting for Health database for research purposes. It was clear throughout that people had almost no salient and positive experiences of databases to draw on.

7.3 Role of commercial companies

There was extensive interest in the group discussions about the qualities of the companies that might hold or share access to databases.

The following quote illustrates some concerns around private companies:

> P1 I'm okay with it, but thinking about it further in more depth, I'm more concerned about these companies now, that have got our information. What kind of research companies are there? Okay, it's medical research but you have to look into all sorts now, it's like ethics and…

R So there might be some question about what type of third party is actually going to be getting hold of your data, say. Would it make a difference between whether it was a commercial company, public, privately funded?

P2 Well, yes, because if you give it for nothing and it goes to a company that uses it without you knowing and then they produce something and charge an enormous price for it, and are making a lot of money, you think, well, that's not really for the good of everybody concerned. It is good for the public, but you've got to pay for it haven't you, and so you would want at some level…

P3 That treatment should be free then.

PUB1-dg01 (535:541)

Participants assume that biomedical researchers within pharmaceutical companies will be able to access databases without the need to pay for this information. Therefore, their concerns are mainly centred on the perceived unfairness of accessing data without having to pay for this information, and then making money from it.

Participants within the patient group also made a similar moral distinction between what they considered to be 'ethical' and 'unethical' companies, with 'unethical' companies being those associated with profit-making organisations that do not fairly distribute any new drugs resulting from the research. The case of AIDS medication being too expensive for poorer countries (for example, Africa) to buy was cited as an example of unethical practice. There was a strong sense that if commercial companies are given access to medical data for research then everyone should reap the benefits:

> Yeah, but people are dying and they're not reducing the amount the medication costs.
> PAT2-dw15 (1173-1190)

It was widely held and strongly expressed among participants across all the groups that medical databases should not be exploited for financial gain.

Interestingly, it is not simply the case that private companies involved in biomedical research are seen as bad and that the NHS in this regard is seen as good. It was clear that sometimes research carried out outside the NHS (including the private sector) is seen by some to be professional, governed by strong standards and as having the resources to achieve and maintain these standards (this resonates with the point made in Section 5.5.2). However, there was a range of opinion on this point, with some participants taking a more pragmatic view of why private companies need to be involved. Participants' acceptance of private companies was not always based on a belief that they had particularly strong governance mechanisms but came down to the fact that it was only large companies that could afford to pay for research because the NHS does not have the resources. Despite this pragmatic approach, as discussed above this does not negate participants' concerns about possible profiteering, and the distaste for this aspect of commercial companies.

7.3.1 Insurance companies

A distinction was often made that while it might be considered acceptable for medical researchers to have access to databases, there was extreme resistance to the same information being made available to insurance companies:

P1 You give the information to one company, and that one company passes it to another company and then you think, well, I haven't given my authority for it to go off on that tangent.

R So there might be some concerns there.

P2 Medical research is one thing, but selling it to an insurance company is completely different.
PUB1-dg01 (561:565)

If you've signed up for research to be conducted by, you know, a particular group of people, say a medical company, then you would expect that they wouldn't really readily disclose any information to perhaps what they view as like-minded people in other areas, like life insurance.
BIO1-rw18 (485:503)

There was strong concern across all the groups around the possibility of insurance companies having access to biomedical data. This notion was invariably linked with individual or personal loss and cost. Participants warranted their concerns in this area with reference to past experiences. For example, a participant from the patient group was recently asked to provide information for her daughter's mortgage company in order for them to assess her daughter's liability. Due to this woman's medical condition, the daughter's premiums were increased. This fuelled concerns that insurance companies would eventually not need to ask for this information but would be able to access patient records without their knowledge.

There was also a lesser concern expressed by some participants who had taken part in biomedical research that the act of participating could be misconstrued, and assumptions made by insurance companies that one had a certain illness when this was not the case. To allay such fears, participants in this group stated that they would require greater transparency from researchers at the outset of the study regarding the use of participants' information once the study was complete.

At no point in any of the groups was it considered that the involvement of insurance companies in this area might be linked with beneficial outcomes.

7.3.2 Linking databases

In part, the discussion about non-NHS bodies holding databases focused on the way in which medical databases could be linked with other databases. Generally people could see the possible benefits of different medical databases being linked but tended to see negative implications of medical databases being linked with other types of data, such as information held by supermarkets and insurance companies. This was compounded by the lack of explicit explanation about what information could be gathered about an individual by a commercial organisation, and this sense of not knowing and not being fully informed made people feel uneasy.

The notion of databases being linked was seen to have the potential for real, and generally negative, impacts on individuals. The most extreme example was provided by a participant whose husband was a fire-arms dealer who had recently suffered depression. Fearing that if this information were made available to the police he would be unable to renew his fire-arms licence, he chose not to go the doctor with his condition so this information would not appear on his records. Therefore, a case was made for the fact that you should have freedom of choice regarding whether you want to give out particular information. Other participants challenged this view, arguing that if the person's condition negatively affected others, individual freedom of choice should no longer have priority.

The guy at my work then that doesn't own up to the fact that he has blackouts and he still drives. How would you feel if your children then got killed by that guy?
PAT1-dw13 (678:688)

There was also a sense that aspects of your health which may no longer be relevant would remain on your record, and linking up this data could lead to false assumptions being made about you as an individual, as a participant noted in relation to their previous alcoholism:

> Yeah, like if I had a car accident, they'd check it out to make sure I wasn't drink-driving because of the previous, you know, association. Unfortunately, it sticks…
> BIO2-dw19 (344:357)

While not having direct experience, public participants also made a similar point, suggesting that information held about you that no longer directly affects your health should not be shown on a nationally available database. The consequences of this information being misinterpreted or applied indiscriminately without consideration for a person's current circumstances were felt to be high, and participants expressed a great deal of anxiety about this issue.

To some extent, however, while unwanted, links between databases were perceived as inevitable.

7.4 Explaining the downsides of databases

People warrant the claim that there are dangers in holding biomedical data in databases in a variety of ways.

Experience allowed participants to readily document the claim that information in databases is not secure. People have little evidence that databases work well. As with consent, people used relevant personal experiences to make sense of the possible futures for biomedical research databases. People are also aware of shortcomings in the current system and experience tells them about the possible implications of, for example, lost sets of medical notes.

While the NHS is viewed as a trusted organisation, it was felt that the compulsion to streamline the system may take precedence over issues around safety and confidentiality which, based on participants' knowledge of the financial difficulties currently experienced by the NHS, might lead to breaches of confidentiality.

> I think that perhaps the NHS, because they're in such dreadful financial difficulties are perhaps not thinking everything, everything through properly. They're looking at cost more than safety of records.
> BIO1-dw17 (1099:1099)

People explain the possibilities for unwanted outcomes from databases both in terms of human frailty leading to mistakes being made around data entry and around more exotic and less experience-based beliefs, for example, about the possibilities of hacking into computers.

> R What do you feel about having computer access to your own health record?
> P1 Horrifying!
> R Horrifying, [P1], why's that?
> P1 Because computer changes over so quickly, months and people get access, they get into it and they will have big problem about identity stealing and things like that it really scares me […]
> P2 It is a secure site though, it is a secure site.

P1 But they say that about a lot of things and they're not.
BIO1-dw17 (573:58)

This theme elicited a range of opinions with some participants reacting very negatively to computer-based storage while others appeared to reconcile themselves to the fact that absolute safety could never be achieved, and that there had to be an element of trust involved.

> My husband gets concerned 'cos back online, when you go onto your bank account, he was told, 'You shouldn't do that. You don't know who's gonna get that information'. You just have to trust. Without trust you'd just be a bag of nerves. Just hope somebody's looking after it somewhere.
> PAT1-dw13 (356:359)

An important aspect of this argument emerged in a number of groups where participants appeared mystified as to why the prospect of someone hacking into a medical database was of such concern. An often asked question was: 'But what's the worst that can happen?' It was felt that the worst an 'ordinary' person would experience was an influx of unsolicited sales literature. The leak of bank details was seen as having a far more immediate, and detrimental impact on the individual, and this scenario was used as a comparator when evaluating the impact of sharing information from medical databases.

The notion that there were particular concerns about databases being accessed via the internet was explored in all the groups. The more common experience of online banking did not seem to offer particular reassurances in this regard. One dimension that was mentioned as being particularly concerning was where the care of the data might be outsourced to a third party. This was associated with a decrease in the levels of care and security that might be reasonably expected.

Regarding sensitive information, some people stated they would feel vulnerable if all aspects of their medical history were made available to personnel other than their GP, even within a medical environment. Participants thought their level of care could be compromised, and that they could be pre-judged.

A background theme to some of the concerns expressed above is that people are increasingly experiencing evidence of the amount of information that is held about them across a variety of domains. Experience also shows that computer databases containing this information are often poorly managed and unable to cope with the quantity of information.

> The downside that I see is in reality that just wouldn't work. It would be like the National Insurance system or the Working Families Tax Credit system where the computers were so badly managed and under-performing, that everyone's records were getting muddled up and it would just end up in a big horrible computer database mess.
> BIO2-dw19 (754:760)

7.5 What reassures people?

People saw it as reassuring that the data protection laws meant that the data contained within such a system as Connecting for Health meant that the data could not go outside Europe.

However, participants found little to reassure them in relation to the care record guarantee, again alluding to human frailty.

> R The NHS have issued something they call a care record guarantee, they're calling these the care records and to reassure you that your records will be kept confidential in this new system […] How far does this guarantee reassure you?
> P1 Not! [laughter]. The NHS, well look at the NHS. Who are these people? They're agency people and they're putting the data into it to start with. Who are they? Mr Manpower – he leaves tomorrow!
> P2 Are they going to sign like the Official Secrets Act or something?
> PAT1-dw13 (950-978)

We have already seen, in relation to the provision of personal data and consent procedures, that the GP surgery has a key role in providing reassurance (see 5.5.2, 5.6 and 6.4.4). The role of the GP and more broadly, the NHS, was also considered in relation to the management of personal health information held in databases. The way in which GPs and the NHS are considered and the role that they have is, however, more complicated than it might first appear. The GP practice occupies a credible and trusted gatekeeping role between the individual on the one hand and wider systems where individual information may reside. However, when the focus is narrower and concentrated on the interface between the individual and the GP practice itself there is a rather different perspective. In this instance, the doctor's receptionist is undoubtedly seen as a weak link. They are seen as not being bound by the same rules of confidentiality and experience suggests that indiscretions may occur here. Consequently, while the NHS is perceived as 'trustworthy', there may be individuals within the system who act in a less trustworthy manner. It was widely expressed among participants that access to medical records should be limited in order to take account of this.

A final mode of reassurance related to the removal of all identifying markers from participants' information. The provision of anonymity would further reassure participants when their information was used outside of the NHS. We recognise this may appear to stand in some tension with our earlier discussion about personal data and reversible anonymity (see Section 5.6). However, participants made a clear distinction between the desire for reversible anonymity within a medical context, i.e. where the use of their data was also a means of finding out about themselves, and the need for the greater reassurance of irreversible anonymity where no immediate personal medical benefit was forthcoming.

7.6 Public good and private cost

People appreciated the potential role of databases in research that improves our understanding of many diseases. As noted above, they are also concerned about the way in which data may leak from such a system with negative implications for individuals. The following quote shows that people are aware of and able to reflect on these tensions and contradictions. Following some discussion P2 suggests that the risks faced by the individual are an inevitable component of their data being part of the potential for societal good:

> P1 If they could do it for that [monitoring disease or infection in the population], they would find the most susceptible areas quickly and stop the spread wouldn't they. They would be able to immunise people against certain things that they can immunise against.
> P2 We've just contradicted ourselves.

P1 That's just it.
R I think X said it depends on the purpose and I gave you a very clear purpose for that piece of research didn't I – to be able to monitor outbreaks of influenza and you thought yes, they could then target the health service […] So people are happy about…?
P2 I think we're worrying as an individual. So that's when the contradiction comes in. We want the best for us, and we want the best for the group, but then if it's broken down and the finger points at you, you think where does this information come from, how do we get access?
PUB1-dg01 (1389:1413)

This exchange is a very good example of how participants adjust their position in relation to the ongoing debate. It enables them to recognise the contradictory nature of their position, but eventually leads them to home in on the fact that it is being personally identified that makes this research scenario problematic. Again, we see a return to the themes around data being rendered anonymous and unidentifiable that have been highlighted as important to participants in Chapter 5. Therefore, while this exchange demonstrates apparent contradictions, some themes remain constant throughout.

Participants also considered whether an individual should have the right to withdraw their information from being included in a database. People were unclear whether that was possible or indeed how one would know that this had been done. Participants were also alive to the financial implications for the NHS if consent had to be sought.

In this discussion too, the principle of the individual being given the choice again emerged. This elicited a range of opinions from those who felt 'freedom of choice' was the fundamental issue at stake, while others were less concerned with the general principle than precisely *what* information was held and who might have access to it.

Where databases were seen to have the potential to bring *personal* benefits this was well received.

7.7 Connecting for Health

7.7.1 Health benefits

There was almost no awareness of Connecting for Health in any of the groups. The fact that this system is being developed but that almost everyone had not heard about it prompted reactions of surprise and even resentment among group participants.

P1 Is this real or is it made up?
R That is real. Any initial thoughts?
P2 I think it's all right.
P3 Yeah, I think so too.
PUB2-dg03 (970:978)

P1 I love it, but with caveats attached.
P2 Is this happening?
R It's in the process. It's in the process
P2 Where's all the pubic information about it?
R Right, so…
P2 That's why it smacks of Big Brother, doesn't it?
PUB4-db11 (1203:1221)

Exacerbating this common reaction to Connecting for Health was the fact that the snippets of information participants had picked up were often via the press, and they felt most of the news they had seen or heard about it had been negative. It often focused on the high cost of implementing the system, and the fact that it was unlikely to work properly anyway.

As the excerpts above might suggest, people were generally positive about Connecting for Health although they suggested that there was likely to be some resistance to such a system simply by virtue of its being new and innovative. It was seen as being a particularly beneficial way of addressing some of the characteristics of modern life, for example that for reasons of mobility or a busy GP practice you may not be able to see a doctor that you know. In such circumstances, Connecting for Health was seen to offer a pleasing continuity of healthcare and the potential for increased efficiency by linking administration, doctors, drug prescriptions for example. People saw a range of personal benefits to such a system.

> P1 They could have a laptop in an ambulance and bring up things like if you're allergic to penicillin so they would know that.
> P2 Or if they're diabetic, they could go straight into the computer, measures it all out and it's there straightaway. Or, when you change doctors, no more filling in forms for 25 hours.
> PUB2-dg03 (844:854)

There were also benefits to be gained for society as a whole, as this participant's direct experience illustrates:

> I know it's not my research but my sister had a rare blood group and she's on the database country-side and they just used to come and pull her out of work and say 'There's an emergency' and she needed to give blood – that sort of thing […] If she hadn't put her details on the database, you know, on this database, then obviously someone may have died…
> PAT2-dw15 (198:198)

One particular aspect of Connecting for Health that, from the information provided, was perceived as puzzling and somewhat problematic was the notion that health record information could be added to by the patient themselves. It seemed that participants found it difficult to envisage how this might work and what the potential benefits might be; there was apparently no precedent for linking this feature of the system to positive outcomes. It was rather the case that the possibility of adding information was more readily linked to the potential of the system being abused. This was a strong theme across public, patient and biomedical participant groups.

> R …and by 2008 you will be able to actually access your own summary health record on the NHS webpage.
> P1 Why would you want to do that?
> PUB1-dg01 (1160)

> I think the thing that I see like a little red light coming on here is that you can access it and you can put additional information about yourself, about you. You said that you can add information about your health needs. Wow, I don't think so! [laughter] That's open to anything isn't it?!
> BIO1-dw17 (589:647)

> … but you'll be able to add information about your health matter – you will be able to! I don't agree with that […] If you've got a druggie who's on, I don't know what it's called in layman's terms, but cold turkey or whatever you like to call it, what's to stop them going into their record and upping their dose?

PAT2-rw16 (257:201)

Although there was some support for the idea that the summary could be used for asking for a repeat prescription, i.e. the functional aspects of medical care, there was a widespread view that only medically qualified personnel should be able to add information to one's medical records.

The possibility of being able to access, and even add to, the Connecting for Health record was also problematic in terms of the unequal access, or desire, to do this in particular sectors of the population, such as older people.

Some were considerably less positive about Connecting for Health, with one participant seeing it as yet another form of bureaucracy using up money that would be better spent on improving services.

> I want a health service to be a health service. I want it to be caring. I want the nurses to have the time to look after me, the doctors not to be on duty for 36 hours and there seems to be an awful lot of money ploughed into things that at the end of the day don't really matter, like this data thing.
> BIO1-dw17 (1105)

The following excerpt suggests that for some their understanding of this way of formalising/systematising their medical records was threatening and led to suggestions that people would not go to the doctors rather than their data becoming part of this system.

> R: So you think there must be an opt-out clause? You don't think it's automatic that you're entered into this system?
> P1: No.
> P2: I think it's far worse than that. I think people will opt out regardless. People, as [P1] as just said, people will stop going to the doctors, because they will be suspicious about what is being recorded and who can access the information, so they won't have this kind of debate, or discussion, or they won't question authorities, they will just drop out of it.
> PUB4-rg04 (1259:1267)

Overall though, people were positive about Connecting for Health when it related directly to improvements in their own medical care. For one group this was the take-home message that they wanted to leave with the Wellcome Trust:

> R Is there anything we've talked about today that you feel particularly…?
> P1 I, I liked the linking.
> R You liked the linking.
> P2 Yes, that's a good idea.
> P1 I think that's fabulous.
> P3 So that all, your GP and your hospital, everything, is all there in one database, and accessible. Definitely.
> PUB3-db09 (3477:3493)

7.7.2 Research uses of Connecting for Health

There was limited exploration of the research uses for Connecting for Health due to participants' unfamiliarity with the concept. Participants wanted more information about this NHS database, and were more interested in trying to understand how it would work for them in a medical context. As a new and untried system that they had little knowledge of, the focus of participants on the mechanics of the database is perhaps not surprising.

However, with the introduction of the issue, there was some support for the use of this database for identifying groups of patients with a certain disease or condition in order for a research study to be carried out, and participants across all groups welcomed this.

> R Let's say you're on a database with your name and address and let's say you have some sort of cancer, maybe quite a rare sort where it turns out there's going to be a very useful study that will be carried out to do with the development of the treatment of cancer and they want to contact those who people have got cancer […]
> P1 As a personal thing, if I actually got cancer I would want to be on that. One of the chaps in my department is in a wheelchair, something to do with wasting away, and he's been offered stem cell in about a year's time, when it comes in. He has to sign up straight away. He's only got about ten years to live – anything to help him improve.
> PUB2-dg03 (302:308)

Perhaps not surprisingly, there was particularly strong support from participants within the patient group and, similar to the theme noted in Chapter 4, there was an altruistic aspect which was predominant among the patient and biomedical groups.

> I'd like to think that we are all, you know, responsible adults and we all want the benefit of, you know, the human race and we're all looking after each other as well, not just for our own generation but our generations ahead of us. That's where I'm coming from.
> PAT1-dw13 (878:890)

However, there was not blanket acceptance to the use of records for this purpose. In part, this was because it was seen to breach one of the most important principles that participants had argued for throughout the discussion groups, i.e. that anonymity must be maintained in research contexts. In order to counteract this, some participants felt it was appropriate that their prior consent should be sought for research where it was necessary to identify individuals. This prompted a range of opinion regarding the usefulness of the data if all identifiers were removed, with some participants arguing that the data had to be useful for research, while others maintained that they too supported this idea but held on to the principle of seeking consent.

The need to seek consent was certainly less problematic if medical records were used for large-scale studies where patients would not be identified because anonymity would be maintained and the individual would not be personally affected. (This ties up with the point made in Section 6.5.2) The following comment is indicative of many participants' position:

> R Would you see, or how reasonable or unreasonable would it be for you not to be asked for your consent [inaudible], something that this anonymous level of data, number of people who've had a particular reaction to a drug, that research would be done without contact you?
> P1 At that sort of level I wouldn't have a problem with that. It's if it's more personal then I would have a problem with it.
> PAT1-dw13 (729:842)

> Well, I think with statistics you need a code of practice to ensure that you're not disclosing information that could be easily identified individually, and that's the only concern I have with this sort of area.
> BIO1-dw17 (658:669)

A second area where there was widespread support for the potential role of Connecting for Health in biomedical research concerned the way in which it might be used to register individual preferences for participating in biomedical research. It was suggested across

all the groups that the computerised records could indicate if patients had given or withdrawn their consent for certain types of research. If patients could add information to their summary care record, it seemed perfectly feasible to participants that provision could be made for patients to state their preferences, and any areas they would wish to opt out of.

> Standardise it then you've got, right at the beginning, you've got the option of medical research using your database, yes or no. If you say no then you're not on it.
> PAT2-dw15 (767:788)

There was little diversity of opinion about this issue although when a similar point was raised in the biomedical group, one participant who had the strongly held conviction that people should not have the right to opt out of this system challenged it. If they were receiving care from the NHS then they should expect to reciprocate by allowing data to be used without their permission. While strongly expressed, this position was not echoed across the groups. (See Section 6.4.3 for more discussion of opting in and opting out.)

7.8 Conclusions

The main issues to emerge in relation to databases centred on the implications of the linking of different types of databases. A variety of reservations were expressed but many of these related to who might have access to the data. Participants drew on their everyday experiences in making sense of the potential benefits and possible risks of databases. Many of these examples came from outside the health area, such as ID cards and online banking, but others were more explicitly within the health area, with particular emphasis being given to the indiscretions of GPs' receptionists.

While the NHS as an institution was perceived as trustworthy, people were not convinced that their data was completely safe and they believed there was the possibility for breaches of confidentiality, which the existence of the care record summary was unable to assuage.

People had not heard of Connecting for Health, other than in a negative context through recent media reports, but when it was explained to them, they were generally positive about the benefits such a system might afford, particularly the potential personal benefits when receiving medical treatment.

With relation to the use of Connecting for Health for research purposes, participants recognised that it was an important resource, but expressed some reluctance for using their data when anonymity could not be assured, especially where people might be identified, and sensitive information be used without their knowledge or consent. Research that necessitated identifying individuals required a greater degree of personal choice in whether or not to contribute, and participants wanted to make the decision as to whether or not their data were used. The giving or withdrawing of consent was an important issue.

Consequently, two main issues arose across the groups as giving cause for concern: assurances of anonymity and restricted access to sensitive information. But people would support the idea of *medical researchers* (as opposed to other third-party access) using their data if they were reassured about these issues.

CHAPTER 8: MODELS OF GOVERNANCE

8.1 Overview

There was general awareness of the Data Protection Act (DPA), some awareness of the General Medical Council (GMC) and British Medical Association (BMA), but less so for peer review, ethics committees and none for the Personal Information Advisory Group (PIAG). While the participants were generally positive about the idea of the DPA, they had many reservations, mainly concerning lapses and breaches. They saw self-regulation as positive because it includes medics who are generally trusted and they were generally positive about the inclusion of lay members. Participants were less aware of ethics committees and PIAG but were generally positive about them when made familiar with their ways of working. Again, people liked the idea of public involvement but questioned the selection of individuals to sit on the committees and groups.

8.2 Introduction

This section explores the views of the discussion group participants on three types of governance: legislation (DPA), professional self-regulation (GMC, BMA and peer review) and external research governance bodies and oversight committees Central Office for Research Ethics Committees (COREC) and PIAG. A great deal of factual information needed to be provided and this was done through a series of three posters, one on each area (see Appendix 1). The discussion proceeded through each of the three topics and then a short film on committees was shown (see Appendix 1).

The main example used for legislation was the DPA, and the Human Tissue Act was also briefly introduced. The information presented on this (Appendix 1) covered the principles of data protection and the way in which the provision of the Act is overseen by the Information Commissioner. It also made clear that there are penalties for failing to comply with the Act and that those adversely affected can seek compensation. This was discussed in terms of how effective the DPA was seen as being, how reassured people were by its existence and the use of a multi-purpose law to cover biomedical research as well as other areas.

Professional self-regulation was covered using the examples of the GMC, BMA and peer review. Each of these was briefly introduced and discussion centred on whether scientific experts are best placed to regulate in these ways and how much people trusted organisations and individuals to put the public's interest first.

The third area discussed was external regulation, where the examples of research ethics committees and PIAG were used. The operation of research ethics committees was briefly described and groups were asked for their views on how effective these were seen and whether all research should be dealt with in this way. PIAG was briefly described and again discussion centred on whether this was reassuring to members of the groups.

One of the key questions in this part of the work was whether the participants viewed each of the different models of governance positively. Another theme was the involvement of lay members as well as experts in the latter two models.

8.3 General

This section of the discussion groups made considerable demands on the participants. It was very heavy in terms of the provision of information and in many cases the participants had not previously heard of the bodies involved or, if they had, did not know how they operated. Unlike the more concrete discussions that participants had developed around personal information, consent or personal information, participants struggled to discern the relevance or consequence of the models of governance.

8.4 Legislation: Data Protection Act (1998)

Across the public, patient and biomedical groups, it was clear that awareness of the Data Protection Act is primarily drawn from work roles or personal experiences of trying to obtain personal information in various contexts. Both the DPA and the independence of the Information Commissioner were seen as providing some reassurance that there are safeguards in place. Participants suggested that the Act makes people aware of the importance of protecting personal information and ensures organisations have procedures in place to protect data. Generally participants were in favour of the DPA as an idea and felt that it did offer some protection, although they often used examples of how it had prevented them from doing things in order to demonstrate its effectiveness.

> You can't ring up the dentist on behalf of your wife and check her dental appointment. If you ring up and say my wife's got a dental appointment tomorrow afternoon, she asked me to ring up and find out when it is, sorry, sir, I can't tell you. And if they ring through to you, you can guess, if it's about two o'clock and say yes. It's bizarre. So obviously it's protecting your rights on that day but you can guess it.
> PUB2–dg03 (1336:1342)

However, while agreeing that the DPA provides some sort of a safeguard, across all the groups there was far more discussion of problems associated with data protection than there was of the benefits. People showed awareness that nothing is totally foolproof and there will be human error and ways around things. Some participants suggested that the DPA may be difficult to enforce, particularly because it is difficult to tell when it has been breached. In general, across public, patient and biomedical groups, participants were not reassured by the existence of the DPA.

In several of the groups there was discussion about whether there had been any prosecutions. The suggestion that there may, as yet, not have been any prosecutions under the DPA against research companies made people feel that it is perhaps not as effective as at first glance it might appear.

> P1 How many prosecutions have been brought, do you know?
> R I don't think there's been any yet, have there?
> P2 No.
> P3 So that means nobody ever breaches it, how wonderful!
> PUB4–rb10 (1501:1509)

Personal experience led people to believe that leakage of personal data must happen, and that a lack of prosecutions just meant that the law is difficult to enforce.

R But we couldn't find any prosecutions that were made for a researcher in one agency, a university, or a drug company, passing on names and addresses of research participants.
P1 That's good to know.
R It may be that it doesn't happen. It may be that it doesn't get picked up.
P2 To me, that gives the opposite effect.
R Does it?
P2 As if to say it's not good enough.
P3 Because it's got to be happening?
P2 Because it's got to be happening, you know.
PUB3–rb10 (927:975)

Just as some participants were able to detail occasions when the DPA had seemed to be working to protect their own data, or a family member's data, so participants were just as able to quote personal experiences of when they have known that data have been leaked and hence a breach of the DPA has taken place. These breaches were not considered necessarily to be purposefully and maliciously committed, but possibly accidentally, through a person carelessly giving out confidential information, information being left around the office instead of being locked away, general human error, or where the people involved in giving out the information really did not understand the DPA or apply it correctly. The examples given by the participants included both personal and professional experiences.

> Just goes to prove that they can't really enforce it that well when you keep getting all your calls from abroad all the time, 7.00 every evening, people trying to sell you double glazing and, 'You need this new phone and that new phone', they're obviously getting all that information from somewhere.
> BIO2-dw19 (1045:1062)

There were concerns over whether organisations follow the DPA correctly. Other participants mentioned the potential for human error. Talking about an incident with the Inland Revenue's Tax Credits Department, one participant highlighted his experience when he asked for a recording of his conversations with the department, and he also received information about another person.

> However, on the downside, you can't help human error, I was saying this earlier as well, on the disk they sent me with my recordings, they also accidentally put on two conversations they'd had with a lady in Wigan, all her private stuff.
> PUB1–dg1 (1550:1576)

Not only did people talk about their personal experiences of data leakage, but they also drew on their experiences of poor data management by other government departments, or within other government agencies. Most of the discussion used examples from outside of the health area and certainly outside of the area of biomedical research.

Other discussion centred on enforcement of the Act. If a person's data are leaked or misused, the ability to enforce the Act lies in the fact that the individual needs to be aware that this has happened, to know who is responsible for the breach and to know how to take action. If somebody is aware that their data have been misused and wishes to seek compensation through the DPA then they need to prove this, which is difficult to do, particularly as it comes down to the individual versus a large, financially secure company. This puts a heavy onus on the individual and makes it difficult to bring a successful case.

P1 But the Act allows for reasonable compensation, doesn't it? So you can have all your neighbours find out that you've got three wooden legs, and it might impact the way they see you, but you can be compensated for it.
P2 But you have to prove, well firstly the negligence was obvious in that case, but you have to prove the damage.
PUB4 – db11 (1695:1719)

Overall the patient groups gave very similar responses to those of the general public groups. While the biomedical groups also gave fairly similar results, they did also call upon their experiences of taking part in biomedical research as seen in the following excerpt:

R In relation to research in particular, in terms of having this information for research purposes and who it allows access to it, are there reassurances within this that information for research purposes [inaudible] misused? Are you reassured about that or not?
P1 Well, nothing's come of the research [inaudible] myself, nothing's come back to, no-one's ever banging on my door about anything.
R So how does that make you feel, that does give you …?
P1 Yeah, confidence, yeah, you know if it did ever happen, if I did another biomedical research and they went against it then, you know, I would have two legs to stand on in a court of law whereas they wouldn't so … yeah, I mean I don't know about anyone else has had any bad comeback from it? Anything they've done?
P2 No.
BIO2-dw19 (1063:1067)

There was also a feeling that in the context of biomedical research failure to comply with data protection could backfire on the organisation carrying out the research if there was a problem. However, this was not seen as a real safeguard because the information would already have been released.

P1 But those organisations, which don't, are not up front, then it will backfire. And they'll also invalidate their research.
P2 But on the other hand, your names would be…
P1 Disclosed. Yeah.
BIO1-rw18 (549:601)

Various participants suggested that the DPA could be made more effective by giving companies huge penalties for breaking the Act, and in this way they would be less likely to breach it. The penalty could be a large fine, or closure of part of their business, etc. The suggestion was made that companies making large profits need a really severe penalty in order to deter them.

One person in the biomedical group also expressed the opinion that they would like to have access to the data specifically in the context of biomedical research.

It would be nice if you could access it so that you could actually see if somebody had taken non-consensual information out of there, so you could sort of go in and tell if somebody has been in there, they've looked at this and you can look into it and say "right, why have they taken that out?", just to sort of satisfy in your own mind they've just taken it out for this sort of research and that's fine. I think it's the unknown piece where it's, you know, to remove data without consent, I mean if you can see what they are taking out and what it's being used for, obviously after the data's been removed then you know, it will help you in sort of, satisfy you that it's being done properly.
BIO2-dw19 (1071:1091)

8.5 Professional self-regulation

Professional guidance (GMC and BMA) and scientific peer review

Across all the groups, participants seemed relatively comfortable with professional self-regulation as a model of governance. Just as people referred to the doctor as a point of trust, as the GMC and BMA are medical organisations, which are involved with and include doctors, so these organisations were generally felt to be trustworthy and professional. The GMC and BMA were seen as upholding the guidelines and working towards the benefit of society, rather than trying to cover up for the people who break these guidelines. In general the GMC was viewed more positively because it has powers over doctors, with the ability to prevent them practising.

> P1 You'd think they'd spend their whole time looking after themselves and their members and covering their backs, whereas just in the same way as the Law Society, their role is to maintain the highest possible standards, and if a solicitor abuses his client account say, he'll be struck off, no mucking around and it will be done by his own people, and I do believe this is exactly the same thing; these people are working to the highest possible moral standards and the interests of the people who are being looked after, not the people who are looking after them.
> P2 They've got too much to lose haven't they? So they've got to be professional.
> P1 So they're not hiding the Harold Shipmans, they're trying to seek them out.
> PUB1-dg01 (1700:1720)

However, there was also a view that self-regulation without any outside oversight or lay involvement could be a problem and that this might lead to abuses. The Harold Shipman case was mentioned on several occasions as an example of the failure of the system. Although this is used as a counter-argument in the above quotation, reference to Harold Shipman was more generally used an argument that pure self-regulation does not work.

Participants were generally concerned that letting experts regulate themselves could lead to a conflict of interests. Although not common, some people reported experience of the medical profession appearing to look after its own interests through these types of bodies and as in many other areas called upon personal experiences to illustrate this.

> I've found in practice when I was misdiagnosed and then everybody shut down, the profession shut down and didn't help me for two years and then they started coming round, but it was still never said, 'we got it wrong' or nothing, it was just covered up and …
> BIO1-dw17 (795:806)

Including lay members in these bodies allayed worries about potential conflicts of interest and was seen as providing a balance of interests. It was also considered to overcome the idea of a self-serving group 'covering their backs'. There was a concern that there could be a difference between what experts want to happen scientifically versus what the public wants. Involving members of the public, people from outside this scientific/medical background, was felt to give some reassurance that this will not happen. However, several negative aspects of public involvement were also raised, e.g. getting in the way of the proper process of the committee due to lack of knowledge.

> If ever you've got a committee where there are people who are there that don't understand what you're trying to achieve, they get in the way, they slow it down, you've got to go right back to basics, explain why it makes good common sense to do it. I think all that having untrained people on the committee would do is just slow it down and it would get clogged up.
> PUB1-dg01 (2136:2136)

Also participants were concerned that lay members' views might not always get listened to and that experts would just do what they wanted anyway. Part of this worry was based on the fact that the lay members lacked this expert knowledge and understanding. However, overall lay involvement was seen very positively and there was felt to be a need to have such people on committees and bodies regulating this area.

The general public groups had little to say on the issue of peer review beyond noting the possibility of experts having vested interests. However, the biomedical groups showed a somewhat more sophisticated view on this. They generally saw experts as the ones who should review research but in this context also brought up issues of the need to have external ethical review, which was subsequently raised with them later in the session.

> I do agree with it, I mean they're experts in that field at the end of the day, I mean they're studying it all of the time.
> BIO2-dw19 (1121:1129)

> As long as they're publicly published then yes, because probably the best people to do the review work are other kind of leading scientists in that field, because there's so much, there's so much kind of academic study that goes on, they've got a real incentive to kind of critique that work and to find something wrong with it and come up with a better idea so … I, you know, and also obviously they've got the background knowledge and everything that would be necessary so yeah, it seems to be the right way of doing it to me.
> BIO2-dw19 (1130:1137)

8.6 External research governance bodies and oversight committees (COREC and PIAG)

There was little initial awareness of research ethics committees and no awareness of PIAG, although one participant felt that the name was familiar. Views on these bodies were mixed. Much of the discussion centred on how people were chosen to be on these groups, including lay membership, and on the regional nature of ethics committees.

Participants in the general public groups were generally in favour of using committees as a model of governance examining whether research is ethical, although this was not so clear in the biomedical and patient groups. People were reassured that research is controlled and assessed and that researchers have to go through these committees in order to gain approval for their projects to go ahead. The idea of a committee making decisions was favoured because it allows ideas to be challenged and thoroughly discussed and debated by a group of people.

> 'Cos some, I could sit here and you could present me with the lines, and I could think, 'Oh, you're wonderful', but I mean, without that ability to challenge and dig that little bit deeper, which is why I don't want it to go to governments, I want it to go to committees. I want to scrutinise, that people will challenge and seek evidence, and not just accept what they're listening to, and I think that's an important part of the process.
> PUB4-rb12 (2061:2061)

However, there were contrary views with one person in the biomedical group suggesting that unethical research happens despite these types of safeguards. Also in the patient and biomedical groups there was some surprise expressed that a research ethics committee can stop research and there appeared to be no appeal against the committee's decision. Although this was not a topic of very much discussion, this could

be interpreted as their seeing these committees as having too much power over whether particular pieces of biomedical research are conducted.

In another case the view was expressed that research should not go through an ethics committee if it were very important or urgent (e.g. avian flu) and when this was raised there was general agreement within that group that the procedure would not be followed in such a case. In such circumstances, people were very permissive.

R So you're saying in that situation, a public health issue, it would be warranted to sidestep this particular process?
P1 Yeah …
P2 Absolutely, yeah.
P3 I think it would be completely taken out of your hands anyway wouldn't it? I think government would …
P3 The public would demand it I should think more than anything.
BIO2-dw19 (1165:1180)

In this case the procedure of going through a research ethics committee (REC) was seen as dependent on the type of research and would only be used for more routine research.

Negative views on ethics committees included that they are bureaucratic and that the committees do not have a clear set of criteria or benchmarks against which to assess proposals.

P1 So these people don't have any kind of criteria, established criteria for making their assessment? There's no formal criterion that they make that [inaudible] for each …
R Do you think they should?
P1 Yes. Almost like a benchmark process perhaps.
BIO1-dw17 (903:907)

A great deal of discussion took place about who sits, and who should sit, on a committee. Generally, participants liked the idea of public involvement. Lay membership on both the RECs and PIAG was seen as a positive thing by the public groups but this was less clear for the biomedical and patient groups. Participants felt it was necessary to have a variety of people from different backgrounds on the committee, so that a range of views could be represented. Lay involvement was seen as help to protect against any vested interests of the experts. This was similar to the discussions reported earlier in relation to self-regulation.

P1 No, I think you need more than the medical experts.
P2 You need that balance.
P3 Especially ethics, it doesn't mean you're right, you have a different view or a different objective…
PUB1-dg01 (2041:2053)

The members of the public sitting on the committee were not seen as actually having to have medical knowledge, as the actual scientific decision making was seen as more appropriately left to the experts, but the public should be there to provide an alternative opinion, to debate the ethics of the decisions.

Lay representation was seen as adding transparency to the proceedings. Being transparent and open, e.g. making minutes of meetings publicly available, as PIAG does, was valued by participants. They were more likely to put their trust in that committee or body. Although participants were in favour of lay representation on the committees, they were interested to know how people were chosen for the committees and whether they

were in any way representative. As with many of the areas discussed, they did not know how this happened.

As transparency of proceedings was important, the fact that RECs meet in private was seen to be an issue because they were not felt to be open and transparent by all of the groups. In a number of cases the participants used the phrases ‘behind closed doors’ or ‘cloak and dagger’ to express their concern over this lack of openness.

> It’s all sort of behind closed doors isn’t it?
> PAT1-dw13 (1147:1163)

Across all types of groups there was a great deal of discussion about the regional nature of ethics committees. There was not an overall consensus but rather some felt that this would be good because it would take account of differences in the needs of different regions whereas others felt that it would lead to inconsistencies across the country.

> P1 Well it’s like the postcode lottery in the NHS isn’t it, what’s okay in one area might not be okay somewhere else.
> R Inconsistency?
> P1 Yeah, so it’s the whole … consistent, applying the rules kind of approach which ...
> BIO2-dw19 (2:99)
>
> P1 I think the structure breeds inconsistency. If you talk about the NHS is going to have a national record, why have regional...?
> P2 I think you’ve got to have regional because what affects us here in Surrey won’t affect Scotland.
> P1 I see that but there’s going to be duplication and inconsistency. There's an argument for both; I'm not sure.
> PUB2-dg03 (1562:1578)

In general people were positive about PIAG although it is not clear that they fully understood the role of this body. However, in some cases there was disagreement on this.

> R And there’s a group, the Patient Information Advisory Group, which monitors these registers, what do you think about that kind of arrangement, that there’s a monitoring body but there is this exemption, so if you had this, have a cancer, it might be that your GP says, ‘I’ve had a request to ask you whether you'd like to take part in a further study’?
> P1 Why not? It’s gonna benefit you and possibly future generations, I can only see the benefits.
> P2 I can’t.
> P3 I have friends who join things like that, yes.
> PAT1-dw13 (1209:1217)

Some participants were also concerned that PIAG has the power to override an individual’s decision not to give their consent to take part in research/certain types of research, as discussed in more detail in Chapter 6 (see 6.5).

> R What about issues around confidentiality? PIAG can override some of the other aspects of [inaudible] benefit society at large and so your rights to confidentiality have been removed. Is that, does that kind of making anyone concerned or do you think it’s a perfectly acceptable scenario? Or would it go back to some of the things you said earlier, you would need to know all …
> P1 You'd need to know, they can’t just take your rights away.
> BIO2-dw19 (1227:1232)

Despite PIAG offering some reassurance that research was properly controlled and some expressions of approval, we cannot infer from this that people become more permissive in relation to the giving of consent. As the comment above illustrates (and is discussed in detail earlier, see 6.5.3) the giving of consent is considered a basic right, and attempts to bypass this are not well received.

8.7 Conclusions

The participants were generally aware of the DPA and there was also some awareness of the GMC and BMA. Research ethics committees and peer review, however, were less familiar and PIAG was not familiar to the participants. While the participants were generally positive about the idea of the DPA they had many reservations, mainly concerning lapses and breaches. They tended to call upon personal and professional experiences of examples of lapses and this undermined overall confidence in the working of the Act. Also the lack of prosecutions concerning research led to a degree of cynicism about how effective the Act really is.

Participants saw self-regulation by the GMC and BMA as positive because it includes medics, who are generally trusted. They were also generally positive about the inclusion of lay members since it was felt that they would bring wider views to these groups and maybe temper the views of those inside the profession but felt that they might be hampered by their lack of expertise. Participants were less aware of ethics committees and PIAG but, after explanation of how these committees worked, were generally positive about them. Again the participants liked the idea of public involvement but questioned how individuals were selected to sit on committees of this type.

CHAPTER 9: THE VALUE OF DELIBERATION

9.1 Overview

It was clear in all the groups that people were happy to reflect on their lack of previous knowledge of biomedical research and to suggest that the day workshops and the reconvened groups had highlighted many issues of which they were unaware. People said that they had been interested in and engaged with the material that had been presented and in the discussions of their group. The impacts that deliberation had on people's views were complex; some said that they were more willing to take part in biomedical research, others said they had increased reservations. Whatever the nature of their evaluation, however, people felt that the groups had enabled them to feel more equipped and empowered to be able to ask appropriate questions.

9. 2 Introduction

Using a deliberative methodology was central to our aim of eliciting detailed reflection on a series of largely unfamiliar, complex and interlocking concepts relating to the governance of biomedical research. In Chapters 4 to 8 we discussed the substance of some of these reflections and outlined the way in which people made sense of what biomedical research is, of personal data, consent, databases and models of governance. In this chapter we consider the evidence we have for the impacts of deliberation.

We consider what people said about how the groups had increased their awareness of issues around biomedical research governance and explore participant reflections on the way in which the groups had affected their views on biomedical research governance.

9.3 Increased awareness

It was clearly evident across all the groups that people were very willing to reflect on the insights and discussion that the films and other material provided. In tandem with this, participants identified and reflected upon their lack of previous awareness and knowledge of this area.

> Never ever really thought about it to be honest. It's never been brought to my attention before. It's only like you're awakening things now, I suppose most people are the same, you know.
> 15-Bio-D-B (538:540)

> P1 I only had one thought that keeps coming into my mind and I, I suppose it's quite a personal thought because it's how I feel about everything that's been talked about here is the amount of knowledge I've learned today is phenomenal, because I didn't realise there were government bodies like this and what they did, perhaps you know more people should know about that. It's getting that information out to everybody because maybe this information will make you feel, people feel better about …
> P2 Yeah, that's …
> P1 Going into research studies and doing it or maybe it's, it turns them the other way but at least they've got the amount of knowledge to make a reasonable decision.
> BIO1-dw17 (1089:1091)

Although many participants said that they required more information, the emphasis here

was more on their desire to know more and to be able to make informed decisions rather than constituting a request for the provision of information. Indeed participants were explicit that they would not have been able to deal with the information that had been exchanged in the groups had it not been presented in such a user-friendly way and made sense of as a joint project within the group.

People said that they enjoyed participating in the groups and that overall they had found the discussions very interesting. People commented that these were things that they did not ever usually think about, that it was more interesting to learn in conjunction with hearing the views of others and that this was a good way of not simply considering things from your own perspective.

9.4 Changing understandings

It was often evident that the views of at least some group members shifted at different points in the group discussions. In part the expression of different views was related to how the discussion was framed by the researcher but it also seemed that some changes occurred as new information was deployed and tested in the arguments participants made. The participants themselves recognised that they were discussing things differently and that sometimes their views had changed. This process is clear in the following excerpt where the participants are discussing Connecting for Health (see Chapter 7).

R I think you all seem fairly positive about that. I guess at some point it'll come in and… I don't know how it would work, whether people will be told about it in a consultation or whether we get letters about it. Initially a couple of you said, oh, I feel like I should have known about this.
P1 I did. First of all I thought it's a bit of an invasion of privacy but that's an old-fashioned attitude, it's my age, I think, but the more I think about it, I think it is a really good thing.
P2 This morning we were sort of going against it and now we're going the other way.
P1 It's strange, isn't it?
R This morning it was more concerns and limitations and now there's a slightly more permissive sense around this.
P1 It seems to make sense now.
P3 It's just the understanding of it, I think.
P2 And how the information's being used and for what reason.
P3 And reassurances.
P2 And really the key, right back to the beginning, is that when we used to do these forms, we never knew what they were for, how they were going to affect us or how they were going to benefit anybody in particular but at least this is a little bit more…
P3 And it's staying in the NHS and I think that is the key thing.
P2 Security. There's a boundary.
07-Pat-D-G.doc - 7:54 (1846:1868)

Other participants were explicit that their views had changed; that they had 'changed their minds' over the course of the discussion process. They noted the value that 'word of mouth' had in the groups and in effecting changes in their everyday lives. It is not necessarily the case, however, that the groups led to people becoming more positive about the possibility of participating in biomedical research. Some participants were positive at the outset and remained so. However, overall there is no simple or single way in which changes in participant positions can be characterised.

In the following excerpts, participants asserted that previous fears had been allayed. The increased understanding afforded by the discussion processes was linked with increased confidence to take part in research.

P1 One of the key things that would come out of this would be information given to us so that we can understand it and that we know where our information is being held and where it's going to.
R And you feel that you understand more now than you did at the beginning?
ALL Yes.
P2 And also that it's inevitable, isn't it, really? We know that now, that it is going to happen.
P1 I'm happy about it now.
P2 Yes.
P3 Yes, I feel fine about it.
P1 Because I know where it's going to be, I know where it's going to be kept and I know what information is going to be on there and I'm accessible to it and I can look at it and change it as much as I want to. So, I feel in control.
P2 At first I thought it all seemed Big Brother-ish and didn't like the idea of it at all but now I feel quite confident about it.
P4 I think it's all about understanding it.
ALL Yes.
07-Pat-D-G.doc (2714:2734)

Some of the complexity of responses to the workshop is evident in the excerpts below, where participants are weighing up the different issues and trying to reach an overall position. There was no simple change in the direction of the first participant's evaluation. It suggests that the workshop day was initially linked with concerns about the possible risks of participating in biomedical research. Over the intervening week, however, the material that had been covered resonated with both personal experiences and with news coverage. Although it seems that the collective good that biomedical research can afford became more salient, the concerns about the privacy of data persisted.

> I was quite impartial when I arrived last week, because I'd not really given it a lot of thought. As the day went on I became more cynical and had conspiracy theories drawn on my forehead when I left. But then over the week I remembered thinking about for the greater good or the higher good or whatever it was, I think it's for the greater good, and I found myself using it in lots of different situations and thinking about a more collective benefit from it. And then there've been a couple of things that have affected me personally. A friend of mine was diagnosed with skin cancer this week and she's very disturbed, obviously she would be. And I thought, right, there must be lots of research, so let's go on the internet and look, and so… And then this morning on the news there was something about the bone marrow donors from black and minority ethnic communities and there were very few people coming forward to be donors. Then I thought, yeah, the more for that reason, then the better, but I was still a bit worried about the 1984 being followed around everywhere you go in the world with your little floppy disk, toenail deficiencies or something.
> PUB4-rb12 (39:39)

> I can see the need for it, but there's just a bit of me which is… well around the accountability side and how do you ensure that data issues for the right reasons have appropriate structures in place? I mean I didn't think of it too much before I came in on the Saturday, but I liked the options of you know what you're signing up to, so it feels a bit Big Brotherly that everybody's got your data and can access it and etcetera. But if you know that, well hang on, this is what it can be used for, and then you've got your options of opt out, if you want to opt out, and then if you're opting in, you've got some confidence that there are structures in place that will protect you as an individual and as a society and as a community.
> PUB4-rb12 (49:49)

Other participants were explicit that the discussions had made them feel more vulnerable

and concerned. This was not necessarily seen as bad thing – part of this was about feeling more informed – but this participant asserted that this was a good thing it increased awareness of what she was doing and "what I get myself into".

> As I say, last week I was all in favour of, you know, let's share, let's not worry, there's nothing to worry about, and I would have been up for, yeah, take some of my blood, that's fine. But I went away to think about it, and now I just think, no.
> BIO1-rw18 (3:41)

For some participants, hearing alternative and opposing views provided the opportunity to re-assert more confidently their starting position. Others had an appreciation that they have learned a lot but this may not necessarily lead to changed opinions.

> I certainly have a clearer view of it because I knew nothing about it before last week to be honest, or what the word actually meant. I don't know whether my opinions have changed on it. It depends on the circumstances of what it is and what it's for.
> P 6: 06-Pat-R-G.doc - 6:4 (61:63)

9.5 Changing efficacy

The impacts of the deliberation process were thus varied. The position of some participants was unchanged; some had become more positive and others more negative. It was much clearer though that one effect across all the groups was that participants generally considered themselves to have gained the ability to ask challenging questions and to acquire the tools to make decisions.

> P1 One thing I'll be grateful to this group for apart from a pocket full of beer tokens is the fact that I will now be able to make an informed decision on what I wanted to do. I'd know what to look for, what pitfalls, but I still have a very open mind about doing and trying to do as much as I felt I could.
> R Okay, I think that's an important point because you all have had a lot of information, you had the time to think, we went through it all last week, to kind of think about it in the intervening time.
> P2 We've got far more knowledge now.
> P3 It's been a real eye opener.
> P2 It has, yeah.
> PUB2-rg02 (694:702)

In the following quote there is a clear sense that the new perspectives that have been gained have enabled a sense of being empowered to ask relevant questions about the conditions under which they might be participating in research:

> I think I'd feel more confident in the fact that I would be able to ask questions. I think that's an important thing whereas before I didn't. If you went to a GP and they said we want to do this bit of research, you'd think, and you'd probably sign the bit of paper and you really wouldn't have time to understand or anything like that. But now I think looking at the positive, but also looking at the not-so positive side to research and what the information's going to be used for, I'd be more likely to ask more questions about what my information was going to help with.
> Pat-R-G.doc - (471:485)

We also had an interesting reflection by one group member of being able to draw on what she had learnt in the workshop in the concrete situation of completing a consent form during the week following the initial group.

> I had to take my son to the hospital on Monday, cauterised, and the doctor gave me a form and said please sign this, you know, it's for anaesthetic. When I read it, it didn't mention anaesthetic; it was giving away the tissue, and I queried it and said to him this isn't for anaesthesia, and he said no, but this paragraph on the flip-side of the page is. Nothing was explained to me, I only picked, I think I wouldn't have even thought about it because I've been here.
> P16: 16-Bio-R-B.doc (30:30)

9.6 Working with new understandings

Over the course of the groups and the intervening period between them it was clear that people used, and reflected upon the new understandings of biomedical research they had gained, in a variety of ways.

9.6.1 Talking to others

Participants were encouraged to reflect on the group's conversations and the material they had been given and, as they felt able, to talk to other people about it. It was clear in the reconvened groups that people talked to friends and colleagues as opportunities arose; one participant even discovered that her husband was working on an IT project on behalf of Connecting for Health. Some participants were very enthusiastic about what they saw as 'spreading the word'. The reactions they had received had clearly been mixed: some had not wanted to discuss it, some had been positive about the ideas that were communicated, others less so. Participants tried to make sense of the reactions that others had given. For example, where there were concerns about the uncertainties of others accessing personal data these were often explained in terms of the characteristics of the person, for example that they were older. Those who are most familiar with technology and the notion of information sharing are seen as being least concerned. Other participants drew attention to the way in which the people they spoke to were more positive if they had had experiences of being ill and thus the possibilities of benefiting from medical research were seen as particularly salient. Participants reported that those they had spoken to tended to express concerns around the broad issues of surveillance, computers, hackers and leaked data.

The views of others were sometimes represented by participants as being irrational or uninformed. In the quote below where the group was discussing whether consent should be opt out or opt in, discussion was identified as the route to changing these views.

> P1 I think that it should be, no, you don't want to do it... so it's your decision to do it and not...
> P2 Yeah. Either way.
> P1 I mean, if you say you've got to say you want to do it, then it means that 56 million people are not prepared to take part in research, but if you do it the other way round and 56 million are, then you start... you know, people start saying, I don't want to do it.
> P3 Yeah, born out of ignorance, 56 million like your friend that instantly said, oh, no, no, I wouldn't be interested. Until they were talked... until it's discussed, they don't actually realise...
> PAT2-rw16 (543:549)

At the end of the groups it was clear that some participants felt equipped to be take a more active and inquiring role; others felt confident and willing to take a more ambassadorial role and suggested that they would be motivated, and felt able, to explain issues to others as and when they arose.

9.6.2 Needing and using information

It was clear that people consistently endeavoured to actively make sense of notions of biomedical research governance with reference to whatever 'tools' were at their disposal. Often this sense making was in relation to their own experiences. Another way in which people were active in trying to make sense of some of these issues was, as has been made clear, to make suggestions as to how research governance could be more effective. It was also clear, though, that some participants went to seek out information. However, in these instances no-one said that they were satisfied with the results; they had either not known where to look or had looked and not been able to find useful information.

> P1 I don't think you should have to be asked, I think just a general notice or something in a doctor's surgery if they were carrying out this type of test in Surrey. Every doctor should have a notice saying just so you're aware, da da da da. I think that would help and make people more aware. I tried to look this up on the internet this week and I couldn't find anything and Welcome Trust was fourth on the list, and that's how I found any sort of information at all.
> R Right, what did you look up?
> P1 Literally just more information on it. I think it's knowledge and making people aware and before Saturday I wasn't really aware of it and I think a lot of people I talked to this week weren't aware of it. When I did ask them they had the same opinion as me and, like, who cares, what's going to happen if they do? But then on the flip side some nutter can see your identity or whatever.
> PUB2-rg04 (268:272)

However, although a need to know more was expressed, there was seen to be a particular value to discussion and that the benefits of this were far more substantial and useful than simply being faced with reading information.

> But what I think that has come from this, is that just simply reading alone is not enough because we've just proved that in this last one... is that at home on your own, which I'm sure the Government will do this, and they will send out a little flyer thing, or a little booklet, supposedly explaining it all, and unless you can bounce your ideas off somebody else, or ask another professional or somebody else that maybe has investigated in a different way, then I don't think that you can make an informed choice, and a lot of people will slip through the net and will go anti it, like, say, maybe I would have been a bit more before. So I think discussing it is more beneficial than just the written word, because it... you can interpret it in different ways. And also even about this postcodes thing... it didn't say at any point in here that they were actually going to contact us, but you put two and two together and if you've got a whole wad... I mean, in fact, because by me having it... had we not gone through this last, I would have gone, what? Okay, that's a lot of stuff I don't need to know. It's a lot of stuff that's beyond me. I can't change it! So, I think actually that sitting and discussing it is vital and if they want to implement all these things and let Joe Public know about, there will at least have to be more sessions like this. I know obviously they can't, you know, have the whole population sitting down for debate. I know that they can't do that, but they at least need to sort of have it that there are core groups that can, of a wide variety of people and then at least you can...
> PAT2-rw16 (889:895)

9.6.3 Noticing media coverage

When the biomedical and patient groups reconvened many participants were aware of the extensive media coverage of Connecting for Health that had occurred in the intervening week.

> Yeah, well I was quite surprised... having done this a week and a bit ago, it's almost every day since then, I've seen something either, either in the paper or in the news, something... it may

> be my awareness, you know, about the, you know, the computer, the NHS new computer, about, you know, the police using medical information off of it, you know, having access to it. There was quite a few of us, that's what I could think of... it was only yesterday I heard about that. But I was quite amazed. You know, it's quite, quite interesting as well and the people I've spoken to... you know, like my wife and it just... well, I knew it was mainly only family, but they all seemed to have the same sort of view as I did, that it could only be a good thing.
> PAT2-rw16 (29:105)

Even in the public groups, however, where the intervening period had included no particular coverage of relevant issues, some snippets had caught the eye and this resonated with the group discussions the previous week. Some participants had brought newspaper cuttings to the group. In the example below the cutting was about a convicted criminal who had returned to court in an attempt to keep his medical records private and not be used as evidence against him. She explained why this had caught her interest.

> He urged the court to keep the information from the public. I think when you hear about something you hear a bit more because you're more aware.
> P 8: 08-Pat-R-G (190:204)

Where media coverage had been extensive, participants tended to represent this as them having been sensitised to these issues and therefore noticing them more. Others jokingly wondered if the research team had arranged the coverage to coincide with the groups.

> I thought, no this can't be real, you know. And I think it was the following day, there was an IT supplement, and they were talking about e-gov. So it was just like, this is really strange, you know, either because my awareness is much more acute, or seemed to be you know, a big coincidence, and I thought, well these guys know something I don't know. Why is it in the *Guardian*? That sort of thing. But again it was all about the sort of the government's agenda, the, you know, it does make you, it made me wonder about how intrusive all this is going to be. At the moment it's not; it doesn't appear to be so intrusive now; we're just aware, you know, this sort of information exists. Will it actually start becoming much more intrusive? And what do we mean? And I was thinking, well, in terms of intrusive, you know, how would it actually affect me as an individual? And again, there's always, you know, sort of the opportunity perhaps, people get used to the information, they get used to some of the ideas and concepts, and then your guard is lowered, and, you know, it's like; so that's why, why everyone's reading the *Guardian*. And then the *Guardian* is saying, if you have concerns about this, then write to the Secretary of State, that whole letter in there that you could use, things like that. I didn't go that far, but you know, it just makes you wonder.
> BIO1-rw18 (71:71)

Again it was evident that people tried to make active sense of the media coverage they had come across and used it as an extra available resource with which they could make sense of the material that had been discussed.

9.6 Conclusions

People assessed the way in which participation in the groups had (or had not) changed their views in a variety of different ways: the effect of deliberation is not simply to provide reassurance or to increase the willingness to participate in biomedical research. Importantly, one key impact of deliberation in evidence across all the groups was to increase the ability and confidence of participants to further engage with these issues in the future.

CHAPTER 10: DISCUSSION

While the earlier chapters have presented the detailed findings associated with particular domains of biomedical research (personal data, informed consent, databases and models of governance), this chapter will address some of the more general themes running across these areas. It concludes with a set of implications that can be drawn from the research for those involved in the conduct and governance of biomedical research.

Across the public, the patient and the biomedical participant groups there was strong support in principle for the value of biomedical research and for the importance of participation in it. The notion of the greater public good that such research could afford was equally clear. Cutting across this to varying degrees, however, were a range of concerns and practical considerations that could have the effect of constraining willingness to participate.

While experts and researchers may often assume that publics see biomedical research and the structures of governance within which it sits as special categories of activity, it is clear from this research that people make sense of it by drawing on familiar, everyday and easily accessible resources. Thus, questions around the adequacy of research governance were more strongly anchored around concrete concepts like consent and databases than in the much less tangible concepts of legislation, self-governance and external regulation.

The act of providing explicit consent, of being asked and agreeing to the request, is key in signalling the adequacy of research governance. This transaction, with which we are increasingly familiar in our everyday lives, is not detached from everyday cultural concerns and obligations and is grounded in social conventions of courtesy: it is polite to ask. Not being asked is impolite and signals disrespect and being taken for granted. Implicit consent is no consent at all.

10.1 Group differences

The group participants were purposefully drawn from people with a long-term illness, from those that had participated in biomedical research and from people that fell in neither of these categories. This was done in order to access as wide a range of views around biomedical research as possible. When we consider the nature of the groups we note that the biomedical research groups made little reference to their previous participation in research and there was no evidence that their previous activities in this area constituted an important part of their identity. This lack of a particular identity around biomedical research made them very similar to the public groups. In contrast, participants in the patient groups frequently suggested that their health status was considered as part of their identity.

When we consider the views and opinions of the groups there were surprisingly few differences between the groups and considerable similarities. The differences between the views of participants *within* each group were much more evident than any differences *between* the groups.

There were participants in all the groups that were extremely positive about participation and did not see the costs of this as outweighing the benefits to the common good. This

clear appreciation of the value of biomedical research was perhaps most clearly evident in the patient group and in those participants that had a conception of the value that biomedical research had, or might have, to them as individuals. When we consider the reservations that were expressed around participation it also seemed that in the public groups these were more often located in the 21st-century cultural realm of risk and anxiety, for example around surveillance, identity theft and hacking into IT systems. The patient and biomedical groups recognised and shared these concerns but tended to downplay their significance or simply set them aside.

10.2 Strength of agreement and the importance of framing

Much more obvious than any group differences was the way in which the position taken on a particular topic varied. Sometimes this seemed a function of the learning that had gone on in the group. More importantly, it seemed that the same topic could be seen and evaluated in different ways depending on the 'lens' through which it was viewed. To explain: where the object of discussion was a topic such as consent, views varied depending on the lens(es) through which the object was being viewed, for example, what the type of research was or whether the participant would remain anonymous. It was clear that some lenses were much more important in making a difference than others. Anonymity, for example, made a clear difference to willingness to participate. Other lenses, such as models of governance, hardly made any difference at all to how the object was viewed. This may be a very important lens for experts but it is unlikely to be so for potential research participants unless it is linked to concrete practices around research participation.

We can continue to use this metaphor of a lens to specifically address the question of what it was that best reassured people about participating in biomedical research. The lens that people primarily used to appraise how they viewed participation was that of the consent process. Our analysis suggested that the process of obtaining consent is highly indicative of the value placed on participation and signals (or at least has the potential to signal) the care that will be afforded to the information or tissue for which access is being sought. Where, for whatever reason, the lens of consent affords an unsatisfactory view, this is often associated with concern or reluctance to participate. The importance of anonymity was secondary to consent in the sense that if the consent process was satisfactory people were well able to conceive of situations where they would be willing to participate without guarantees of anonymity being given.

People thus consider the lens of consent to be a key way of appraising how reassured they are entitled to be about participation in biomedical research. In contrast, it was clear that mechanisms of research governance were the least effective lens for helping such decision-making processes. Whether or not the situation was appraised through the lens of governance made little difference to the practical reality of deciding whether or not to participate and to creating a sense of confidence that this was a good and safe thing to do. In the light of the remoteness of research governance mechanisms it would seem valuable to visibly locate the role of these bodies in relation to the concrete mechanisms of participating in research. It would seem that the processes of eliciting consent and the substance of the guarantees that this provides are likely to be the most effective way of doing this.

10.3 Information provision

The results of this research suggested that people rarely consider biomedical research issues separately from real-life decision-making contexts but when they *do* consider them in these contexts they can be dynamically engaged with the idea of research, notions of how research is done, what standards should pertain, and what they wish to be informed about.

Participants valued the learning that the deliberation and dialogue in the groups afforded. This provided an opportunity for exchange and consideration of the views of others alongside reflection on their own experiences and views. The films provided accessible and meaningful introductions to the issues under discussion. Alongside this, however, participants were consistent in saying that they felt their awareness of the issues was low and that in order to facilitate their decision-making process around biomedical research they wanted to understand processes of research governance better than they did. To some extent this desire was exemplified in saying that more information was needed.

The challenge of how to respond appropriately to people's desire to be more 'research literate' is an important one. The groups themselves gave important clues as to characteristics of such a response. For example, people were explicit that although they want more information, they do not want reams of paper just to read. They said that they would not have been interested to read the material that was presented in the films had this been a matter of individually assimilating the printed word. On the other hand, participants noted the value of knowing that there was a 'place' to go that would be a source of relevant information that could be used by people. The groups clearly showed that relevant information meant information that was grounded in practical contexts. They also pointed to the way in which becoming aware of the views of others was instrumental in developing their own positions. The need for simple, clear information alongside fuller information if required is suggestive of the value of two-tiered information that enables people to exercise choices about the amount and depth of information that they require. Finally, the ability to be able to ask questions, and have these responded to, is also an important characteristic of seeking and using relevant information. There would seem to be considerable value in developing a 'one-stop shop' of information on the web that incorporates these ways of presenting information around biomedical research.

10.4 Trust

The importance of trust is routinely noted around the interface between experts and publics. The findings of this research are no exception. Breaches of trust around the research governance process have implications not only for understandings but also for behaviour. The nature of some participant accounts makes it hard to envisage ways of repairing serious breaches of trust in the way that personal data have been handled. Models of governance have a limited role in providing reassurance. Such reassurances are much more effectively located around practical dimensions of research governance such as the consent process and effective guarantees of anonymity.

The GP is undoubtedly the key repository of trust around processes of research governance and, notwithstanding the clear-sighted understanding that people had around the practical implications of this, was almost invariably the chosen way of mediating participation in biomedical research. S/he is a counterbalance to weaknesses in systems of research governance. Although to some extent people were happy that

practical ways in which the GP would effect this role might include letters and posters in the surgery, the essence of their trust in the GP was that it was a trusted *relationship*. That is, as well as trusting that s/he would advise or act in the best interests of the patient, the relationship was also one where people had the opportunity to actively respond to the advice, to ask questions and think for themselves.

10.5 Implications

There are a number of implications that follow from the research for those bodies and individuals involved in the conduct and governance of biomedical research. These are listed below.

- The role of bodies involved in the governance of biomedical research should be more visibly grounded in the mechanisms of participating in research, e.g. consent, protection of anonymity, etc., since these bodies are currently seen as remote by potential research participants.

- Researchers need to proactively engage with participants' desire for more transparency about the research process, including why certain data are required, how data are stored and who will have access to their data.

- Implied consent should be conceptualised as no consent and the same ethical considerations should apply.

- Explicit consent can be refined to be more permissive by providing opportunities on the consent form to specify a range of potential future/other uses of data. One way in which this might be useful could be to signal the agreed use of Connecting for Health data in research.

- Research participants require evidence and reassurance on the security of databases.

- The ideal brokers of research participation are GPs, although participants are also mindful of the issues of workload that personal contact would entail.

- Doctors' receptionists are not seen as appropriate to be part of the research process.

- Reflecting people's wishes for more active involvement, a website (one-stop shop) could be developed where participants could access information on aspects of participation in research, e.g. rights, explanation of terms, route for complaints, FAQs, links to other relevant sites.

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APPENDIX 1: Stimulus materials

Session 1: Day Discussion Groups

BASELINE AWARENESS EXERCISES

ACTIVITY 1 – Definition

Participants were introduced to a definition of biomedical research: *"Any health-related research that involves humans, their tissue and/or their data".* In groups of three/four they were then asked what sort of things were included within this definition and asked to write these down on an A3 flipchart sheet. After doing so, they were given a handout which detailed some examples of biomedical studies. These examples included 'taking part in a clinical trial to test a new treatment for a health problem', 'having your NHS notes looked at by a researcher to get data for a study into, e.g. link between smoking and cancer', and 'after you have had your appendix or gall bladder taken out it could be used for research at a later time'.

ACTIVITY 2 – The H-form

Participants were then provided with an A3-sized 'H-form' or 'Rugby Post Form'. The H-form is created by drawing a large H on a piece of paper with the question to be discussed written in the top centre of the H-form. The question under consideration for this activity was *"How important is it that people participate in biomedical research?"*. The end of the left side of the horizontal line of the H was labelled 'Not at all important', and on the right was 'Very important'. In turn, each person in the group was asked to place a cross on the line in response to the question of how important they felt it was to participate in biomedical research. Next, participants were given Post-it notes and asked to provide the positive reasons for their score, the reasons that it did not score lower down on the scale. Once every person had written down their answers these were then stuck down under the heading 'Didn't score lower because …', which was written on the left side of the H-form. Participants were then asked to do the same, but this time to give negative reasons for their score, the reasons that their cross did not score higher up the scale. This was placed on the right-side of the H-form under the heading 'Didn't score higher because …' Each person then read out his/her reasons to the group and explained them.

ACTIVITY 3 – Reasons not to take part in research

For this activity, still in their groups of three/four, participants were asked *"Why might people not want to take part in biomedical research?"*. People were encouraged to give their ideas and these were written down on an A3 flipchart sheet. Everybody in the team was asked to say at least one main thing.

PERSONAL INFORMATION

FILM 1 – Personal Information (theme)

Mrs Barker, an elderly lady, sits in a café drinking tea and recounting her recent experience of registering at a new doctor's surgery. The doctor's receptionist, Meredith, provided Mrs Barker with some forms to complete, which required her to provide personal information. Mrs Barker was concerned by some of the sensitive information she was asked to for, particularly the question on 'How many sexual partners have you had in the last five years?'. She was especially concerned as to how confidential the information she provided would be. Meredith assured Mrs Barker that it is all confidential and that nobody but the doctors would have access to her information without her consent. After completing and signing the form Mrs Barker notices the small print at the bottom of the form and a box to tick, and Meredith explains that this allows her the opportunity to opt-in or opt-out for her personal information to be used for research purposes. Meredith assures her that it would all be anonymous. In the end Mrs Barker decided not to give her permission for her details to be used in medical research. However, thinking about it now, she cannot remember whether she had to tick to opt in or tick to opt out and is left worrying about the consequences and whether she can change her mind.

This scenario addresses the following issues:

- the nature of personal information (including sensitive information), name/address, medical history, sexual history
- assurances of confidentiality
- tick box to opt in or opt out to using data for research
- anonymisation
- consequences of opting in or out.

CONSENT

FILM 2 – Informed Consent

A university professor is interviewed on camera by a young female interviewer. She questions him about the issue of consent in relation to medical procedures and biomedical research. They discuss the need to obtain consent in response to different situations. The professor suggests that in a medical emergency it would be appropriate to proceed without the patient signing a consent form first. The professor further discusses the potential to use personal information from medical records for research purposes, for example, to spot trends, along with the possibility of also using existing samples. He suggests that as this information is already available and its use would not have any effect on or consequences for the individuals involved, then it is not necessary to gain consent. However, the interviewer is worried about possible misuse of the data. The professor assures her that there are strict guidelines in place to safeguard against this. The interviewer suggests that in the future rules might be changed and refers to the Government's changes on sperm donation. She then announces to the professor that he is her father.

This scenario addresses the following issues:

- circumstances (if any) where consent not needed
- appropriateness of explicit consent, implied consent or 'blanket consent' by type of personal information and nature of participation (active vs passive)
- should consent always be in writing?

- consequences.

HANDOUT: Types of consent

Participants were given a handout which named the three types of consent and gave a brief explanation of each. These were explicit (informed) consent, implied consent and no consent. *Explicit (informed) consent* refers to when an 'individual opts in to a process fully informed of what it entails'. *Implied consent* is consent which 'is inferred from an individuals' behaviour or conduct'. Lastly, *no consent* means an 'individual is not asked whether or not they wish to participate'. Discussions then began about these three types of consent and how people felt about each one.

HANDOUT: NHS consent form

Each participant was given a copy of an NHS consent form for *'Patient Agreement to investigation or treatment*' and allowed some time to look over the form. The form is four pages long and the front page offers provision for the 'patient details' (e.g. name, date of birth, NHS number, gender) to be completed. The second page is to be completed by a health professional detailing the 'name of the proposed procedure or course of treatment' and the 'statement of health professional' is an acknowledgement that the procedure has been fully explained to the patient. On this page there is also a 'statement of interpreter' (where appropriate). The third page is the 'statement of the patient', which the patient signs to show they understand and give their consent to the investigation and treatment. The final page is 'guidance to health professionals', in terms of explaining 'what the consent form is for', 'the law on consent, 'who can give consent', 'when NOT to use this form' and the need to give patients' full 'information' about what the treatment will involve, including benefits and risks and any alternatives. The moderator then asked participants for their impressions of the form and a discussion ensued.

DATABASES

FILM 3 – Databases

Kate and Pete are sitting across a table from one another, leaning in close, and discussing the NHS Connecting for Health initiative which plans to put all patient medical records onto computer, with the potential for linking databases. They talk about the advantages and disadvantages of this. Kate is worried about who will be able to look at and access her records, especially as she suffers from a medical condition that she is rather embarrassed about. Pete sees the advantages of computerised records in the linking that can be made between GPs and hospitals, allowing them to see your records straight away and what medication you require, and this could be particularly useful if you are away from home and are taken ill. Kate points out the need to keep accurate records and the possibility that the information could be incorrect. She is further concerned about the potential for third party access, that her details might get sold on. Perhaps her medical records will be linked to information about what she buys at the supermarket, which might lead to consequences of her then being refused treatment unless she changes her eating/drinking/smoking habits. Pete assures her that access would be restricted, but then begins to worry about the consequences of data linking himself.

This scenario addresses the following issues:

- circumstances where appropriate to have personal information on a database by type of information
- volition vs compulsion

- public vs commercial interests
- third-party access
- consequences of data linking.

HANDOUT: Connecting for Health

A handout was given to all participants outlining the NHS Connecting for Health programme. It explained that starting from 2006, NHS patient records will be put onto a national database, and every patient will have their own NHS Care Record. It advised that each record will have a unique identification code that contains their NHS number. This will enable an individual's health information to be linked together across GP, hospital and pharmacy. Furthermore, by 2008 people will be able to access their own summary health record online and add information about their health needs. This handout stated that access to care records will be controlled by an NHS 'smart card' using Chip and PIN technology. It also explained that anonymous data may be used for health research, planning and audit purposes. Participants were allowed time to read through this handout and then the moderator opened up a discussion about the Connecting for Health programme, the changes due to take place and options this offers for research purposes.

MODELS OF GOVERNANCE

POSTER: Legislation

This poster outlined the Data Protection Act (1998). It advised that the Act is overseen and enforced by an Information Commissioner, an independent authority which reports directly to UK Parliament. The principles of data protection were given and these included how personal data should be handled and dealt with, and the relevance of these principles to biomedical researchers. The penalties for breaking the Act were also detailed.

POSTER: Professional self-regulation

This poster provided examples of two professional self-regulating bodies, the General Medical Council (GMC) and the British Medical Association (BMA). It gave some background information about each organisation in terms of their purpose and the type of guidance they provide and to whom. The poster also introduced the issue of scientific peer review, explained this process and gave an example of the cancer registry.

POSTER: External research governance bodies

This poster introduced participants to two external research governance bodies: Research Ethics Committees (RECs) and the Patient Information Advisory Group (PIAG). It explained the purpose and the process of each organisation. It also provided examples of research projects which would be examined by the RECs or PIAG.

COMMITTEES

FILM 4: Committees

A couple are sitting in a doctor's waiting room. The husband picks up a leaflet entitled 'Volunteers wanted for a medical advisory committee' and suggests that he would be suitable to participate. His wife suggests that as he does not have any medical knowledge he would be unsuitable, but he points out that lay members are required to add balance and transparency to the process. They discuss the role of committees and their ability to deal with biomedical issues. The husband is very positive about the process and keen to become involved, however his wife is more sceptical. Only when she learns that the committee meetings are held in London, with all expenses paid, does she become interested.

This scenario addresses the following issues:

- satisfaction with process
- fairness
- representativeness
- reactiveness
- lay vs expert involvement.

Session 2: Reconvened discussion groups

VIGNETTE 1:
This vignette outlines a situation where researchers in a laboratory want to study blood samples that people first gave to their doctor when they had a routine blood test. They wish to do this to further their knowledge, not to find a cure to an illness. They need a large sample of 10 000 people. Although the blood samples are stored with an individual's NHS number this will be permanently removed by the researchers. They aim to publish their results in a journal. After reading this vignette, participants were then asked about the need to obtain consent and how they felt about the level of anonymity in the study.

Participants then individually completed the H-form which asked *'How comfortable are you that your blood sample might be involved in this study?'*. The end of the lef side of the horizontal line of the H was labelled 'Not at all comfortable', and on the right was 'Very comfortable'. Participants placed their cross on the line and then wrote down their reasons as to *'Why not lower?'* and *'Why not higher?'*.

VIGNETTE 2:
The scenario is this vignette is that 12 years ago, researchers carried out a study on diabetes. Five-hundred adults with diabetes gave their consent for the researchers to look at their medical records. Today, a different team of researchers wish to contact the original participants in order to collect some new information and investigate a new theory of diabetes. After reading the vignette, the moderator then asked participants how acceptable it was for the new team of researchers to re-contact these participants, and if so, how this should be done. Again, they were also asked how they felt about the level of anonymity in the study.

Participants then individually completed the H-form which asked *'How comfortable would you be about being re-contacted in this situation?'*. The end of the left side of the horizontal line of the H was labelled 'Not at all comfortable', and on the right was 'Very comfortable'. Participants placed their cross on the line and then wrote down their reasons as to *'Why not lower?'* and *'Why not higher?'*.

VIGNETTE 3:
Here, the researchers have written a proposal outlining research they would like to conduct on sexual health and possible variations in health behaviours in different parts of the country. They have already undertaken a large survey of 3000 people about their sexual health. These people gave explicit consent for anonymous information about them to be used for statistics and research. However, as this survey did not include any detailed geographical information, the researchers now want to link this survey data with information about local areas collected in the 2001 census. Once linked the identifiable information will be removed. This new data set will then be used for research purposes. After reading the vignette, participants were asked how acceptable this data linking was, as the participants who completed the original survey had consented for their information to be used for 'statistics and research'. As with the other two vignettes, they were asked how they felt about the level of anonymity in the study.

Participants then individually completed the H-form which asked *'If you had taken part in this survey, how comfortable would you feel about this research proposal getting the go-ahead?'*. The end of the left side of the horizontal line of the H was labelled 'Not at all comfortable', and on the right was 'Very comfortable'. Participants placed their cross on the line and then wrote down their reasons as to *'Why not lower?'* and *'Why not higher?'*.

APPENDIX 2: Method

Chapter 2: Secondary analysis

The general public

In total, 40 interviews were carried out with the general public, 20 of which were with individuals who had been affected by genetic illness. Participants were interviewed having watched a ten-minute film about a range of topics around genomics including genetic therapy, the use of genetic data and genetically modified crops. This strongly framed the interview, the film topics providing the context for the exploration of the issues.

In addition, eight focus groups were carried out with the general public, of which four comprised participants who had been affected by genetic illness. These were more open-ended and provided an opportunity for participant-led discussion around genetic technologies more generally.

The experts

Thirty interviews with experts from industry and research were carried out adopting the open-ended approach used in the general public focus groups. Just as the public are not conceptualised as a homogeneous group (a distinction having been made between the general public and those affected by genetic illness), the experts represented within this data set are also drawn from a diverse range of backgrounds representing different types of expertise. Not all are from a human science orientation but are concerned with research into new bioscience technologies, albeit concerning plants or animals. Furthermore, as several of the expert participants claim to speak on behalf of a public constituency, it is useful to see how they view public involvement in research. For this reason, we have categorised the experts to allow for a more nuanced understanding of the positions they take up (Fig 1). When we refer to a particular participant we will cite the interview number and the category of interviewee (e.g. PA, SC).

Fig 1: Categories of experts represented

GROUP DESCRIPTION	**PARTICIPANT ID NUMBER**
Policy Advisers (PA)	1,2,3,16,21
Scientific Community (SC)	5,6,10,15,19
Health Practitioners (HP)	4,13,18,24
Independent Watchdogs (representing the public) (IW)	7,8,12,27,29,30
Special Interest Groups (lobbying for a specific cause) (SIG)	9,11,14,17,20,22,23,25,26,28

i) ***Policy Advisers***
Most have a science background but are now working as advisors for either the government or science organisations.

ii) ***Scientific Community***
Refers to those currently working as scientists such as biochemists and botanists.

iii) ***Health Practitioners***
General Practitioners or specialist nurses.

iv) ***NGOs/Watchdogs***
Publicly funded 'watchdog' organisations set up to represent the public and raise concerns on their behalf on issues such as GM crops or genomics.

v) ***Special Interest Groups***
While these groups also rely on public donations, they often lobby on one specific area such as a particular disability or area of environmental concern. Many take on an 'activist' role in highlighting their particular cause through visits to institutions such as schools, religious groups and opening up public debate via dedicated websites.

Data analysis

To begin this process, five members of the team each manually analysed two interviews and one focus group (all different, and drawn from both types of general public group), in which emergent themes were highlighted and compared. By working in this way we were able to agree a relationship between our research question and the available data. This was geared towards sharing a common framing of what constitutes governance within the secondary data.

Having established this common framing, subsequent analysis initially entailed producing a written summary of each interview and focus group. The summary included information regarding the personal context of the participant, for example whether they had experience of genetic illness or an involvement in issues relating to biotechnologies, together with relevant themes that had been drawn out from the transcript. A combination of manual and computerised analysis (ATLAS-ti) was then used to develop the analysis further and in more detail. Emergent codes and themes were shared among the research team in an iterative process, which supported further development of the data analysis.

Chapters 3 to 10: Reconvened discussion groups

A total of 89 members of the public sampled in England or Wales participated in reconvened group discussions on biomedical research governance. Separate group discussions were held with participants characterised in one of the following three groups:

- Group 1: Members of the lay public with no prior experience of participation in biomedical research (N=60);

- Group 2: Members of the public who self-reported a long-standing illness or medical condition (N=14);

- Group 3: Members of the public, with and without a self-reported longstanding illness or medical condition, who reported prior participation in biomedical research (N=15).

Two central city locations in England were used to run the groups. One-third of the lay public sample participated in Birmingham and the remainder in Guildford. People in Group 2 took part in Guildford, while those in Group 3 met in Birmingham. All Group 1 discussions took place concurrently in July 2006, Groups 2 and 3 were held in October and November 2006.

Recruitment

Market research recruiters identified participants for this research using sample quotas designed by the research team and agreed with the Wellcome Trust.

The following specification was used to maximise diversity in the sample according to age, gender and ethnic group. Attention was also paid to participants' educational level as a proxy for socio-economic group.

Box 1: Sample specification

- Equal numbers of men and women.
- Within each gender, equal representation of those under 30, aged 30-45 and over 45 years.
- Approximately one-third belonging to a non-white British ethnic group.
- Approximately half with educational qualifications ranging from none to GCSE or 'O' Level equivalent and half with qualifications at 'A' Level or above.

For Groups 2 and 3, a screening questionnaire was used in addition to the quota controls described above. This questionnaire is given in Appendix 3.

Box 2 illustrates the following characteristics in each group:

Box 2: Participant screening criteria

Group 2:
- Report a long-term medical illness or health problem.
- Have no prior experience of participating in biomedical research.

Group 3:
- Report prior participation in biomedical research, either actively or passively.
- Participated in biomedical research either as a healthy volunteer or a patient.

A variety of means were used to recruit participants across the three groups, including off-the-street recruitment, networking and a patient database.

Participants were paid an incentive totalling £100 for taking part in the reconvened discussion groups; £30 was paid on completion of the first session and the remainder at the end of the final session. All people at the first session returned for the second and final session.

Deliberative method design

The deliberative research method used in this research was qualitative reconvened discussion groups. This process involved informing participants on key issues associated with biomedical research governance, then allowing time for people to consider and discuss the issues both within small groups and away from the research setting. Reconvening the same participants approximately one week later allowed further exploration of people's attitudes after they had had opportunity to more fully reflect on the material presented to them.

This approach has several key advantages for the purposes of this research. First, for a topic such as biomedical research governance where prior public awareness and factual knowledge is likely to be low, it allows people to engage with a range of material over a relatively short time period. Second, the discussion groups are hosted by non-expert moderators who explore with participants the issues they raise and follow up queries on their behalf, rather than seek to provide an 'expert opinion' or give precedence to one viewpoint over another. Third, it provides an opportunity to study attitude change at an individual or group level over the course of two discussion groups, thus probing beyond people's first responses to allow a more considered view to emerge.

The deliberative method does however rely on what, when and how information is presented to participants. For this research, a strong emphasis was placed on making the information as accessible as possible, keeping technical or legal terminology to a minimum and wherever possible relating the more abstract principles of governance to situations or structures that people would be familiar with in their everyday life. For these reasons, key information on a small number of issues was presented to participants via short information films.

Film development

In conjunction with Glasshead film production company, our research team developed short information films in the following key areas: personal information, informed consent, databases and committees.

Films on each area lasted approximately two minutes and were preceded by a short montage of visual images designed to portray key referents in the area of biomedical research governance, including scientists working in a laboratory and blood samples being taken in a GP surgery.

A number of steps were taken to ensure that the films were as relevant and interesting as possible to research participants. Firstly, the films adopted a 'talking heads' approach whereby a male and/or female actor voiced opinions that were often at odds with each other, were at times exaggerated or deliberately misunderstood. In addition to eliciting humour to engage the audience, these positions were intended to reflect the sort of arguments we know that the public might make or see reproduced in the media. By presenting such arguments, the aim was to avoid simply replicating them in the group discussions but to instead encourage further reflection. Everyday language was used in the films and the dialogue was located in a 'real-world' context. For example, issues around sharing personal information were presented using the example of a supermarket reward card. The background to the films was kept simple to keep attention focused on the dialogue. The topic and content of the films is summarised in Table 1. Further detail on the film content is available in Appendix 2.

Table 1: Content of films relating to biomedical research governance

Film topic	**Setting**	**Dialogue**
Personal Information	Older lady in a cafe: monologue	Registering at a new health centre
Informed Consent	TV interview of an academic	Seeking consent for biomedical research
Databases	Close up of two actors sitting across a desk	Medical records held on a database
Committees	A couple in a doctor' s waiting room	Public perceptions of committees

The second method used to maximise public interest in the films was piloting. Prior to using the film in the reconvened discussion groups, two focus groups were held in order to allow members of the public to discuss and comment on pilot versions of these films. Each focus group comprised eight people who gave feedback to the research team on the visual imagery used in the film, as well as the appropriateness and relevance of the dialogue. Wherever possible, this feedback was incorporated in the final edit of the film.

Group discussions

Each group discussion was divided into two separate sessions over a period of approximately one week. The first was an all-day session that ran on a Friday or Saturday. It was in this session that participants were introduced to material on biomedical research governance through a variety of means. First, they participated in a practical orientation exercise that was designed to assess their initial awareness of biomedical research, what they considered to fall within its remit and the importance of public participation. Then, over the course of the day, participants were taken through

material in the following areas: personal information, informed consent, databases and committees, using the films but also other stimulus material that included posters and handout material focusing on relevant examples. All groups encountered the material in the same set order. Discussion was structured using a detailed topic guide that probed responses to the film material and other stimulus information. Although effort was made to cover all probes in the guide, this did not preclude respondent-led discussion in relevant areas.

Approximately one week later, a shorter session of 1.5 hours was held on a weekday afternoon or evening with the same participants. This session encouraged people to reflect on the material they encountered last time, in particular to share with others their deliberations and any exchanges on the topic they had had with others outside the discussion group. In this session, people were also introduced to three vignettes that built on key issues around informed consent, anonymity and confidentiality covered previously. Drawing on the material they had already encountered, participants were asked to make judgements about how comfortable they would feel taking part in different types of research outlined in the scenarios and to outline their reasoning in each case.

All group discussions were recorded using digital audio recording equipment with the consent of all participants.

APPENDIX 3: Findings from the expert data

The following main themes were identified from the 30 expert interviews:

- attitudes to research governance mechanisms
- the impact of over-regulation
- limiting public participation
- qualifying public participation.

When referring to experts, we use the following abbreviations to indicate which group they represent (see pp. 96-97 in this report):

i) Policy Advisors (PA)
ii) Scientific Community (SC)
iii) Health Practitioners (HP)
iv) Independent Watchdog (IW)
v) Special Interest Groups (SIG)

Attitudes to research governance mechanisms

Implementation of legislation
Similar to the some of the views expressed by the general public, policy advisors and scientists within the expert cohort were likely to suggest that the mechanisms currently in operation were generally good in terms of how research is regulated, in part because of the relatively slow pace of development and implementation of new legislation. This allowed for proper reflection:

> And actually you come up with some rather sensible answers, which is you start low-key, you go a bit more slowly than the protagonists would wish […] you gradually decided whether you move forward or you retrench…
> (Participant 14, SC)

Legislation as 'reactive'
Alternatively, there were some within the policy and science community who took the opposing view that recent legislation was the product of 'knee-jerk' reactions to various crises, with insufficient thought given to the negative implications for research. Representatives from IW and SIGs also expressed concern about the 'reactivity' of legislation but this was framed as 'dragging a long way behind in terms of dealing with issues', whereby current mechanisms could not keep pace with new developments.

Unilateral forms of regulation
Similar to the concerns expressed by the public, unilateral research governance was viewed as unsatisfactory because multi-national companies could still conduct research in countries with fewer restrictions, forcing research into the private sphere. Consequently, with less oversight in the private sphere, this could pose a threat to the rights of human subjects, scientific progress and openness.

The impact of over-regulation

As noted above, while there was some suggestion that research regulation in the UK proceeds at the right sort of pace, there were some SC and PA experts who were critical of what they saw as the effects of over-regulation.

The UK as a 'client country'

Some regulatory mechanisms may stifle technological innovation and application. This will have a detrimental effect on the UK's position as being at the cutting edge of new technologies because of its negative impact on the economic prosperity of the UK, and could lead to the migration of scientists into the private sector:

> At the moment, I think the regulatory regimes are causing huge problems for researchers and we've got a block almost.
> (Participant 2, SC)

> The way forward […] is don't control your free spirits. This is true in science, in the arts, everything. So the notion that you can make progress by governance of discovery is wrong…
> (Participant 1, PA)

Opponents 'thwarting' research

Policy advisors and scientists envisage research potential being thwarted whereby the input of opponents of new technologies (such as GM crops) allowed them to 'successfully' inhibit further research. Consequently, they positioned any voices of dissent as 'anti-technology' and 'anti-development', which those from the SIG and IW communities also drew attention to, and the difficult attributions it carried:

> …here we are having to say again, hang on, you can't do that to human beings, and we're not opposed to scientific advance. We're not saying – we're not Luddites – we're simply saying that science, like every human activity, must be subject to moral norms.
> (Participant 22, SIG)

The impact on wealth creation

Over-regulation could significantly impact on the country's potential for wealth creation and a country will not prosper if it 'does not have top, free-ranging blue skies research going one' (Participant 1, PA). Representatives from IWs and SIGs offered a more circumspect interpretation of this suggesting that the claims made for this economic rationale were exaggerated or even false:

> …it's interesting, you know, the research and development agency and the Department of Trade and Industry and everybody else are very excited about genetics bringing jobs and profits, as well as bringing cures but it's all hype, and who knows where we'll be in ten years' time.
> (Participant 14, SIG)

Implicating the public in the problems of over-regulation

There is some suggestion that SC and PA representatives wish to maintain the independence of scientific research by limiting public involvement that is unwelcome and often viewed negatively. There is a perception of the public as 'over-cautious' and unable to make appropriate risk assessments, which reduces research capability:

> You won't have the opportunity to exploit science, understand it and exploit it as and when you need to […] Essentially that's the way research has been deconstructed as part of the GM debate.
> (Participant 5, SC)

Limiting public participation

Balancing individual rights and those of the community
Representatives from all communities within the expert cohort recognised the difficulties of balancing the rights of the individual over the rights of the community and that, in some instances, the public had too much influence on what should not be supported. Providing no harm comes to the individual, it was not upheld that individuals should have any over-arching rights to prevent their information being used for research, as some publics who are more directly affected could be denied potential benefits:

> And it may be that embyronically derived therapies will not deliver the treatments […] But, if we don't do the work we'll never know […] people with these profound health conditions are, in effect, condemned to remain affected…
> (Participant 12, IW)

The public as scientifically deficient
An overwhelming reason for limited public involvement was founded on the public's perceived lack of understanding about scientific issues, and inability to cope with the complexities of the technical language:

> It's difficult to see how the public can be more directly involved in the regulatory process. You could, for example, have lay people on regulatory committees, but the problem is that a lot of information that comes to those committees is highly technical and very, very difficult to understand.
> (Participant 3, SC)

A similar concern was expressed by an expert from the SIG community:

> The only opinions worth having are informed opinions, and it is very difficult for Joe Public to achieve this given the complexity of the issues.
> (Participant 22, SIG)

Criticisms of the public's mode of contribution
There were examples of experts from all communities who suggested that the public's involvement should be limited because they are incapable of behaving appropriately, and lack objectivity:

> And, you know, when you do that, I've been involved in lots of public debates and discussions and meetings and all these sorts of things and some of them, you know, end up being like Nuremburg rallies, you know. They're just simply dreadful.
> (Participant 9, SIG)

> Whereas the public debate was just a shouting match and it was sort of, I guess, has, had the worst aspects of sorts of yah boo politics really. People just stood up and yakked at each other and nobody changed their mind […]
> (Participant 5, SC)

Qualifying public participation

While certain aspects of research governance are considered 'off-limits' to the public because of their lack of expert knowledge, other areas of involvement are tolerated by some groups of experts.

Experiential knowledge, morals and ethics

Despite concerns by experts that the public's involvement in governance issues should be limited because they lack the requisite knowledge or language, there was some recognition that it was perfectly natural that the public should make ethical and moral judgements grounded in their own experience. Furthermore, it was appropriate that the public should make some contribution here because it is not the job of scientists to make these sorts of decisions:

> 'What's [unclear] scientists are saying, we can't solve the social issues, we actually need people to comment on the possible uses of the discoveries we're making and to guide us in some ways.
> (Participant 10, SC)

Public involvement at an earlier stage in the process

While a view less often expressed, there were some within the expert cohort who favoured a more 'upstream' approach to public involvement and welcomed their contribution, and were critical of those who sought to exclude the public:

> I'm very interested actually in some experiments that are involving concerned members of the public in the actual design and research itself […] Secondly, this is a fairly radical suggestion, but I don't think we have enough lay input into priorities in research funding although I'm not sure how we do it.
> (Participant 10, SC)

Expert data: conclusions

The discussion above highlights the often competing views between the scientific and policy community and those who represent special interest groups and public watchdog organisations. On the one hand, those from the former are concerned about over-regulation because of the possible economic implications to the country and its impact on research capacity, while experts from the latter group, while sometimes sharing these concerns, frame over-regulation in terms of its impact on health benefits rather than economic ones.

While some experts may agree with the idea of increased public involved, there are competing views about how they envisage the public's role. However, this position is not universally held by all groups of experts, some of whom position the public as poorly equipped to make any significant contribution to discussions about research governance.

APPENDIX 4: Topic guide for initial groups

PUBLIC ATTITUDES TO THE GOVERNANCE OF BIOMEDICAL RESEARCH

UNIVERSITY OF SURREY

TOPIC GUIDE FOR RECONVENED GROUPS

SESSION 1

7–8 JULY 2006

Introduction to participants: 5 mins maximum

Thank you very much for coming to take part in this research. We hope you will find the day enjoyable and interesting. We are a team of researchers from the University of Surrey working on behalf of the Wellcome Trust, a medical research charity, to find out more about what the public thinks of biomedical research and how it is governed and controlled.

My name is [name] and the other researchers here today are [names].

During the day we'll be talking about a number of different issues to do with controlling and governing research. To do this we are going to ask you to participate in some practical exercises and some discussion groups. In the discussions we will use short films to illustrate some of the issues we want to focus your thoughts on.

You do not need any prior knowledge about this topic. Our aim is to explore what you think, the issues that concern you, and your views about controlling biomedical research. We really want to hear your views and opinions. The purpose of the research is to help the Wellcome Trust understand what concerns people about taking part in research and what gives them reassurance and confidence.

When we report on our findings we will not reveal your identity, and the recorded discussions will only be heard and seen by members of the research team.

If the discussions we have today raise questions for you we will do our best to answer those. However, if we can't answer any of your questions we will suggest resources which might give you relevant information, e.g. websites, or address the question when we meet again next Thursday. You can also contact us via the email address or phone numbers on your information sheet.

We do have a lot of material to cover in a limited amount of time. So there may be occasions where we need to 'rein in' discussion in order to re-visit those same issues later in the day.

We will also be 'organising' you quite a bit so bear with us if we seem bossy at times! So, here goes….

First then we have a couple of practical exercises and then we will go on to the group discussions. If you look at your name badge you will see that you have either a black square or circle on it, or a yellow square or circle. The researchers are each holding up a card with on of the symbols on it. Can you go to the researcher with the same symbol as you have on your name badge. She/he will then take you through the practical exercises.

BASELINE AWARENESS: Exercises

Activity 1: 7 mins maximum

- Four researchers standing at four tables spaced out in room with flipcharts.
- People divide into four groups and one group to each table. The Powerpoint slide of the Wellcome Trust definition of biomedical research will be visible in the room:

> *BIOMEDICAL RESEARCH: any health-related research that involves humans, their tissue and/or their data.*

- **Ask people what sort of things they believe are included within the definition on slide.** Write these down on flip chart. (One-minute warning on time)

- **NOW GIVE OUT HANDOUT 1:** Explain these are five examples of biomedical research.

Handout 1:

These are some examples of biomedical studies:

a) taking part in a clinical trial to test a new treatment for a health problem

b) having blood taken by your GP to test your health, which is also then used for research into how many people have got anaemia in a particular city

c) having your NHS notes looked at by a researcher to get data for a study into (e.g.) link between smoking and cancer

d) after you have had your appendix or gall bladder taken out it could be used for research at a later time

e) agreeing that your NHS notes could be looked at for research into (e.g.) how many times women/men go to the GP changes in a year depending on their age, over a ten-year period.

Activity 2: The H-form (10 mins max)

- Read out the statement on the flipchart and draw attention to the scale. Give each person their own pen and ask them to mark a cross on the scale to represent their view about the importance of people participating in biomedical research. Emphasise we just want an idea of what they think *at the moment*.

- Then give everyone some Post-it notes and ask them to write down the main reason for:
  a) why they did not score the importance lower;
- and then on another Post-it note
  b) why they did not score the importance higher.

Didn't score lower because…	**"How important is it that people participate in biomedical research?"**							Didn't score higher because…
Post-it notes	Not at all important						Very important	*Post-it notes*

Activity 3: Reasons not to take part in research (5 mins)

- Third flipchart sheet with question already on it. Ask for ideas, researcher writes down participants' comments. Encourage each person to say at least one main thing.

Why might people not want to take part in biomedical research?

FILMS AND DISCUSSIONS

IT IS ESSENTIAL *THAT MOBILE PHONES ARE TURNED OFF* AS THEY WILL INTERFERE WITH RECORDING EQUIPMENT IF LEFT SWITCHED ON (EVEN IF RING IS ON SILENT)

When everyone is seated, ask each person to introduce themselves. Explain that we will now watch some films that involve actors talking about different issues to do with biomedical research and how it is governed.

SHOW FILM 1: Personal data (11.00 to 11.45)

- What struck you/caught your attention?

- Mrs Barker was fine about providing some types of information and less sure about providing other types. In the end, she decided not to give her permission for her details to be used in medical research. What do you think of this decision: reasonable or not? What would be important to you if you were making this sort of decision?

- Mrs Barker had to tick a box to give her permission for her personal data to be used. Do you think you should always be asked to explicitly give your permission (EXPLICIT CONSENT) or are there times when it should just be assumed it is okay to use your personal data for research? (PRESUMED CONSENT)

Wider discussion points:

- What do you think of as personal biomedical data? (PROMPTS: individual records, tissue or blood samples, DNA)

► Now we are going to think about different issues to do with personal biomedical data.

► The personal data you could be asked for, or that might be got from your records, could include your name and address, just your postcode, or your NHS number for example.

- Would you have reservations about providing any of these, and if so what reservations?
- What reassurances would you want before you gave this information? (Note: this is about **identifiability**).

► Some researchers need information that might be considered **SENSITIVE** personal data.

- What kinds of personal data would you consider to be sensitive? (PROMPT: sexuality religion, ethnicity)

- If the data you are asked for are sensitive, do you feel that should be treated differently compared to non-sensitive data? (PROBE: In what ways? What are the issues about this?)

► When you agree to take part in research, you may be given an assurance that your data will be **ANONYMOUS.**

- What does it mean to you if you are given an assurance that your personal data will be anonymous? (PROBES: Can information/samples from individuals ever be 100 per cent anonymous? Do people perceive anonymity to be same as confidentiality?)

CONCEPT FOR INFORMATION
Reversible anonymisation where 'key' to identifying individuals is removed but retained elsewhere, versus *irreversible anonymisation* where this key is destroyed so link to individuals cannot be re-made.

► Often when you agree to take part in research, you are given an assurance that your data will be **CONFIDENTIAL.**

- What does it mean to you if you are given an assurance that your personal data will be confidential? (PROBE: Can information/samples from individuals ever be 100 per cent confidential?)

- Do you think the importance of confidentiality varies according to the type of personal data? (PROBE: individual records, tissue or blood samples, DNA)

► Now thinking about different ways in biomedical research might be done. Let's think about one situation where a researcher is allowed access to data already held in your NHS medical records, to research something like the incidence of heart diseases in a sample of 2000 people.

- Do you have any reservations in this situation about assurances of anonymity and confidentiality?

► Now thinking about a slightly different research situation where you are specifically asked for personal data. For example, you are asked to take part in a particular study researching the link between heart disease and lifestyle factors which requires you to give at least one blood sample along with some information about your lifestyle.

- Do you have any reservations in this situation about assurances of anonymity and confidentiality?

► Sometimes personal biomedical data are gathered for one study and then made available to other researchers for other studies.

- What do you think about this? (PROBE: type of data, anonymity, identifiability, confidentiality)

- Does it matter who the third party is – does this affect what you think? (PROBE: academic/commercial, publicly or privately funded; other third parties such as insurance, police)

► Finally, thinking about what how personal data are stored by researchers:

- Do you think there are any issues that should be considered about the storage of personal data? (PROBE: e.g. security concerns; if on a computer; how long it's kept, who keeps the identity key, does it matter what the data is e.g. numbers, records, tissue samples?)

Finish by 11.45.

SHOW FILM 2: Informed Consent (11.45 – 12.30)

- What struck you/ caught your attention?

- The view of the professor was that it was fine that research was carried out on tissues and samples without consent. Do you agree with that?

- The film refers to a change in the rules. If circumstances do change after research participants have given consent, e.g. the data will be made available to a third-party or the study design is altered in some way, do you think that researchers should seek your consent to the changes (re-consent) or go ahead?

Wider discussion points:

- What meaning does the term 'consent' have for you?

DEFINITION OF CONSENT: You give permission for something to happen.

- When you signed our consent form earlier today, what did it mean to you? (PROBE: did you read it? understand it? significance attached to it?)
  FOR BIOMEDICAL PARTICIPANT GROUP: PROBE OWN EXPERIENCES.

► I'd like to now explore your expectations of giving consent more generally.

- What do you think about consent and issues of privacy; ownership; responsibilities; nature of ongoing contact; knowing risks to your health based on the research findings.
- If you were considering participating in a medical research study, what information would it be important for you to have before you gave your consent? (PROBE: risks-benefits; demands; implications, short and long-term; use of data)

Hand out TYPES OF CONSENT card:

EXPLICIT (INFORMED) CONSENT: Individual opts in to a process fully informed of what it entails. IMPLIED CONSENT: Inferred from an individuals' behaviour or conduct. NO CONSENT: Individual is not asked whether or not they wish to participate.

► There are different types or 'levels' of consent. Thinking first about explicit consent: you 'opt in' to a process having had clear information about what is needed and all questions answered. Typically, explicit consent is a signed statement of agreement that can be withdrawn at any time.

HANDOUT NHS CONSENT FORM: Patient Agreement to investigation or treatment (4 pages). *Allow two minutes for people to look over the form.*

- What is your impression of this form? (PROBE: does it reassure you? satisfaction with process; clarity)

► Now thinking about implied consent, which is where it can be reasonably inferred from your behaviour that you have agreed to something, even if nothing is signed or said.

- Can you think of any circumstances where it would be appropriate/justifiable to proceed with research with only implied consent? (PROBE: using routine blood samples for additional research; access to health records for public health monitoring)

- How important/effective do you think it is to inform people via more general means, such as a poster in your local surgery about instances where consent is implied?

- Should you always be able to 'opt out'?

► Finally, now thinking about research where there is no consent asked for: where data is used or blood/tissue removed without the person being asked or given opportunity to object.

- Can you think of circumstances where it would be appropriate/justifiable to proceed without consent? (PROBE: audit of health records in the NHS; emergency medical treatment)

- If medical research has no effect on the individual studied, has been ethically approved and is for a non-commercial purpose, how acceptable do you think it is to proceed without consent?

Finish by 12.30 – LUNCH.

Show Film 3: Databases (13.15 –14.00)

- What struck you/caught your attention from this film? What do you think?

- Pete could see the advantages of all our medical records being linked up with other databases. What do you think about this? (PROBE: type of information – genetic/non-genetic, sensitive, personal).

- Kate was worried about a medical records database being linked up to other databases. What do you think about this? (PROBE: seek re-consent for data linking?)

Wider discussion points:
Give out CONNECTING FOR HEALTH handout. Allow people a few minutes to read it.

Starting from 2006, every NHS patient will have their own NHS Care Record put on a national computer database. Your record will have 2 parts:

1) A detailed record will record your medical treatment and consultations;
2) A summary record will contain essential medical information, such as allergies or medications that you take.

Your record will have a unique identification code containing your NHS number. This code will enable health information about you to be linked together in a way not previously possible. For example: your GP will have computer access to hospital consultation notes; your local pharmacy can be notified of your prescription.

By 2008, you will be able to access your summary health record on a protected NHS web page. Here you will be able to add information about your health needs. If you wish, you can limit who has access to sensitive information in your record.

Access to your care record will be controlled by an NHS 'smart card' using Chip and PIN technology. Only people directly involved in your medical care will be able to access your individual record and all access will be recorded on the computer. Data that is anonymous – that is, does not contain uniquely identifying information about an individual – can be used for health research, planning and audit purposes.

Discussion points

- Can you see any advantages of moving patient records from paper files onto a national computer system in this way? (PROBE: 'joined-up' services; fewer lost records, easier access; improved care)

- Do you have any concerns about this change? (PROBE: confidentiality, lack trust/faith in centralised system, corruption and misuse; cost/value for money)

- How do you feel about having computer access to your own health record? (PROBE: any concerns on data access controls; awareness that already have rights of access under Data Protection law)

► The NHS has issued a *care record guarantee* to reassure patients that their records will be kept confidential in the new NHS computer system. Among the 12 commitments given to patients are that identifiable information about them will not be shared outside the NHS without their permission.

- How far does this guarantee reassure you? (PROBE: third-party access commercial, e.g. insurance and non-commercial, e.g. police, social services)

- Do you think it is acceptable or not for the NHS database to be used by medical researchers to select people for a research study such as (EXAMPLE) to search the database for people with history of cardiovascular disease aged 50 to 55 years in England? (PROBE: nature of contact [direct or indirect] and participation [passive or active], funding of research [public or private])

- Do you think it is acceptable or not for the NHS database to be used by medical researchers to monitor disease or infection in the population? EXAMPLE: to study outbreaks of influenza or clusters of leukaemia.

- Should you always be able to withdraw your consent to having information about you held on a database? (PROBE: What are the implications for research [sample bias] if a particular population group has largely 'opted out' and hence is missing from the database).

Models of governance

► There are different rules for overseeing research, some are laws, others are commonly accepted protocols or review processes. There are three main models of governance:

* legislation
* professional self-regulation
* external research governance bodies.

1. Legislation
Handout the legislation model of governance sheet

► One model of governing biomedical research is by using the law. Talk through the poster information.

A key piece of UK legislation is the 1998 Data Protection Act. This Act seeks to protect the rights of individuals with regard to a wide range of personal data – not just medical data – about them.

► The Act does this by restricting what the holders of personal information may do with that information and with whom they may share it. It also requires those who are in charge of that data to seek explicit consent from individuals before collecting, processing or passing on 'sensitive' information about them.

Principles of data protection

Personal data must:

- *be fairly and lawfully processed*
- *not be further processed in a way incompatible with the purpose for which it was obtained*

[Biomedical researchers must obtain your consent to process your personal data. The Act does allow for personal data to be processed without consent where the data controller can demonstrate that this is for a legitimate interest that does not prejudice the rights and freedoms of data subjects and is necessary for a medical purpose]

- *adequate, relevant and not excessive*
- *accurate and up to date*
- *not kept longer than necessary*
  [Must not hold any information about you that is irrelevant to the aims of the study or is no longer needed]
- *processed in accordance with the individuals' rights*
  [To have reasonable access to information about you and to claim compensation if you personally suffer as a result of your data being misused]
- *secure*
  [protect against loss, destruction or illegal access, especially where data is sensitive]
- *not transferred to countries outside the European Economic Area that do not have*

adequate protection
[data will not be shared with other countries doing similar research if their data protection systems are inadequate: this includes the USA].

The Act is overseen and enforced by an Information Commissioner. The commissioner is an independent authority who reports directly to the UK Parliament.

It is a criminal offence if:

- *a Data Controller processes personal information without first notifying the Information Commissioner of this fact*
- *someone knowingly or recklessly obtains or discloses information without the consent of the Data Controller.*

► Any individual who suffers damage as a result of the DPA being contravened is entitled to compensation from the data controller.

► General discussion points around Data Protection Act:

- How effective do you feel the DPA is in protecting your personal data and rights? (PROBE: enforcement; clarity; personal awareness of this law)

- Does the existence of an Information Commissioner reassure you that others can be trusted with your personal data? (PROBE: different types of research)

- How far do you think the prohibitions under the Act will function as an effective deterrent? (No criminal case under DPA yet.) (PROBE: different types of research)

► The DPA principles have big implications for biomedical research, which typically uses personal information that is deemed 'sensitive' and so is subject to stringent controls. Biomedical research has some exemption under the Data Protection Act, but this is partial and there is considerable confusion about what it acceptable practice.

► For EXAMPLE: In some cases, patient data that allows individuals to be identified can be exempted from the DPA requirement for explicit consent (under Section 60 of the *Health and Social Care Act 2001,* following recommendation from PIAG).

► EXAMPLE: The requirement for explicit consent set out in the DPA is reinforced in the *2004 Human Tissue Act* for the removal, storage and use of human organs and tissues. Strict penalties apply if consent is not given before human material is used for medical research or public health monitoring. (This doesn't apply to surplus or residual tissue left over from surgical procedures, if research has ethical approval and uses non-identifiable data.)

► Specific discussion points around DPA and biomedical research

- How effective do you think using a multi-purpose data protection law can be in regulating biomedical research? If research is in the public interest, should it have to meet all of these controls? (PROBE: different types of research)

► There are reports that the sharing of anonymous patient data for medical research has suffered because those charged with looking after that data fear prosecution under the DPA.

- What do you think about this? Has regulation gone 'too far'?

► A lot of medical research relies on secondary data – that is, data originally collected for a different purpose. The DPA stipulates that the use(s) of data need to be clearly explained to the individual when they give their consent.

- How realistic do think this is for biomedical research?
- How should public health be balanced against individual rights under the DPA?

2. Professional self-regulation

Hand out professional self-regulation model of governance.
Give people a minute to look at it and then talk through it.

► Another approach to governing biomedical research is through professionals engaging in self-regulation. These can be divided into:

Professional guidance

E.g. The GMC is an independent body that registers doctors to practise medicine in the UK. It has legal powers to enforce proper medical standards of practice in areas such as patient confidentiality and consent. The governing body of the GMC has 35 members, 14 of which are drawn from the general public.
E.g. The BMA is a voluntary professional association of practising doctors in the UK. It publishes guidance and policies decided on by its members, mainly practising doctors, but has no legal powers of enforcement.

Scientific (peer) review

E.g. A research proposal funded by an external agency is sent off to at least two independent and anonymous reviewers. These reviewers are experts in the field and give their opinion on the aims and objectives of the research, the intended method and delivery of results. This type of review typically precedes ethical review.

► E.g. A regional cancer registry is subject to peer review in order to ensure its compliance with quality standards and to disseminate good practice. Teams of specialist professionals conduct site visits, together with patient/user reviewers. Findings are publicly reported.

► Discussion points around self-regulation:

► Some would argue that scientific experts are best placed to comment on the suitability and robustness of medical research and organisations.

- How far would you agree/disagree with this?

- What do you see as the strengths/weaknesses of professional self-regulation for biomedical research? (PROBE: different types of research; extent this kind of regulation can be independent, transparent and fair-minded)

- How far would you trust organisations and individuals involved in self-regulation to put the public's interests first? (PROBE: credibility)

3. External research governance bodies

Hand out external bodies model of governance.
Give people a minute to look at it and then talk through it.

► A third way in which biomedical research can be controlled is to have committees and structures in place to make decisions on acceptable research. In particular, such oversight committees examine whether research is ethical.

There is no single, national ethics committee that considers research that involves humans. Instead there is a centrally administered system of regional ethics committees that looks at any research on NHS patients or premises. Researchers submit a written proposal to a Research Ethics Committee or REC and must get their approval before research can begin.

Examples of research examined by a REC are:

- *randomised trials where people are allocated into groups and each given a different treatment so that their effectiveness can be compared*
- *research involving the use of medical records to contact people with cancer to recruit them to join a medical research study.*

► Discussion points on REC decision-making process:

► Most RECs meet in private and there is no requirement for them to make their minutes publicly available. Typically they make decisions by consensus, but if this is not possible, then a vote of members is taken. They need to decide applications within a 60-day time limit.

- How effective do you perceive this method of working to be? (PROBE: transparency, independence)

► Some researchers have argued that the broad remit of a REC – to look at all research connected to the NHS – means that the process of getting ethical approval for a piece of research is too long and complicated and that research suffers as a result.

- Are there circumstances where you think this process of REC approval is not warranted? (PROBE: low-risk, non-interventionist research, e.g patient surveys; research involving NHS premises but not patients; routine health monitoring)

► A similar piece of research that does not include NHS patients or premises does not have to gain REC approval unless it involves a clinical trial. As an alternative, the body funding or hosting the research usually turns to their own ethics committee, e.g. a university ethics committee for ethical review.

- Should there be one oversight body for all research or is it acceptable to divide research in this way?

► PIAG (Material Ref: Your health records: safeguarding confidential information: the role of PIAG)

Sometimes researchers need to use NHS data that identifies individual patients in circumstances where it is not considered practically possible to get their informed consent to do this.

► (EXAMPLE: study including tens of thousands of patients; patients deemed mentally incapable of giving consent). In this instance, research proposals can be submitted to the Patient Information Advisory Group (PIAG), who can give dispensation from the requirement to obtain consent if they think appropriate.

PIAG is an independent public body whose members are patient groups, healthcare professionals and regulatory bodies. PIAG advises government on cases where research using identifiable information can proceed without consent as the following apply: it is for a medical purpose; it is in the wider public interest; consent is not practicable; anonymous information will not suffice.

► PIAG meets four times a year and publishes its minutes and a register of all approved studies on its website.

► EXAMPLE OF RESEARCH approved by PIAG: **National Cancer Registry database**. Individual data on patients supplied from multiple sources and over long time periods. Register used to look at trends, compare groups, evaluate effectiveness of screening. Researchers approved by PIAG can also receive names of individuals eligible for particular Cancer research. These individuals may be contacted - this will be via their GP and their informed consent will be required for any subsequent participation in research.

- Does the existence and operation of PIAG reassure you of your patient rights/ confidentiality?
- Do you think they have an important role? Do they make a difference? (PROBE: different types of research)

SHOW FILM 4: Committees

Discussion points relating to film:

- What struck you/ caught your attention?

- The people in the film were talking about how committees make decisions about the sorts of biomedical research that are carried out. It was suggested that these things are really 'best left to the medical experts'. What do you think?

- Another argument was that having ordinary people on these committees would make them more balanced and transparent. EXAMPLE: RECs include lay and expert members. What do you think about this? Is it not possible that they could be balanced and transparent with *just* experts? (PROBE: representativeness; balance; conflict of interest; independence)

Round-off session

► Give general feedback from small-group discussions drawing on materials generated during these sessions.

► Move discussion away from specific cases and towards more general principles of governance:

- If we had to feed back to people in charge of research the things that are key to making people feel happy about participating in biomedical research in the UK, what would those key things be?

Close
Thank people for their participation.

APPENDIX 5: Topic guide for reconvened groups

PUBLIC ATTITUDES TO THE GOVERNANCE OF BIOMEDICAL RESEARCH

UNIVERSITY OF SURREY

TOPIC GUIDE FOR RECONVENED GROUPS

SESSION 2

13 JULY 2006

ONCE PARTICIPANTS HAVE ARRIVED, DIVIDE INTO SAME TWO GROUPS AS IN SESSION 1.

1. General overview by research team

Thank people for coming.

Recall that we focused our discussion last time on biomedical research as health-related research involving human tissue and/or data. We watched some films exploring issues around personal information, consent, databases and committees.

Begin by feeding back some key themes across all discussion groups:

- Many felt that biomedical research is important, that individual participation is needed particularly where there is a public good, e.g. medical cures, new medicines, etc.

- At the same time, concerns were raised about biomedical researchers and third parties having access to personal information about you, particularly where this information identifies you as an individual or is sensitive in nature.

- We talked about how you would like to be informed about when and how your biomedical data is used. Your opinions differed about whether or not you should be asked for your explicit consent for your data to be used when we considered that research may or may not use information that can be traced back to you and that research can be for a range of purposes, e.g. for audit, for routine health monitoring or specific research studies.

We did have some specific questions that we weren't able to answer last time, for example around lay representation on committees and how regional cancer registries operate. A number of you were particularly interested in finding out more about the NHS database, Connecting for Health and the Patient Information Advisory Group (PIAG). We have information sheets with us today that you can take away to read more about these.

2. Reflections from participants

Explain that in this session we are interested in any thoughts or reflections they have had over the last week or so about the topics we covered last time.

Invite reflections and comments
(PROBE: did they re-read material; talk to friends or family; seek out further information; have their views altered; further questions?)

3. Vignettes

Explain that for the remainder of the session today, we want to get their opinion on three different examples of biomedical research. STRESS THAT THESE ARE NOT REAL-WORLD EXAMPLES BUT ARE HYPOTHETICAL.

Will now consider each example in turn:

VIGNETTE 1: (20 minutes max.)
HAND OUT VIGNETTE TO EACH PERSON, ALLOW TIME TO READ

Researchers in a laboratory want to study blood samples that people first gave to their doctor when they had a routine blood test. To further their understanding and expertise in cell biology, the researchers want to look in detail at how different types of blood cells work at different temperatures. To do this, they need a large number of samples – 10 000 in total. All of these blood samples are stored with an individual's NHS number on them. Before they begin the study, the researchers will permanently remove the NHS number to make the blood samples irreversibly anonymous. The results of their work will be presented in academic journals.

1. Does it matter that people won't have given their consent for this to happen and why? (PROBE: concerns; difficulties; practical measures to obtain consent, e.g. at point of contact with GP)

2. How do you feel about the level of anonymity in this study? (PROBE: irreversible vs. reversible anonymity; purpose of research)

3. H-form:
   TO BE COMPLETED SEPARATELY BY EACH INDIVIDUAL ON A4 SHEET

   'How comfortable are you that your blood sample might be involved in this study?'

   Not at all comfortable ----------Very comfortable

   Why not lower? Why not higher?

VIGNETTE 2: (20 minutes max.)
HAND OUT VIGNETTE TO EACH PERSON. ALLOW TIME TO READ

Twelve years ago, researchers carried out a study on diabetes. This study looked at the medical histories of 500 adults diagnosed with this condition. At the time, every individual included in the study gave their explicit consent for the researchers to look at their medical records for this purpose. Today, a different team of researchers want to investigate a new theory about diabetes using the same sample of people. They would like to re-contact them in order to collect some new information.

1. Is it acceptable for researchers to re-contact participants for this purpose and, if so, how should this proceed? (PROBE: which research team; practicalities; lack of provision for follow up at time 1)

2. How do you feel about the level of anonymity in this study? (PROBE: keeping data for 12 years; passing on details)

3. H-form:
   TO BE COMPLETED SEPARATELY BY EACH INDIVIDUAL ON A4 SHEET

   'How comfortable would you be about being re-contacted in this situation?'

   Not at all comfortable ----------Very comfortable

   Why not lower? Why not higher?

VIGNETTE 3: (20 minutes max.)
HAND OUT VIGNETTE TO EACH PERSON. ALLOW TIME TO READ

Researchers have written a proposal about some research they want to carry out in the future. The research is about sexual health and possible variations in health behaviours in different parts of the country.

The researchers have already done a large survey of 3000 people. These people agreed to answer questions about their sexual health and gave their explicit consent for anonymous information about them to be used for statistics and research.

Because their survey did not include any detailed geographical information, the researchers now want to link this survey data with information about local areas collected in the 2001 census. Identifiable information about individuals, such as their postcode, will be required to link the survey with the census to make a new dataset. Once linked, this identifiable information will be removed, making the new dataset anonymous. The anonymous new dataset will be used to generate statistics and will be put in a data archive for possible future use by other researchers.

1. In the original survey, participants gave consent for their information to be used for 'statistics and research'. How acceptable is it that this should include data linking as described here?

2. How do you feel about the level of anonymity in this study? (PROBE: concerns if you were making decision about whether or not to give this ethical approval; confidence in data protection and peer review)

3. H-form:
   TO BE COMPLETED SEPARATELY BY EACH INDIVIDUAL ON A4 SHEET

   'If you had taken part in this survey, how comfortable would you feel about this research proposal getting the go-ahead?'

   Not at all comfortable ----------Very comfortable

   Why not lower? Why not higher?

4. Close

APPENDIX 6: Consent form

Consent form
Focus groups

- I have read and understood the Information Sheet provided. I have been given a full explanation by the investigators of the nature, purpose, location and likely duration of the study, and of what I will be expected to do. I have been given the opportunity to ask questions on all aspects of the study and have understood the information given as a result.

- I understand that all personal data relating to volunteers is held and processed in the strictest confidence, and in accordance with the Data Protection Act (1998). I agree that I will not seek to restrict the use of the results of the study on the understanding that my anonymity is preserved.

- I understand that the focus group will be recorded for research purposes but that I will remain anonymous and will not be identified in any way.

- I understand that I am free to withdraw from the study at any time without needing to justify my decision and without prejudice.

- I acknowledge that in consideration for participating in the study I shall receive the sum of £100 cash (£30 will be paid at Session 1 and £70 at Session 2).

- I confirm that I have read and understood the above and freely consent to participating in this study. I have been given adequate time to consider my participation.

Name of volunteer.....
(BLOCK CAPITALS)

Signed .....

Date .....

Name of researcher/
person taking consent.....

Signed .....

Date .....

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