18 November 2008

Preface and report:

'Public attitudes to third party access and benefit sharing: their application to UK Biobank'

Part 1. Background information on the commissioned report

Introduction

The purpose of the UK Biobank project is to provide a resource for research with the aim of improving the prevention, diagnosis and treatment of illness and promoting health throughout society. The resource is expected to contain health and lifestyle data and biological samples from 500,000 individuals aged 40-69 at time of enrolment.

Participants will grant access to their health-related records, provide some biological samples (e.g. blood and urine), have various measurements and answer questions about their lifestyle. The cohort will be followed up for decades, capturing all major health episodes and eventual death. The consent obtained at enrolment will allow the resource (data and samples) to be accessed and used for research projects in the future that fall within the purpose of the project.

The UK Biobank Ethics and Governance Council (EGC) is an independent monitoring body that advises on the ethical framework under which UK Biobank operates. In 2007, the EGC commissioned a public attitude survey to ascertain opinions regarding access to the UK Biobank resource (including intellectual property, commercialisation of research findings and models of benefit-sharing).

Why we commissioned this research

A key function of the EGC is to advise UK Biobank on the interests of research participants and the general public in relation to the project. Given this role, in 2007 the Council commissioned a scoping study of the current literature relating to public attitudes to UK Biobank-related issues. The study was intended to provide a firm, broad foundation for this aspect of the Council's advisory role by drawing on the already extensive literature in this area. This study[1] identified a gap in the current literature regarding public opinions in relation to access to the UK Biobank resource (including such topics as intellectual property, commercialisation of research findings and models of benefit-sharing). In response to this gap the Council issued a competitive tender and subsequently commissioned a further study in September 2007, resulting in the report at Part 2 of this paper. The EGC has chosen to publish the report in the interests of transparency.

Research aims

The aim of this indicative research was to provide a scoping study to elucidate whether or not there are grounds for concern from potential donors and potential beneficiaries about the management of third party access to the UK Biobank resource. In eliciting this research the EGC was testing out its own understandings and assumptions in relation to these topics. The research was commissioned to address the following research questions for two distinct age groups:

- Investigate the views of these age groups with respect to third party access to UK Biobank.
- Investigate opinions towards the notion of the 'public good'.

[1] 'Public attitudes to biobanks and related ethics and governance issues' Joanne Sumner (2007) available at www.egcukbiobank.org.uk/meetingsandreports

- Investigate opinions towards how UK Biobank should and should not be used (i.e. What types of research are regarded as falling within UK Biobank's stated purpose, 'to improve the prevention, diagnosis and treatment of illness and promote health throughout society' and what is the scope of the phrase 'health-related research'?).
- Explore opinions towards how access to various elements of the resource should be managed and prioritised (including who would be the most appropriate party to prioritise access and who should decide what constitutes 'the public benefit' in the context of UK Biobank).
- Ascertain opinions towards the circumstances in which access to the resource by researchers outside of the UK can be permitted.
- Ascertain opinions towards access by commercial interests with a focus on a) source of concerns and b) what policy approaches might address those concerns, e.g. more commitment to benefit sharing.
- Explore opinions towards the commercialisation of findings based on UK Biobank, including the granting of intellectual property rights.
- Ascertain opinions regarding the proposed and potential benefit sharing models, potentially through use of case studies or proposed benefit sharing models.
- Are there circumstances in which public (health) interests, may override individual privacy and access restrictions.
- Explore reactions and opinions towards the safeguards that are in place regarding access to UK Biobank (including the role of the Ethics and Governance Council).

Research outcomes

The report is attached at Part 2 of this paper. It should be noted that the contents and conclusions are those of the authors and not necessarily those of the EGC. Indeed, it is also important to note that the views of the respondents do not necessarily represent those of UK Biobank participants or those of the broader public. For example, as the report states, although the majority of respondents said that they would be prepared to participate in UK Biobank, in practice the attendance rate is closer to 10% of those invited. The authors reflect on this point in section 9.6 of the report.

The main messages that the EGC takes from the report are as follows:

- **Support for UK Biobank policies**
  The results of the study show widespread support for UK Biobank and its current policies on access and intellectual property. In particular there was very strong support for the range of restrictions carried within the Access Policy[2] and especially the importance of the role of the EGC in advising UK Biobank on matters such as direct access to biological samples. The Council was reassured to learn of this overarching support.

- **Security of information**
  The report highlights that respondents had more concerns over security of information held by UK Biobank rather than matters of anonymity and consent.

[2] The study reflected on the content of the draft Intellectual Property and Access Policy (January 2005). This policy is currently under revision and the latest version was not available on the UK Biobank website at the time of writing.

The report suggests that security is likely to be a key decisive consideration for potential participants. This finding reflect sentiments expressed by participants at the EGC's public meetings (including comments from a number of people who had been asked to participate but declined due to concerns over data security).

The EGC and UK Biobank have responded to these concerns in a number of ways. First, the EGC is specifically looking for an individual with expertise in information systems security in its 2008 round of recruitment in order to enhance its ability to advise on and monitor this area of the project's activity. UK Biobank provides regular biannual reports to the Council describing recent activities in relation to its data management and security systems strategy. Finally, UK Biobank acted on the EGC's recommendation that it ought to place more information about it security measures on its website.

- **Re-contact**
  The report cites that just over a third of respondents agreed that third parties should be allowed to contact individual participants in the future. The report suggests that this outcome might become a concern for UK Biobank.

  The EGC considers that when considering the issue of re-contact it is important to explore the purpose of re-contact. First, participants might be re-contacted by UK Biobank as part of its routine follow-up strategy (i.e. to collect more samples or information). Second, participants might be re-contacted by UK Biobank and asked if they are willing to give consent to be contacted by researchers directly (i.e. to be involved in separate research studies). In both cases, as the report indicates, UK Biobank will be the first point of contact and participants are free to decline further involvement.

  UK Biobank's consent form specifically asks participants to agree to being re-contacted. The Council considers this to be sufficiently clear that potential participants who disagree on principle with being re-contacted can exercise their right to decline participation at the point of the initial invite[3]. For those who agree to participate in the knowledge that re-contact is a possibility, any future involvement (with UK Biobank or other researchers) is entirely voluntary. The Council endorses this policy as it gives participants a choice over their future involvement.

  Notwithstanding, even if consent has been provided it is possible that the process of being re-contacted may be burdensome for participants, for example, there may be concern over the levels of re-contact or the reason for re-contact might raise anxiety (e.g. if the participant perceives that this is an indication of ill health). The Council is responsible for monitoring the rates of all re-contact in order to assure itself that participants are not being overburdened. The process by which this monitoring occurs will be developed with UK Biobank in due course. The Council is interested to learn more about participants' expectations regarding re-contact and any potential anxieties that may exist regarding the reasons for re-contact. As such the Council has recommended that UK Biobank investigates both of these points in a systematic post-visit survey of participants.

[3] On average 90% of those invited decline to participate.

- **Developments in the external landscape**
  The report asserts that the work of UK Biobank and the EGC may be susceptible to a range of developments including those within the scientific and the healthcare information environment. The report specifically cites genetic ID systems and the growing market in online diagnostics as two examples of areas that might impact on UK Biobank and/or on the motives of potential participants. The Council will keep abreast of developments in the broader scientific and policy arena and consider the implications of such developments on the work of UK Biobank.

- **Understandings and expectations of participants**
  The report points to a potential slippage for a minority of respondents from 'participant' to 'participant-patient' (where some form of individual clinical benefit might be expected). While UK Biobank's consent materials are explicit on the point that personal benefit should not be expected, and that the benefits will instead be for future generations, it would be a valuable exercise to explore in more detail participants' expectations of personal benefit.

  In addition the Council would be interested to learn more about the participants' expectation regarding the purpose of UK Biobank. The report's findings suggest a bias towards the clinical potential of research conducted on the resource rather than the potential public health outcomes. The Council has recommended that both this and the participants' expectations of personal clinical benefit could be explored by UK Biobank through a systematic post-visit survey of participants.

- **Access by international researchers**
  The report highlights concerns amongst some respondents regarding access by international researchers. UK Biobank's participant information leaflet is explicit about the fact that international researchers will be able to apply for access, meaning that potential participants can decide, prior to giving any consent, whether or not they agree to this condition of participation. Notwithstanding, the Council considers it important to investigate participants' expectation regarding who will have access to the resource and has therefore recommended that UK Biobank tests these expectations through a systematic post-visit survey.

  UK Biobank has a commitment under the Ethics and Governance Framework to maintain ongoing engagement with participants. As part of this commitment the Council considers it necessary for UK Biobank to publish information that explains to participants which researchers have been granted or denied access and with respect to which kinds of proposal. This will allow participants to see the range of researchers who have access to the resource and, for a participant who is, or has become, uncomfortable with the idea of access by international parties they may consider their right to withdraw from the project.

  The report suggests that the matter of the internationalisation of biobanking is an issue that UK Biobank and the EGC will need to prioritise in order to maximise the scientific returns from UK Biobank while still retaining public support. On this point the EGC actively participates in the Public Population Project on Genomics (P3G), an international consortium that aims to promote collaboration between researchers in the field of population genomics. The Council is fully aware of the need for, and benefit of, collaboration and will

support such activities on the understanding that any such collaboration must fully respects the original consent of participants.

- **Access by the police**
  The report states that UK Biobank's current policy to vigorously resist access by the police or other law enforcement agencies is in broad terms supported by respondents but that there was also some ambivalence. However, the report also states that access by the police was seen as 'acutely problematic' in terms of the bank's public credibility.

  The Council's reading of the report is that there were counterposed views within the focus groups but that several respondents felt that if the police gained access this would have an impact on participants' willingness to continue their involvement with the project. Police or other law enforcement agencies can in theory access data held by UK Biobank if they have a court order. This is true of all medical research studies and UK Biobank is not unusual in this regard. The Council is satisfied that the participant information leaflet makes specific reference to access by the police.

- **Benefit-sharing**
  The report found that a fees-for-access arrangement was seen as reasonable by the majority of the respondents within the Focus Groups once the practical implications of sliding scales of profit-sharing arrangements or similar schemes had been discussed. There was however support for profit-sharing where UK Biobank has made a material contribution to the intellectual property behind the new products or processes. The EGC will be mindful of this in its discussions with UK Biobank regarding its access and intellectual property policy. The Council intends to look in more detail at the practicalities of the profit-sharing model (e.g. How is a 'material contribution' defined? What issues are at stake in determining a definition for a 'material contribution'? Should this policy be adopted?).

- **Differences between age groups**
  In the majority of circumstances there was no clear statistical significance found between the opinions of the two age groups. No firm conclusions can therefore be drawn about any differences in opinion that might exist between the two groups.

18 November 2008

Part 2. The commissioned report

Public attitudes to third party access and benefit sharing: their application to UK Biobank

Final Report

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Submission to the UK Biobank Ethics and Governance Council
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Appendices

1. Introduction: focus of the study

The Science and Technology Studies Unit (SATSU) was contracted by the Wellcome Trust, acting on behalf of the UK Biobank and the Ethics and Governance Council (EGC) which acts as an independent source of advice and guidance to the bank. The EGC sought competitive tenders for this work and SATSU was subsequently invited to undertake a study that examines public attitudes towards third party access to UK Biobank, and any concerns that potential participants and beneficiaries may have with respect to UK Biobank's policies relating to access to the resource. An interim report on the results of the data was sent to the EGC as agreed in December 2007. Comments on this report were provided in January and at a subsequent meeting with the EGC in March 2008, and these have informed this final version.

This final report is structured as follows:
Section 2: The current UK Biobank policy on consent and third party access which provides the policy context for the report

Section 3: Summary of the results of the national *telephone survey* (that deployed a computer-assisted telephone interview [CATI] technique)

Section 4: Survey findings

Section 5: Report on subsequent *focus groups* held in five regional cities in the UK

Section 6: Subsequent *follow-up telephone interviews* with a selected range of respondents who had been participants in the CATI element of the study

Section 7: Emergent themes and key issues

Section 8: Summary, conclusions and recommendations

Section 9: Key recommendations

We have not sought to integrate the results of the three research instruments into a single thematic analysis as this could be misleading inasmuch as each of the instruments fostered differing degrees of discussion, were either on a one-to-one or group basis, and more, or less, enabled some prior oral explanation of the issues. There are as a result some notable differences in respondents' views; but this helps provide a better register of how the public[4] view UK Biobank's policies as people are given more or less opportunity to reflect on them.

We also emphasise that the Report offers a range of findings that confirm broad support for current UK Biobank policy, especially with respect to consenting provisions, access and oversight of samples and related health information. We also identify some issues which provide insight into concerns that prospective participants have, and this we believe could be of value for the ongoing development of UK Biobank policy.

[4] We recognise that the term 'the public', and especially 'public opinion' glosses over what is better seen as multiple 'publics', whereby individuals occupy one or more 'public' positions according to their role as 'citizen', family members, worker and so on. Publics are also 'made' by government, as in terms such as 'the public interest'. In the later sections of the report, it is clear that our respondents have a sense of 'public benefit' but also can define this in different ways.

Section 2: Current UK Biobank policy on consent and third party access

As a preface to the study, we include in this Report the current UK Biobank policy with respect to consent (and related issues) and third party provisions. We have reproduced below the current documentation as it is important to use this as a basis for our later recommendations with regard to possible areas for consideration, either with existing policy or new developments. The consent form and the information leaflet must be read together to understand fully what research participants have consented to. There is greater detail to be found in the UK Biobank Ethics and Governance Framework.[5]

2.1 Consent

UK Biobank has sought a broad consent from research participants, as it is difficult to specify all of the research uses and researchers who may use the biobank. Therefore, in the current UK Biobank consent form, research participants are asked to agree to the following:-

- I give permission for access to my medical and other health-related records, and for long-term storage and use of this and other information about me, for health-related research purposes (even after my incapacity or death).
- I give permission for long-term storage and use of my blood and urine samples for health-related research purposes (even after my incapacity or death), and relinquish all rights to these samples which I am donating to UK Biobank.
- I understand that none of my results will be given to me (except for some measurements during this visit) and that I will not benefit financially from taking part (e.g. if research leads to commercial development of a new treatment).[6]

The Information Leaflet provides further information and elaborates on the above permissions. It also details aspects of feedback (which could be construed as an element of benefit-sharing), withdrawal, and the possibility of being recontacted by UK Biobank in the future for further research studies.

a. Feedback to Research Participants

In the Information Leaflet on page 7, it states that:

> Taking part in UK Biobank should not cause you any harm. The project aims to observe what happens to participants over the next few decades so that future generations can benefit. It is not intended to change directly what happens to people who take part: in particular, the initial assessment visit is not a "health check". Apart from providing you with the results of some standard measurements made during that visit, none of your results will be given to you or your doctors (even if the results do not seem to be normal).
>
> This is because such feedback outside of the normal clinical setting is of questionable value, and might even be harmful (for example, causing undue alarm and having potentially adverse effects on insurance status), especially when given without prior counselling or support. For further details on this topic, please call 0800-0-276-276 or look on our website at www.ukbiobank.ac.uk.

b. Withdrawal

With regard to participant withdrawal from UK Biobank three options are available:

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[5] Version 3.0 (October 2007)

[6] UK Biobank Consent Form Version: 20061124 AMENDMENT ONE FINAL http://www.ukbiobank.ac.uk/docs/2006ConsentformA.pdf Accessed 20/05/08

"*No further contact":* This means that UK Biobank would no longer contact you directly, but would still have your permission to retain and use information and samples provided previously and to obtain and use further information from your health records.

"*No further access":* This means that UK Biobank would no longer contact you or obtain further information from your health records in the future, but would still have your permission to use the information and samples provided previously.

"*No further use":* This means that, in addition to no longer contacting you or obtaining further information about you, any information and samples collected previously would no longer be available to researchers. UK Biobank would destroy your samples (although it may not be possible to trace all distributed sample remnants) and would only hold your information for archival audit purposes. Your signed consent and withdrawal would be kept as a record of your wishes. Such a withdrawal would prevent information about you from contributing to further analyses, but it would not be possible to remove your data from analyses that had already been done.[7]

c. Re-contact

At some time in the future, participants might be re-contacted by UK Biobank and asked more questions, although giving such additional help would be entirely optional. Similarly, some participants might be asked in later years to attend another assessment visit (including questions, measurements and samples), although again attendance at such visits would be optional.[8]

2.2 Access

a. Who will have access?

The Information Leaflet that accompanies the consent form elaborates further who will have access to UK Biobank:-

- Information and samples from UK Biobank participants will be available only to researchers who have relevant scientific and ethics approval for their planned research. This could include researchers who are working in other countries and in commercial companies looking for new treatments.[9]

- Results from any tests made on participants or their samples will be put in the UK Biobank database so that they are available to all approved researchers. There will also be a requirement to publish the results of all research based on the resource so that people can benefit from it.[10]

- Insurance companies and employers will not be given any individual's information, samples or test results, and nor will we allow access to the police, security services, relatives or lawyers, unless forced to do so by the courts.

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[7] UK Biobank Information Leaflet, http://www.ukbiobank.ac.uk/docs/InfoleafletEnglish141107all_Pages.pdf Accessed 20/05/08; page 9.
[8] UK Biobank Information Leaflet, http://www.ukbiobank.ac.uk/docs/InfoleafletEnglish141107all_Pages.pdf Accessed 20/05/08; page 4
[9] UK Biobank Information Leaflet, http://www.ukbiobank.ac.uk/docs/InfoleafletEnglish141107all_Pages.pdf Accessed 20/05/08;page 8
[10] UK Biobank Information Leaflet, http://www.ukbiobank.ac.uk/docs/InfoleafletEnglish141107all_Pages.pdf Accessed 20/05/08;page 8

- Results of research conducted on the UK Biobank resource will be made available to participants, and anyone else who might be interested, at www.ukbiobank.ac.uk

2.3 The type of information that will be passed to third parties

In the Information Leaflet, research participants are also told that 'Data or samples provided to researchers will not include personal identifying details'.[11] It also states that:-

> Over the coming years, a very wide range of tests will be done on your blood and urine samples for approved medical and other health-related research. Details that might identify you will be removed from any information and samples provided to researchers in order that they cannot be traced back to you. None of your particular test results will be fed back to you, your doctors or anyone else. So, taking part should not have any adverse effects on you (including your employment status or ability to get insurance).

In the UK Biobank Ethics and Governance Framework, it states that participants will be told the following:-

- the kinds of safeguards that will be maintained, including secure storage of data and samples in reversibly anonymised form (as explained in Section I.C.2), and severe restrictions on access to data and samples that are not anonymised
- the assurance that only research uses that have been approved by both UK Biobank and a relevant ethics committee will be allowed, and that data and samples will be anonymised before being provided to research users

2.4 Control over Access

In the UK Biobank Ethics and Governance Framework it states that

> UK Biobank will retain full control of all access to, and uses of, the resource. UK Biobank will not proscribe any medical or other health related research uses at the outset. However, all proposals will be reviewed by UK Biobank to ensure they are consistent with the participants' consent and this Framework, and that they have relevant ethics approval. All users, whether employed by universities, government, charities or commercial companies, will be held to the same scientific and ethical standards.
>
> Exclusive access to the fully developed resource will not be granted to any party. Use of the biological samples will have to be carefully coordinated and controlled because they are limited and depletable. While the resource is being developed, UK Biobank may use the early data and samples to validate and improve methods of data collection and analysis.[12]

2.5 Decisions on access and use

> The UK Biobank Board of Directors will have the overall decision making authority over access to and use of the resource. In practice, the Board may delegate decisions on routine applications to suitable bodies or persons (such as an Access Committee or specially designated UK Biobank Working Groups). UK Biobank will explain, to participants and the public, the policies and procedures for research access. An overall policy and detailed terms of access has been, and

[11] UK Biobank Information Leaflet, http://www.ukbiobank.ac.uk/docs/InfoleafletEnglish141107all_Pages.pdf Accessed 20/05/08;page 8

[12] UK Biobank Ethics and Governance Framework Version 3.0 (October 2007) p12.

will continue to be, developed (i.e. the IP and Access Policy) which addresses fairness and transparency of decision making, the handling of conflicts of interest and the prioritisation of use of samples. The Ethics and Governance Council will keep use of the resource under review in order to advise on conformance with this Framework and the IP and Access Policy, and to assure itself, and others, that the resource is being used in the public interest.[13]

2.6 Licences for specific uses

Access to data and/or samples will be granted under licence for scientifically and ethically approved research consistent with UK Biobank's purpose. Licences will be for specific uses under strict terms and conditions in standard access agreements, including compliance with the consent given, the provisions of this Framework and other policies. Fees will be charged for licences, with the possibility of charges being higher for organisations that might be expected to derive financial benefit from use of the resource.[14]

2.7 Sharing of data and findings

UK Biobank seeks to augment the value of the resource in order to ensure that the greatest potential benefit for public health may be realised from it. All research users will be required to put results from all analyses made on participants' data and samples, and any relevant supporting information, in the UK Biobank database so that they are subsequently available to all researchers with appropriate scientific and ethics approval.[15]

There will also be a requirement on all research users to place the findings (whether positive or negative) from all research based on UK Biobank in the public domain so that people can benefit from them. Publication should be in the peer reviewed scientific literature whenever possible. UK Biobank will also explore further strategies for dissemination of findings (such as through accessible electronic archives). Researchers will only be permitted to keep results based on UK Biobank confidential for a limited and reasonable period as described in the IP and Access Policy (for example, while they prepare papers for publication, file patent applications or otherwise pursue reasonable competitive advantage for their efforts). This policy will apply to all research users, whether non-commercial or commercial.[16]

2.8 Legal Ownership

In the Ethics and Governance Policy document[17] it states the consent and information form will detail 'the fact that UK Biobank will be the legal owner of the database and the sample collection, and that participants will have no property rights in the samples.' While the consent form asks people 'to relinquish all rights to the samples' it does not state that UK Biobank will be the legal owner.

The Ethics and Governance Framework details the policy on benefit-sharing and IP on pages 17 -18.

[13] UK Biobank Ethics and Governance Framework Version 3.0 (October 2007), p14
[14] UK Biobank Ethics and Governance Framework Version 3.0 (October 2007), p14
[15] UK Biobank Ethics and Governance Framework Version 3.0 (October 2007), p14
[16] UK Biobank Ethics and Governance Framework Version 3.0 (October 2007), p15
[17] UK Biobank Ethics and Governance Framework Version 3.0 (October 2007), p5.

2.9 Benefit Sharing

a) Dissemination of knowledge generally

The purpose of UK Biobank is to learn from the collective health experience of the participants over time, in order to generate and disseminate new knowledge to benefit the health of the public in the UK and elsewhere. Knowledge derived from studies based on UK Biobank will be:

· Published in the world's scientific and medical literature;

· Communicated to UK Biobank participants, the NHS, and others (as appropriate);

· Accumulated and made available by UK Biobank as a resource for further research (e.g. via archives of the findings of studies).

Such knowledge may also be applied to the development or improvement of healthcare techniques, technologies, materials or routines.

b) Intellectual property, income generation and royalties

Intellectual property and access policies are being developed to help ensure that the UK Biobank resource is accessible to all *bona fide* research users, but is not exploited improperly or used in any way that inappropriately constrains use by others. Terms of access will be embodied in legal agreements that reflect UK Biobank's objectives. UK Biobank is not expected in itself to lead to patentable inventions that return significant income either to researchers or UK Biobank, but it is expected to become a valuable common resource for research. Nevertheless, there is some chance that research conducted using the resource (which might be conducted by researchers in the public or commercial sector, as well as the academic and charity sectors) will subsequently support the development of an invention that returns a profit.

The biotechnology and pharmaceutical industries can play an important role in realising health benefits in a practical sense by developing and improving the use of biomedical products. Commercial companies and other research endeavours that stand to make a profit will, therefore, be allowed access to UK Biobank if their proposal falls within the UK Biobank purpose and complies with the usual scientific and ethics requirements.

Any income that UK Biobank secures from access fees or intellectual property will be reinvested in the resource.

2.10 This completes the summary of current UK Biobank policy. As we shall discuss, many if not most of the current provisions receive widespread support from the study population. There are, however, within this broad consensus, some differences of opinion with regard to some of the issues we have explored that relate to existing practice and some points we identify that could help shape future policy advice by the EGC to UK Biobank.

Section 3: Report on the Study

3.1 Background to the CATI survey

The Survey design and specific questions were developed by SATSU, our external experts (RT/JK) and QA Research during the early part of September 2007. A penultimate version was sent to a member of the EGC Commissioning Panel for information prior to the start of the survey. Respondents were provided with a summary of the study, a brief note on UK Biobank, and an explanation of benefit-sharing and the meaning of intellectual property. (See Appendices for details of the survey instrument and related material). The survey was subject to ethics approval by the University of York's Social Science Ethics Committee.

The overall design of the survey was as follows:

- Firstly, an introductory survey pack was sent by QA Research to named recipients from a randomised database of contacts across the UK;
- Prospective respondents were then contacted by phone and screened to ensure that interviewees fitted the age criteria for inclusion within the research and were prepared to take part in the survey
- Finally, interviews were completed using computer assisted interview (CATI) technology.

This first part of the report presents and provides a discussion of the CATI data

3000 letters were despatched across the UK in two stages – a pilot and full distribution, the former to allow the CATI material to be tested for clarity and accessibility. The first mail-out was made in the final week of September as planned, though a series of national postal strikes resulted in delays to the delivery of the initial round of correspondence. QA Research staff continued the survey through to the end of the first week of November to secure as many respondents as possible.

QA Research provided us with interim findings as the survey progressed and these were used to help frame the issues that would be followed up in the Focus Groups, especially in regard to access to UK Biobank.

3.2 Description of the sample

Sample population
QA Research recruited 504 respondents across two age groups (18-30; 40-69).Though we had hoped to secure 600, we were unable to do so despite making exceptional efforts: individuals were called in some cases up to 10 times (normally QA try to call someone 4/5 times). The final population was made up as follows:

40-69	Respondents	n = 353
18-30	respondents	n = 151

Male	50%
Female	50%

Urban:	50%
Rural:	50%

Ethnic minority 9%

We discuss below the representativeness of the sample through reference to comparable data secured in other recent studies that measured factors such as the rate of long-term illness of the UK population.

Table 3.2.1 Distribution of sample by age and gender

	Males		Females		All	
Age	**Count**	**%**	**Count**	**%**	**Count**	**%**
18-30	56	23	95	36	151	30
40-69	183	77	170	64	353	70
Base	**239**	**100**	**265**	**100**	**504**	**100**

Of the total sample, 175 people (35%) reported that they had some form of long-term illness (including heart disease, diabetes, cancer and stroke). As might be expected, there is an apparent variation in the incidence of long-term illness by age – which would appear to be statistically significant.[18]

In terms of national data from other sources, the prevalence of reported longstanding illness according to the "Living in Britain Survey 2001" was 32% for male and 31% for female respondents, across all ages, and 22% and 21%, respectively, for males and females aged 16-44.[19] However, the incidence of self reported limiting illness for adults in England may be as high as 40%. This suggests our sample in this regard is broadly comparable to wider UK figures.[20]

Table 3.2.2 Incidence of long-term illness

		All	18-30	40-69	Males	Females
No	Count	329	129	200	149	180
	%	65	85	57	62	68
Yes	Count	175	22	153	90	85
	%	35	15	43	38	32
Base		**504**	**151**	**353**	**239**	**265**
%		**100**	**100**	**100**	**100**	**100**

[18] There would appear to a statistically significant difference in the extent of reported illness between the two age groups (Chi-square test).

[19] http://www.statistics.gov.uk/lib2001/Section3529.html

[20] See for example, Oxford Textbook of Primary Medical Care, Jones R et al, p 210: "Self reported long standing illness occurs in 40% of the English adult population, rising from a fifth of those aged 16-24 years to two thirds of those aged over 75 years" and Population Trends, 2005, No. 120 pp 17-18 http://www.statistics.gov.uk/downloads/theme_population/PT120_V1.pdf

Just over one in three respondents overall 174 (35%) reported a *family* history of chronic illness: a characteristic more likely to have been reported by females 103 (39%).[21]

Table 3.2.3 Family history of chronic illness

		All	18-30	40-69	Males	Females
No	Count	330	99	231	168	162
	%	65	66	65	70	61
Yes	Count	174	52	122	71	103
	%	35	34	35	30	39
Base		**504**	**151**	**353**	**239**	**265**
%		**100**	**100**	**100**	**100**	**100**

Table 3.2.4 shows that a relatively low number of our respondents (n=16) reported they were members of a patient self help or advocacy group.[22]

Table 3.2.4 Involvement with patient self-help or advocacy group

		All	18-30	40-69	Males	Females
No	Count	488	149	339	229	259
	%	97	99	96	96	98
Yes	Count	16	2	14	10	6
	%	3	1	4	4	2
Base		**504**	**151**	**353**	**239**	**265**
%		**100**	**100**	**100**	**100**	**100**

Overall, 216 (43%) of respondents reported they were economically active, a further 141 (28%) were retired and 94 (19%) were either unemployed or long term sick.

The data suggests that the economic situation of younger people responding to the survey was somewhat more polarised, in terms of economic activity, than perhaps might be expected: 86 (56%) reported they were employed whilst 37 (25%) reported that they were either unemployed or long term sick. Females in the sample, in line with nationally reported data, are apparently more likely to be economically inactive – although, again, the unemployed and long-term sick are aggregated in the current research sample data.

Levels of economic activity within the sample are significantly lower than those reported in the Economic & Labour Market Review (December 2007). However there are two further points to note: 1) data in the ELMR is restricted to the population of working age and 2) data for the unemployed within the current research sample is aggregated with that for people reporting long term sickness.[23]

[21] The apparent difference in the extent of reported history of family illness by gender would appear to be a statistically significant (Chi-square test, but only just, at the 0.05 confidence level): see, for example, Babbie, E and Halley, F, 1995, Data analysis using SPSS for Windows.
[22] There was no statistically significant difference in any of the demographic groups (Chi-square tests). However, upon running regression analysis, and t tests, there would appear to be a relationship that is statistically significant, between the predictor variable (current long term illness) and the dependent variable (use of a self help or advocacy group).
[23] http://www.statistics.gov.uk/elmr/12_07/2.asp

Table 3.2.5 Economic activity and inactivity

		All	18-30	40-69	Males	Females
Employed	Count	216	84	132	103	113
	%	43%	56%	37%	43%	43%
Self-Employed	Count	24	4	20	16	8
	%	5%	3%	6%	7%	3%
Student	Count	29	26	3	11	18
	%	6%	17%	1%	5%	2%
Retired	Count	141	0	141	79	62
	%	28%	0%	40%	33%	23%
Unemployed/Long Term Sick	Count	94	37	57	30	64
	%	19%	25%	16%	13%	24%
Base		**504**	**151**	**353**	**239**	**265**
% *		**100**	**100**	**100**	**100**	**100**

(Note: data in percentages may not sum due to rounding)

Finally, 44 respondents (9% of the sample) described themselves as belonging to an ethnic minority group – a total only just short of the 10% target set for the survey sample. We sought to compensate for this slight shortfall by seeking more respondents from ethnic minority backgrounds during the follow up telephone survey (see below).

3.3 Survey results

In this final report, we provide the main results of the survey, identifying and reporting on some of the key issues we saw emerging from the interim report and during discussion of the research findings.

Firstly, we provide a note on statistical analysis. We have used the following characteristics within the cross tabulations supporting this written report, and to help analyse the responses to the survey, namely: Total; Age Group: 18-30, 40-69; Gender: Male, Female; Ethnicity: White British/Irish, Non-white British/Irish (Prefer not to say). In addition, we also used three self-reported characteristics, as follows: currently have long-term illness; family history of chronic illness; and belong to a patient self-help or advocacy group. We also note when results are statistically significant and where not.

In relation to the frequencies and percentages presented within the report we have used the following rationale for data analysis and reporting. Where we asked people to tell us if they "would be prepared", "might be prepared" etc. we treat this as ordinal data. Again, where we asked people if they agreed or not with statements, for example "agree" or "strongly agree", we have also treated responses as ordinal data (scale items standing in some kind of relation to each other but essentially of an arbitrary, not true, nature) in line with standard methods for reporting on data such as these. [24]

We have indicated within the text or footnotes where there are statistically significant differences. With regard to one specific variable – the different age sets – while we do find some differences between the older and younger groups, these cannot be seen as being statistically significant. Further research with a larger comparative base would be need to determine whether this was the case.

3.3.1 Awareness of, and preparedness to help, UK Biobank

In total, 35 (7%) of all people interviewed had heard of UK Biobank prior to receiving the introductory letter and information pack and undertaking the interview. [25]

Figure 3.3.1 Awareness of UK Biobank prior to the survey

		All	18-30	40-69	Males	Females
Yes	Count	35	10	25	17	18
	%	7%	7%	7%	7%	7%
No	Count	469	141	328	222	247
	%	93%	93%	93%	93%	93%
Base		**504**	**151**	**353**	**239**	**265**
%		**100**	**100**	**100**	**100**	**100**

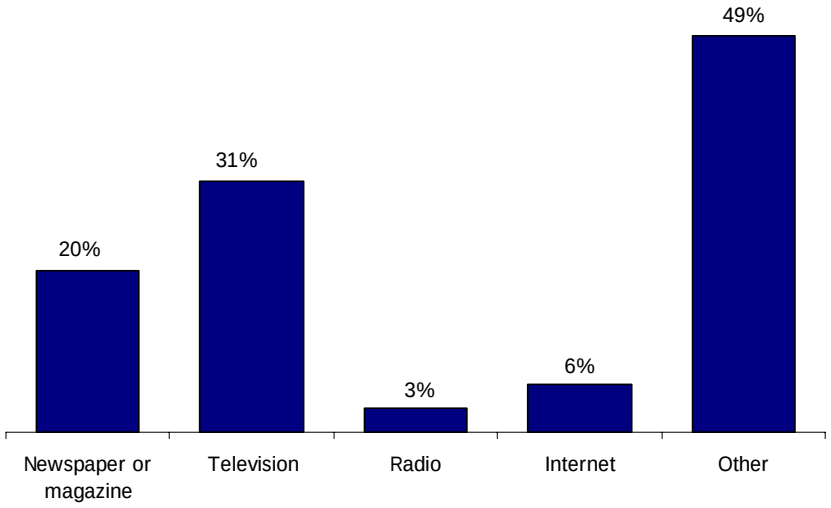
The following chart shows that, for those people who were aware of UK Biobank, the two single largest sources of information were television and newspapers.[26]

[24]See, for example, Bowling, A, 2002, Research Methods in Health pp 144 – 147: "ordinal data must be treated as ranked, not scored, data – they must not be averaged or mathematically manipulated.

[25] There was no statistically significant difference for any of the defined demographic groups (Chi-square test).

[26] There was no statistically significant difference for any of the defined demographic groups (Chi-square test).

Figure 3.3.2 Source of information on UK Biobank



* Responses not mutually exclusive
Base = 35

Five out of the 35 people aware of the UK Biobank (18%) had already been recruited as participants – all of whom, therefore, were in the older age group. [27]

Figure 3.3.3 Percentage of those aware, recruited as participants in UK Biobank

		All	18-30	40-69	Males	Females
Yes	Count	5	0	5	3	2
	%	14%	0%	20%	18%	11%
No	Count	30	10	20	14	16
	%	86%	100%	80%	82%	89%
Base		**35**	**10**	**25**	**17**	**18**
%		**100**	**100**	**100**	**100**	**100**

[27] There would appear to be no statistically significant difference for any of the defined demographic groups (Chi-square test).

Section 4: Survey findings

4.1 Introduction

This section of the report sets out the findings from the survey overall and provides some detailed analysis for differences in views and opinions by gender and age. Clearly, those who have already been recruited as participants in UK Biobank have considered and given approval and consent with respect to many of the issues we examine below. Here we provide results principally about the views of the public who may or may not be *prospective participants*. These results might, therefore, be of some value in future recruitment and public-facing aspects of UK Biobank inasmuch as some issues raised by respondents might help shape future policy development.

4.2 Views on health related research and preparedness to assist UK Biobank

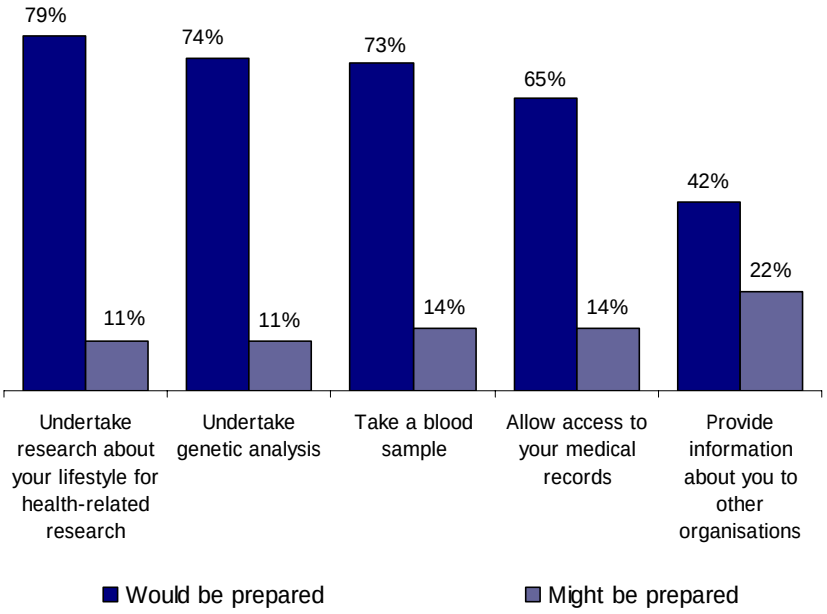
Figure 4.2.1 below provides a summary of respondent views on health related research and the extent to which they would be prepared to help. Roughly nine in ten respondents overall were definitely prepared to help with health related research: i.e. 79% would, and a further 11% might, be prepared to allow UK Biobank to undertake research about their lifestyle. Younger people were apparently less likely to be prepared to help: 75% and 14%, respectively, would or might be prepared to help with research into their lifestyle.

A slightly smaller percentage of respondents were prepared (74%), or might be prepared (11%), to allow genetic analysis to be undertaken on samples held by UK Biobank. A similar proportion would (73%), or might (14%), be prepared to provide blood samples to UK Biobank. People within the older age group of the sample were apparently more likely to be prepared (78%), or might be prepared (10%), to allow genetic analysis to be undertaken than their younger counterparts. Some of the data for younger people would appear to be more equivocal: in relation to providing blood, only 60% of younger people definitely would be prepared, and 22% might be prepared, for UK Biobank to take blood samples.

Roughly three in four people responding to the survey overall would (65%), or might (14%), be prepared to allow UK Biobank access to their medical records: younger people being less likely (58% and 18%, respectively). And, finally, just under two in three people in total would (42%), or might (22%), be prepared for UK Biobank to provide information about them to other organisations[28]. Younger respondents were more likely to (49% would and 19% might) be prepared to permit information sharing of this nature.

[28] See footnote 26

Figure 4.2.1 Preparedness to help with UK Biobank research

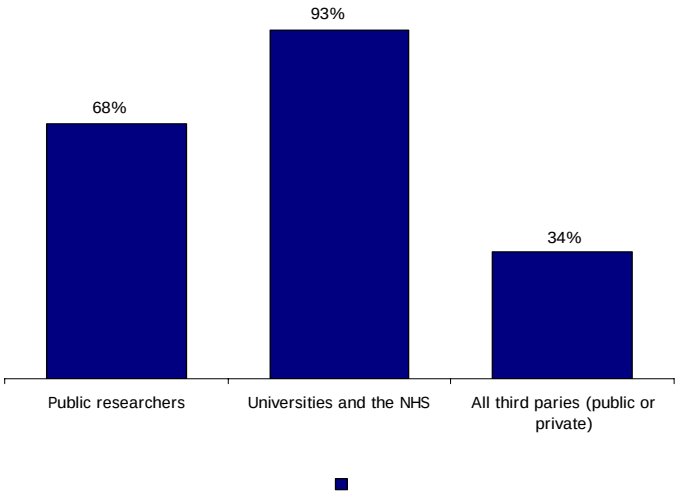


Base = 504

4.3 Which organisations should have access to UK Biobank?

Respondents were informed that UK Biobank is expected to operate for the next 25 years and that third party organisations would have access to UK Biobank. We were interested in seeing whether our respondents differentiated between different types of organisation as being more, or less appropriate to being able access its material. Although current UK Biobank policy does not permit any preferential access in the early period of its operation, we were interested in whether respondents prioritised access by certain organisations during this initial period: over nine in ten respondents thought that universities and the NHS (93%), whilst just two in three thought public researchers in general (68%) should have access.

Figure 4.3.1 Which organisations should have access in UK Biobank's formative stages of development?



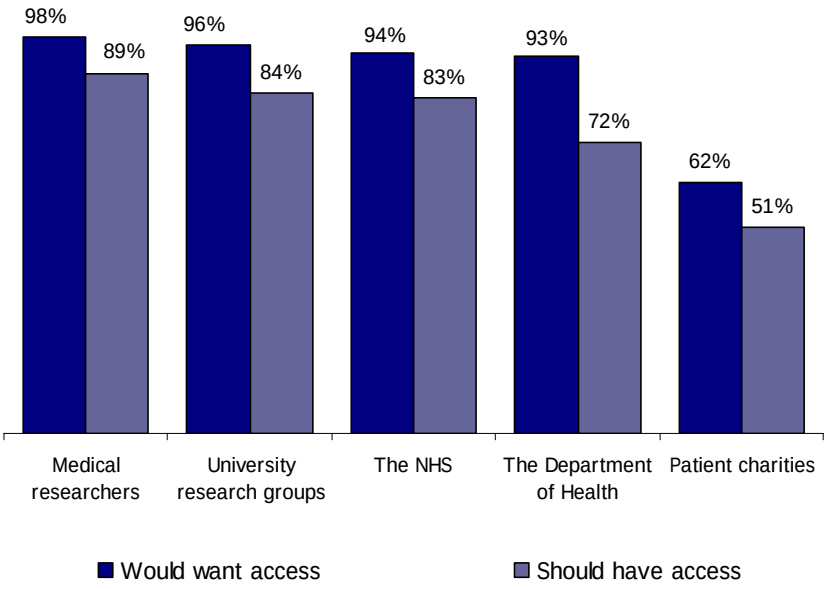
There would appear to be a substantial consensus about the range and type of organisations that would want, and *should have*, access to UK Biobank data.

Almost all respondents said they thought medical researchers (98%) and university research groups (96%) would want access to the UK Biobank: and almost nine in ten (89%) and over eight in ten respondents (84%), respectively, said they thought these organisations *should have* access.

Over nine in ten respondents said they thought the NHS (94%) and the Department of Health (93%) would want access; and over eight in ten (83%) and seven in ten (72%), respectively, thought that these organisations *should have* access to the data.

Roughly three in five respondents thought that patient charities would want access to the data (62%) and just over one half (51%) agreed these types of organisations *should have* access to, UK Biobank data. Younger people were more likely to think that patient charities would want access (75%) and *should have* access (64%) to, UK Biobank data.

Figure 4.3.2 Views on "public sector" and university sector access to the UK Biobank



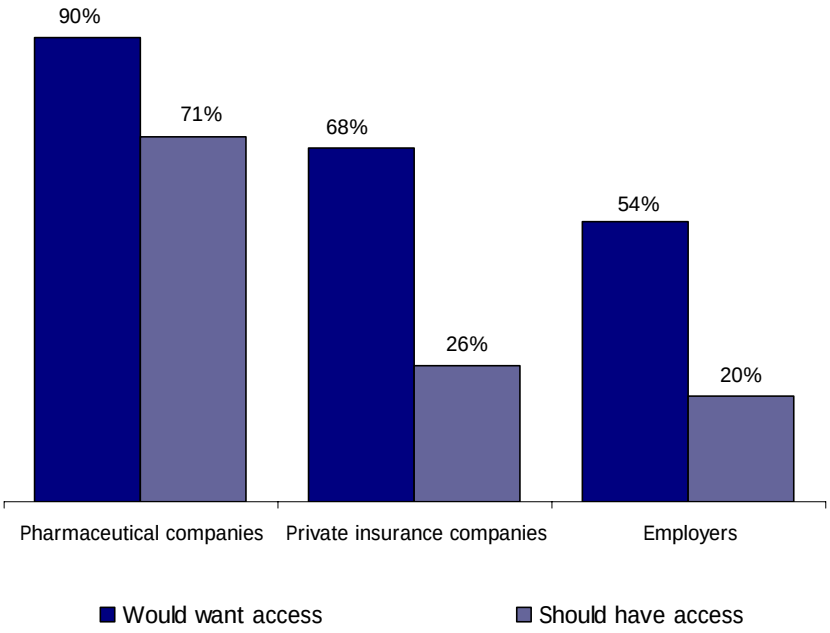
Base = 504

There was a much more marked variation in the extent to which respondents thought that private sector organisations would want, and *should have*, access to the UK Biobank and its data.

Nine in ten (90%) of respondents said they thought pharmaceutical companies would want access to the UK Biobank whilst 71% concurred they *should have* access to the data. However, only 68% and 54% of respondents, respectively, thought that private insurance companies, and employers, would want access to the data and only 26% and 20% said

that these organisations *should have* access to the UK Biobank. Paradoxically perhaps younger people were slightly less likely to think private insurance companies would want access to the data (64%) but more likely (28%) to report that these organisations *should have* access to the UK Biobank.

Figure 4.3.3 Views on pharmaceutical industry, insurance sector and employer access to UK Biobank



4.4 Access to UK Biobank data and participant related information

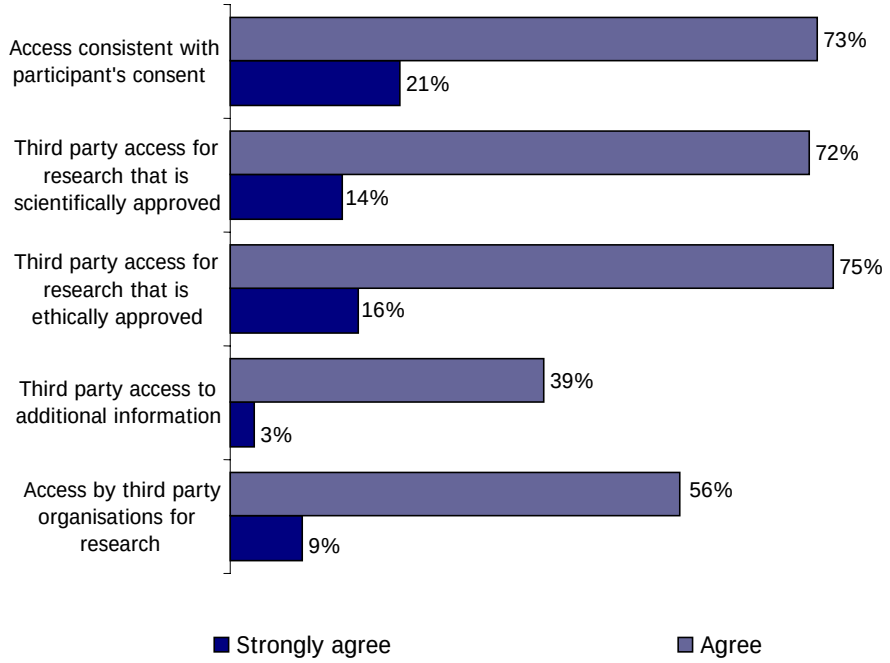
Overall, roughly two in three respondents agree (strongly agree 9%; agree 56%) that UK Biobank resources should, as current policy, be available to 'third party' organisations for research purposes. We raised a question about specific third parties, prompting for insurance companies and employers, even though UK Biobank would *not* permit such usage to determine whether there was any variation here from existing policy; the majority result confirms that the public would support UK Biobank's policy not to allow information to be accessed by such groups.

There appears to be a substantial consensus of support for research that is ethically and scientifically approved and also consistent with participant consent. Overall, 91% agree that UK Biobank's Ethics and Governance Council should advise that access to UK Biobank be given for research that is ethically approved and almost as many (86%) think the Council should advise access for research that is scientifically approved. Although in line generally with the consensus view, there would appear to be a larger proportion of younger people who "strongly agreed" about the need for ethical (24%) and scientific (19%) approval.

There is an even stronger consensus (94% at least agree), within which a significantly larger proportion of people "strongly agree" (21%), that UK Biobank's Ethics and Governance Council should advise access to UK Biobank for research that is consistent

with the participant's consent. Again, a greater proportion of younger people would appear to be more likely to have held strongly held beliefs: 59% "agree" and 31% "strongly agree" that access should be permitted that is consistent with participant consent.

Figure 4.4.1 Purposes, types and levels of access to UK Biobank



Base = 504

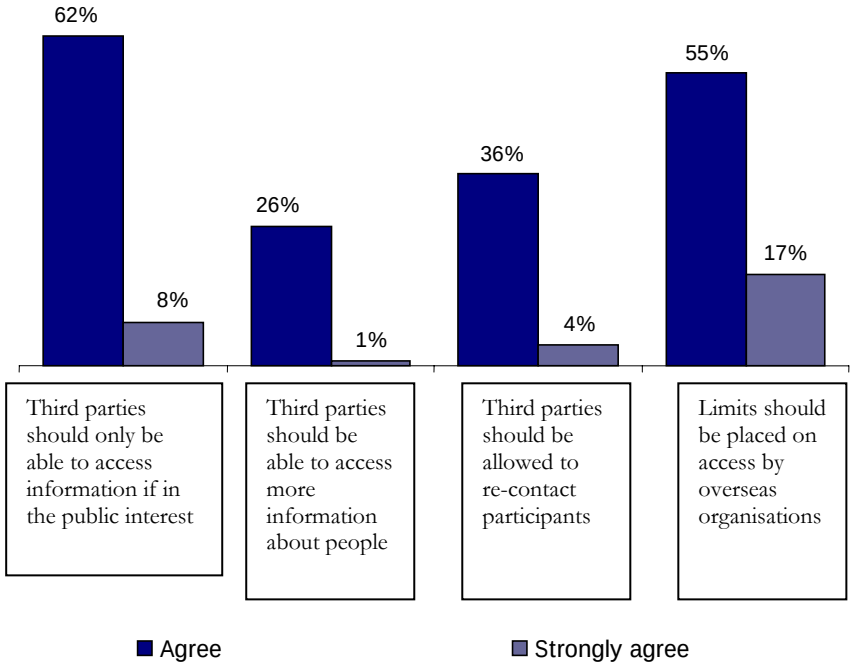
While, as noted above, our respondents clearly accept that corporations will want and should have access to UK Biobank material and related information, there were, even so, reservations about a commercial company accessing data given by participants in UK Biobank, a view that is slightly more likely amongst people in the older age group (64%) and females (66%). This was more about anxiety over the possible use to which information might be put than access itself. An even higher proportion (63% agreed, and a further 22% strongly agreed) endorsed current UK Biobank policy that it not allow any particular 'third party' exclusive access to samples or information – with young people again tending to hold more strongly held beliefs on this matter.

Again, there were some strongly held and complicated views concerning access to UK Biobank data and participant related information by other parties beyond the UK: 75% of all respondents agree (57% agree, 18% strongly agree) that limits should be placed on access to UK Biobank's information by overseas public or commercial organisations. At present overseas organisations are not treated any differently to domestic ones in terms of the limits placed on their access, and consent provisions make this clear to prospective participants. This might point to an issue to be addressed in the longer term.

Furthermore, only 27% of respondents felt that third parties, whether public or commercial organisations, should be able to access more detailed information[29] about those people whose data is on UK Biobank database, with 70% of the sample agreeing that should happen where this is seen to be in the public interest – a view that is held by an even higher proportion of younger respondents (79%).

At the same time, once 'in the system' 40% of those surveyed, and 51% of younger people, said that third parties should be allowed to contact individual participants with their consent in the future if further information is needed about them.

Figure 4.4.2 Access to UK Biobank information



Base= 504

4.5 Perceptions of "public good" research and who should benefit from research using UK Biobank

Only 15% of respondents reported they were familiar with the term "public good" research: although male respondents would appear slightly more likely to have been aware of the term (19%). [30]

Overall, more than nine in ten people think that medical science (96%) and the NHS (94%), and almost as many thought patients (87%) should benefit from "public good"

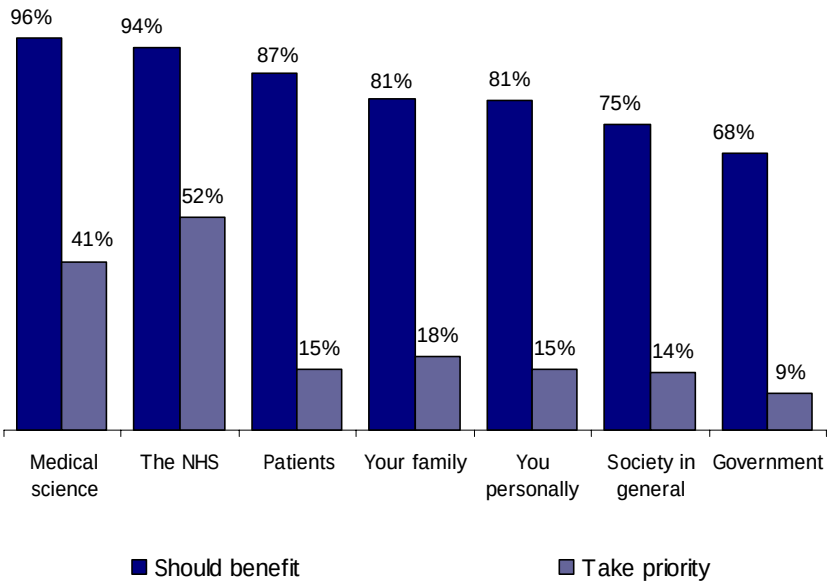
[29] The meaning of 'more detailed information' was not defined in advance by the researchers nor were respondents invited to provide a definition of this phrase. Moreover, the difference between the figure of 27% here and the earlier figure of 42% (para 4.2, p.15) can be explained by the latter couched in terms of access only through UK Biobank itself.

[30] Care needs to be taken interpreting observed variations due to the small size of the sub sample.

research. Two in three people overall (68%), and almost eight in ten young people (79%) thought that the government should benefit from 'public good' research.

Some eight in ten people overall (81%) said they themselves as participants and their family (81%) should benefit, and three quarters (75%) that society in general should benefit, from "public good" research. There would appear to be a substantial higher level of consensus that the NHS (52%) and medical science (41%) should take priority in benefiting from "public good" research compared to other organisations, patients generally, themselves personally or family members.

Figure 4.5.1 Who should benefit, and take priority, from UK Biobank research?



Base = "should benefit" 504; "should take priority" 489

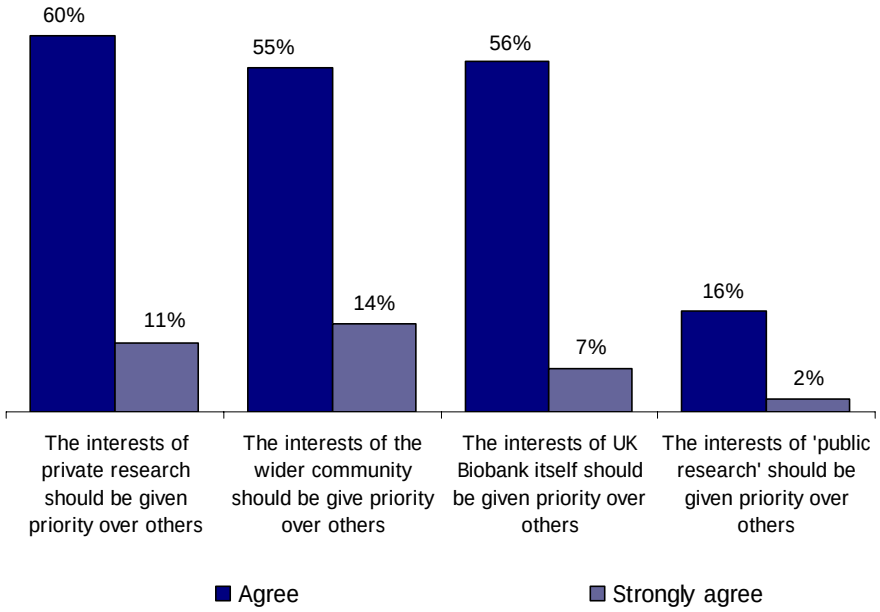
Finally, almost nine in ten (89%) of those surveyed, consistently across gender and age, agreed that commercial firms should pay a fee to access UK Biobank.

4.6 Views on public and commercial rights and intellectual property

Interestingly, seven in ten respondents (71%) reported that the interests of private research, and only 18% that the interests of public research, should be given priority over others; a similarly high proportion report that the interests of the wider community (69%) should be given priority over others.

Younger people were generally less likely to have agreed with the statements that the interests of private research (65%) and the 'wider community' (56%) should be given priority over others in relation to access to the UK Biobank.

Figure 4.6.1 Who/what should receive priority of access to UK Biobank



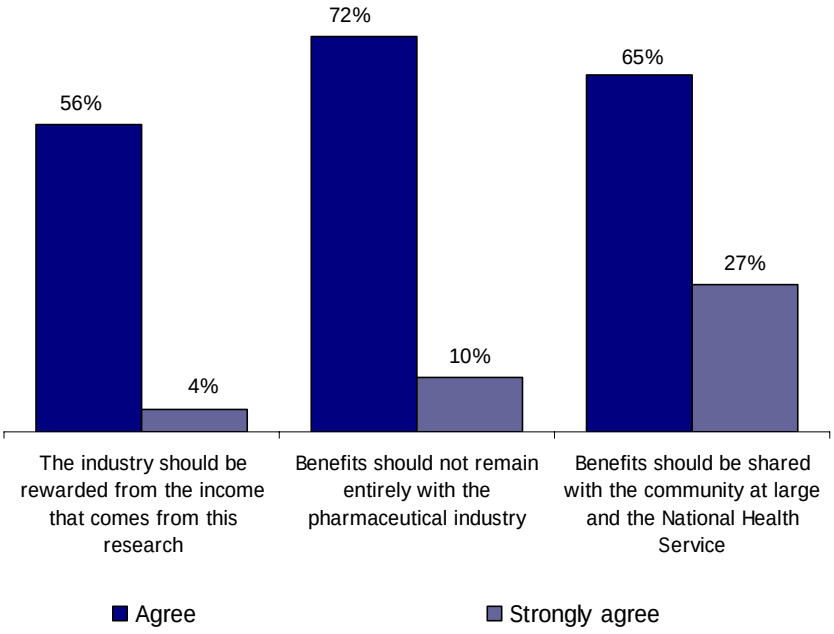
Base = 504

The data above again might appear to mark a shift in perspective, to those presented earlier relating to affording priority of access by medical science and the NHS to the UK Biobank. Alternatively, it is quite possible that 'private research' could have been interpreted in the context of this question as research that respects 'privacy', rather than research by commercial agencies. This may well therefore have been an ambiguity within the question itself. Certainly, as we shall see later in the more nuanced exchange possible during the Focus Groups, this higher level of support for private compared with public was not present.

Respondent views appear to be marked with specific reference to the pharmaceutical industry. Overall, 60% of respondents agree (56% "agree" and 4% "strongly agree") that, as the efforts of the pharmaceutical industry make long-term benefits possible, the industry should be rewarded from the income that comes from that research (using UK Biobank material / data).

However, there would appear to be a substantial consensus that the financial and scientific benefits of that research *should not* remain entirely within the industry (82%). Rather, respondents said that the benefits derived from that research should be shared with the community at large and the NHS (92%): with a larger proportion in strong agreement on this issue. We return to this issue in our consideration of the focus group data where, as we shall see, there was a strong belief across all but one of the groups that some form of profit sharing would be appropriate.

Figure 4.6.2 Views on the pharmaceutical industry and UK Biobank

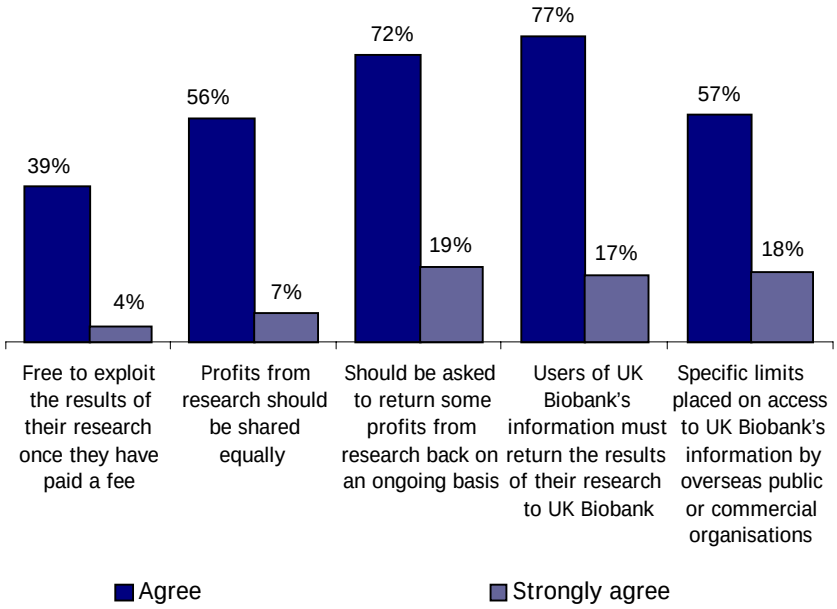


Base = 504

Despite some of the findings reported above relating to "public good" research there would appear to be a strong sense of equity in respondents' views in terms of commercial gain and the nature of "provenance" and ownership UK Biobank research materials. Fewer than one half of all respondents (43%) agree that commercial organisations should be free to exploit the results of their work using UK Biobank material once they have paid a fee for accessing (as current policy), although older respondents were more likely to have agreed to some extent with this statement (50%). Almost two in three respondents (63%) report that profits from research should be shared equally between UK Biobank and commercial organisations.

Moreover, 91% of respondents in total believe that these commercial organisations should be asked to return some of their profits from the research, back to UK Biobank on an ongoing basis: a view that was slightly more likely amongst older than younger respondents. And finally, on the issues of ownership and "provenance", over nine in ten respondents (94%) report that users of UK Biobank's information must return the results of their research to UK Biobank for future use by other users (again as current policy).

Figure 4.6.3 Views on commercial research and derived benefits



Base = 504

Three quarters of respondents (75%) suggest that specific limits should be placed on access to UK Biobank's information by overseas (public or private) organisations.

4.7 Views on potential participant benefits and willingness to assist UK Biobank

There would appear to be an acceptance of the premise that specific benefits should not be derived from participant involvement with the UK Biobank. 67% of respondents agree that UK Biobank participants should not enjoy any special benefit from providing blood samples – although younger respondents would appear less likely to be in agreement (50%) than older respondents (74%).

93% of people surveyed report that they would be willing to assist with future research (only 7% overall were aware of the UK Biobank prior to the survey).

4.8 Initial conclusions drawn from the CATI Survey

There are some interesting findings within the data.

Firstly, there are some useful outcomes relating to the characteristics of the sample achieved itself. The defined sample, in terms of distribution by age was met – although younger people were in general more difficult to secure for the study. In relation to the sample overall, females were slightly under-represented in the older age group.
Taking into account the relatively small sub set of younger people, i.e. aged 18-30, there would appear to a statistically significant (though perhaps not surprising) difference in

the extent of reported illness between the two age groups – essentially, older respondents were more likely to have a self-reported, long term limiting illness.

Also, more females in our sample reported a history of *family* (i.e. not personal) illness: this apparent difference in the incidence of self-reported family history of illness by gender would appear to reflect the ways in which responsibility for and knowledge of family health is typically the provenance of women.

For those with chronic illness, regression analysis and t tests, would appear to show a relationship that appears to be statistically significant, between the predictor variable (current long term illness) and the dependent variable (use of a self help or advocacy group). Once more, this is an outcome that would be expected for this particular sub group of the population.

In terms of findings from the survey, only 7% of all respondents had heard of UK Biobank prior to the survey. Five people, out of the 35 who were aware of UK Biobank had been recruited as participants.

Almost nine in ten people interviewed overall would be prepared to provide blood samples and a similar proportion would accept that genetic analysis could be undertaken on samples provided. A slightly smaller proportion, eight in ten, agreed that UK Biobank should have access to medical records and fewer than two in three agreed with the provision of information (about the individual) to other organisations.

In general terms, with the exception of information sharing, data for respondents in the younger age group would appear to be slightly more equivocal compared to that for their older counterparts, with respect to sample and data collection.

The findings would appear to suggest that once blood has been provided, there is a substantial amount of consensus that it can be used for a wide variety of research purposes, and that UK Biobank can make the required linkages with the samples to establish potential (causal) relationships with other health and lifestyle factors: but the proportions agreeing with the statements do diminish somewhat in relation to access to medical records and providing information to other organisations. This may be one possible source of hesitancy affecting recruitment of participants.

Given some of the apparent contradictions reported above, UK Biobank's objective and practice of providing clear information to potential participants setting out the types of analysis undertaken on, and linkages made to samples is essential to continued successful recruitment.

There are a number of apparent differences in responses made by younger people, although care would need to be taken when interpreting the observed variations due to both the small sub set of the sample they represent and also, at times, the limited scale of the variations. That being said, younger people would appear to be less likely to provide, or to permit access to their medical records etc, but appear more prepared to help with lifestyle related research.

Similarly there would also appear to be a fairly widespread acceptance of the need for information sharing to support research undertaken.

In general terms, the vast majority of respondents or roughly nine in every ten surveyed, recognise that medical and university researchers, the NHS and Department of Health, would *want* access to UK Biobank data.

However, there would appear to be a slightly smaller proportion of respondents agreeing that the above organisations should *have* access to the information and samples held on the UK Biobank.

Respondents also appeared to have differentiated between a recognised need for access by specific commercial organisations, such as pharmaceutical companies and other types of corporations. In contrast, a small proportion of respondents were prepared to admit access to the data by other organisations, such as private insurance companies and, more generally, employers, and did not necessarily endorse the current policy adopted by UK Biobank which prevents access to such groups.

There was a limited unprompted understanding of the term "public good" research. However, once explained, almost all people surveyed thought that medical science in general, and nine in ten that the NHS in particular, was associated with and so should benefit from "public good" research.

Interestingly, whilst nine in ten people reported patients (generally) should benefit, a slightly smaller proportion suggested their family and they themselves should benefit, from "public good" research and an even smaller proportion recognised that society in general should benefit.

Moreover, there would appear to be a substantial consensus of opinion, roughly one half of all those surveyed thought that the NHS, and two in five that medical science should have priority in benefiting from "public good" research.

There would appear to be a majority in agreement that UK Biobank material, and related health and lifestyle information should, in principle, be available to 'third party' (public and private) organisations - but only, as current policy requires, for *research* purposes. Again views differ when segmented by age: and it that would appear these views are more likely to be held the younger the respondent is.

There were some strongly held views in relation to the ethical and scientific underpinnings for research undertaken with UK Biobank samples: respondents clearly articulated the need for the Ethics and Governance Council's role in monitoring and approving access requests in these matters and endorsed the current policy that requires research consistent with participant consent. Younger people would appear to hold particular, strongly held, views on these matters. The consensus for approving access to research that is ethically approved was even higher (92%) and a similar proportion (88%) agree to some extent to giving approval to research that is scientifically approved. These views overall confirm the current and planned policies and provisions of UK Biobank.

There was a clear message that the interests of the 'wider community', and that of UK Biobank itself, should not be subjugated entirely to commercial potential. Whilst there was a substantial amount of support for the pharmaceutical industry to profit from research, taking into account long term benefits derived from its contribution to research, responses suggest the UK Biobank has a responsibility to ensure that profits do not remain entirely with the pharmaceutical industry.

More specifically, responses confirm there are widely shared concerns that financial and scientific benefits of research undertaken by the pharmaceutical industry, using UK Biobank material, should be shared with the community at large and the National Health Service. To this extent respondents would appear to support the UK Biobank's policy of requiring third parties to make available the results of their research. That is, the view that users of UK Biobank's information must return the results of their research to UK Biobank for future use by other users was very substantially supported.

A little over two in five respondents overall, and a smaller proportion of young people, supported the view that commercial organisations should be free to exploit the result of their work using UK Biobank material. And nine in ten report that organisations should have to pay a fee for accessing it. Clearly, there is a reasonably strong sense emerging from the data that access should be restricted, payment for access should take place and some return or sharing of profits derived from research should be made to UK Biobank.

Thus, there was substantial support for commercial organisations returning at least some of their profits from research back to UK Biobank on an ongoing basis but a slightly smaller body of support that profits from research should be shared equally (between UK Biobank and commercial organisations). In short, the CATI data indicate that respondents prefer some form of profit-sharing, as opposed to a single fee payment system, with differing views about whether profits should be shared equally or whether only a percentage to be determined would need to be shared between commercial users and UK Biobank. This issue became less clear cut, however, when, as we discuss below in regard to the Focus Groups, the practical matter of determining level of profit-return was given much fuller consideration in the groups.

While current policy and consent provisions allow this, some respondents expressed concerns about access to UK Biobank's information by overseas public or commercial organisations, suggesting that some limits might be put in place[31]. In contrast, and confirmatory of current policy, seven in ten respondents report third party organisations should only be able to access more detailed information *where this is seen to be in the public interest*.

Only two in five respondents would support the view that 'third party' organisations should be able to contact participants where there is an identified need for more data about the participants, indicating that the majority agree with UK Biobank's policy that it is the only route through which participants can be contacted (and that separate consent would be sought for contact by others). And, there would appear to be a substantial consensus endorsing current policy that the UK Biobank should not allow any particular 'third party' exclusive access to the resource – again, younger respondents would appear to strongly support this view.

Finally, almost seven in ten people (67%) interviewed recognise that UK Biobank participants should not derive any special personal benefits from providing their blood samples and over nine in ten would be willing to assist with future research: although this

[31] The limits on access were not specifically defined, but respondents themselves suggested a range of limitations that perhaps should be imposed, including: screening of applications (for example of an ethical nature) restricting access by overseas organisations (particularly those in the private sector), and others relating to demonstrate that access was in the 'public interest'.

view is much more likely to be held by older, rather than younger, respondents. Over nine in ten people (93%) would be prepared to help with future research.

These final observations represent very positive findings and relate back to the widely shared belief that medical science, and the NHS, should benefit from and take priority from UK Biobank research. For example, a greater proportion of respondents thought patients should benefit – rather than they themselves and their families – from UK Biobank. The responses suggest people see themselves as beneficiaries in the longer term – i.e. as opposed to expecting any (immediate) benefits to derive from participation itself.

Section 5: Follow-up Fieldwork: Focus Groups

The Focus Groups were held in five cities on the following dates:

Manchester	16th November
Cardiff	16th November
London	17th November
Edinburgh	22nd November
Leeds	23rd November

Prior to each focus group, participants were sent background information on benefit sharing and a summary of the Access Policy of UK Biobank. Vignettes were developed for the session. These vignettes (see Appendix 4) were discussed with and signed off by members of the EGC.

Participants for the focus groups were recruited through local co-ordinators identified by QA Research. Each Focus Group had 5 or 6 members drawn from the local community purposively sampled to reflect the demographic range adopted for the study as a whole, and this was successfully secured (in terms of gender, age [the youngest was 19, the oldest 65], and ethnicity) within each group. Meetings took approximately 1.5 hours and were recorded (with the consent of the participants) and the data transcribed in full. We have organised the initial review of the data from the five focus groups according to the main themes raised by the three vignettes. We illustrate various points with verbatim comments from one or more of the groups.

Theme 1: Access to samples and health and lifestyle information

The majority of the Focus Groups (FGs) agreed that access to both analysis of biological samples and to related health and lifestyle information was legitimate, and could be expected. One exchange[32] (in the Cardiff FG) reflects this:

> CFG1: Most health conditions are linked to your lifestyle, so you need both to make the connection
>
> Facilitator (F): Both sources of information are there, and you'd think it will be OK to have access?
>
> CFG1: I think it'll be difficult to go to a company who would not want access to both
>
> F: Why do you think that?
>
> CFG1:Because of exactly the reason this young lady said, you need both forms of information to make an analysis, I think you would find most companies would want, they'd want everything anyway, whether it was of use or wasn't of use, they would want as much as they could get
>
> CFG2: It's research, in depth research, you talk about someone's data and everything, needs to be in depth.

A similar picture emerged in the Manchester FG, with some quite nuanced observations, such as:

[32] The numbers (such as FG1) relate to different respondents speaking at the time prefixed by the letter for each City, Cardiff (CFG1), Leeds (LFG1) (LonFG) etc.

MFG2: Surely that would be the case they would have to do that anyway because it is a cross-referencing between the actual sample and the personal data because otherwise there are going to be questions from just purely the sample, with any company I would have thought, because they would want to analyse from a qualitative point of view why that information had come about, so they're going to need further research into the background of that particular sample, I would have thought for any kind of research they'd want both qualitative and quantitative, they've got to have a situation with both analysis anyway

Many commented that participants in UK Biobank are aware that when they are recruited they will be expected to provide both types of information, and so should expect both to be sought by third parties.

EFG3: Surely that would be par for the course, if you're finding you have actually come out with results for a particular group of individuals in an age group, and it is highlighted, you're going to turn around and say should we look at these people, so should we do another test, not necessarily the same one, let's see if this one pops up with the same group again, they're in actual fact going to come back to you more than once, it's not going to be just once, they're going to see if there are anomalies there, let's counsel them for if they are then let's find out they are there

EFG2: think as well when somebody, if they're going to offer to provide in the first place, if it is explained to them, they're going to be fine about getting it done again

EFG3: I would think so as well

EFG2: If they are quite comfy in the beginning, knowing it's not going to be completely anonymous anyway, somebody is going to get information somewhere

At the same time, all FGs agreed with UK Biobank's policy with regard to the handling and management of biological samples through specialist labs. At the same time, there was some concern expressed about what type of lifestyle information (such as sexually transmitted disease) might be held by the bank:

LFG3: STDs, it's not relevant to the research so maybe they should keep that bit of lifestyle back

Most importance was given to UK Biobank acting as intermediary and guarantor of the proper use of any information by third parties:

LFG3: Because you wouldn't mind your personal information given out to someone else, if it goes through Biobank.

LFG2: It's all about control isn't it, they have control over everything, it's not just out there, it might put a lot of people off if companies were just phoning them up at home.

This was echoed in the Manchester FG:

MFG1: I think the Biobank would have to prove that they are reputable, in good standing of research. It's going to be used for the good of society.

MFG2: The application subsequently approved by the board, the request meets the ethical principles, so if you said to me any future request for further information would have gone through that process or it wouldn't make it in [...] I would be happy with that

Re-contacting UK Biobank participants raised more concerns, especially if this meant repeated contact by the bank itself on behalf of a third party (unlikely though this would be). The following exchange from Edinburgh illustrates not only concerns over the number of times someone might be contacted but also what that then suggests:

> F: Do you think there would be any, do you think that could cause any anxiety, somebody who volunteered to take part in it?
>
> EFG1: Suddenly they have 30 requests for their blood, yeah, what's going on here, is there something wrong with me
>
> EFG2: …and contacted by research groups and might produce anxieties and is there something wrong'.

Members of this same FG also were concerned that apart from re-contact raising new anxieties there was the wider issue of not even knowing whether such anxieties were justified: this came up in respect to the scenario about 'Mary' who had been diagnosed with breast cancer:

> EFG3: Maybe if they brought up something else in addition to breast cancer, they are not obliged morally or otherwise to tell her GP 'by the way we have found something in this and you need to check it out' *I would be quite uncomfortable thinking somebody knows more about my health than I do* (emphasis added).

At the same time, the requirement that third parties go through UK Biobank was endorsed by all FGs. Moreover, it was also noted that participants were not obliged to agree to re-contact: as one observed '… it's not an ID card, if you don't want to be involved in the programme you don't have to be' (LFG4).

Even so, respondents in broad terms in all the FGs acknowledged that the need to continue to monitor participants on a regular basis was important if the value of UK Biobank were to be realised, though this raised matters of privacy and trust. Respondents weighed up different types of research, and expressed certain sensitivities about research on different diseases. The exchange below illustrates not only matters of privacy but also choice and control: it raises concerns about knowing what you are disclosing to whom and why (and maybe what you think the risks are but also the benefits).

> CFG1: I don't see it's any worse than being on the computer at your doctor's in a way; they know you more intimately than anyone
>
> CFG2: I think in some ways it's good because I see my doctor's receptionist around town all the time. With Biobank, there is less threat than that really, at the end of the day it's a matter of choice, nobody's forcing this lady to give the information, anytime she can stop giving information, if she has concerns about her privacy however ill founded they may be she has the choice to take the information away
>
> CFG3: It's not your bank details or anything
>
> CFG4: They're not going to be able to do anything with your blood group are they?
>
> CFG5: All they will have is do you smoke, do you drink, if someone has your age and if you smoke or drink are you really worried?

The references in this extract to what 'they' might do with one's blood group or the idea of cloning raises concerns about the extent of personal control prospective participants feel they have over provided material, but also what such material actually means in relation to us personally and how the information might be used later on: information derived from DNA may have little real meaning for people. This compares with the way they speak about more tangible matters such as smoking etc. Obviously UK Biobank is predicated on people relinquishing control over their biological samples and data to allow researchers to do their work but what this means for the respondents is a more open question. And it is worth noting that a number of observations were made across the different FGs with respect to the ways in which people (as patients) are required to give samples that subsequently are used for purposes other than an immediately diagnostic one. As one member of the Edinburgh FG observed:

> EFG4: To be quite honest with you, I can appreciate where you are coming from and I'm inclined to agree with what you're saying, but if you look at it from the point of view that every time you go to hospital, the majority of times you go to hospital you're going to give a blood sample, a urine sample or some kind of sample, half the time you're going to be taking part in tests that you don't even know about

Police access

There were counterposed views on the question of police accessing UK Biobank information. Apart from the Leeds FG, the other four FGs were broadly sympathetic to the possibility that the police might need access to material held in the biobank. Many thought that people should be prepared for the police to access information and those that were not were more likely to be criminals themselves: '…as long as they are made aware that it is possible that it can be used by the police I don't see what the problem is (CFG3).

In contrast the Leeds FG felt that UK Biobank's policy of strongly resisting requests from the police was directly related to the trust it would secure from the public, otherwise, as one member rather pithily remarked:

> 'Instead of the Biobank we would have the burglar bank'.

Even so, within the Leeds group, as they explored the issue, they themselves had contrasting, not necessarily contradictory views on this issue. Compare the following two exchanges within the LFG:

> Fragment 1
>
> F: Do you think it is right they should resist the police?
>
> LFG3: Yes

LFG4: I do, they've got to protect their reputation haven't they, and they have got to say we're a medical research body and set themselves apart from everything else

LFG2: Or what you will lose is a lot of participants

LFG3: What's the police got to do with the good of your health?

LFG1 If people were signing up to it than the police could get you: you wouldn't get as many people, like you said

LFG2: The thing is, I would be unlikely to give my, to provide, even though I don't think I'm going to be involved in any criminal activity, I would still be unlikely, knowing I was just giving all my information and then putting police work above health, I think health is more important than police work'.

Fragment 2
LFG3: I think it could work the other way, it could be the you're not necessarily the criminal, you are the victim and if all your information is with Biobank, I think the law comes above, not that the law is more important than medical science for the future and so forth - but law has to come above everything and that's why we have a law and that's the way we live and it is necessarily, if someone has given all this information and they're a child killer and if there is a way that we can then find it out, they say that in any confidentiality agreements, the law still comes above

LFG2: It may deter people, but … it's got its benefits as well, if I knew that all of my DNA on all of my information were somewhere, something happened to me I know the police have access to all the information on me that could help solve something, do you know what I mean, in that light, is not just about that they might find a criminal, they might find a victim as well.

A similar sense of ambivalence about police access was evident in the Edinburgh FG. Some members felt that access by the police should not necessarily be resisted while one thought it should lest it jeopardise the trust that participants put in the bank:

F: What about access by say the police?

EFG1: I think they should

F: What about if the police want access to the DNA?

EFG2: I don't think it is right

EFG3: I wouldn't have an issue with it

EFG4: Personally I've not got a problem with that

EFG2:I do

EFG3: Personally if there is a murderer or a serial killer or a paedophile

EFG2: I know, but there have been stories about DNA, they have the technology now to plant people's DNA and you're talking about 99.9 per cent accuracy for DNA, the if someone has access to that and plants it, you could be looking at a whole host of pointing the finger 'you done that, you done that' I just think it is dangerous to start getting into that

EFG3: What about the good side of DNA?

EFG2: Yeah, fair enough

EFG4: At the end of the day if someone came along and murdered somebody who was close to you, would you say no you can't

EFG2: I'm not talking about that, I'm talking about accessing all these people's information to find one particular person, I'm not saying if someone comes up to you and says I want your DNA off you, fair enough, I think our privacy is far too much invaded as it is, there is information and everybody, I know you're talking about things that can be taken for bad purposes, I know they can be used for good as well, I realise that, but I still don't agree

Another issue explored in the FGs was whether access should, at least in the early stages of UK Biobank's operations, favour public sector researchers, to see whether respondents would want to discriminate in this way. In fact all FGs dismissed the idea of giving priority to public (university/NHS) research teams, arguing that they are no more likely to be able to exploit the resources of UK Biobank more quickly than private sector parties; moreover, many argued that the product of any research was not more worthy or valuable by virtue of its being the result of public rather than commercial work:

MFG2: I think it would be wrong to say this is initially first offered to public bodies, who is to say that the commercial operation can much more quickly go down the route of finding essentially the product, why hold them back from doing so.

MFG1: If it's going to do the public good I don't think there is a difference who accesses the information first, because it is all for the public benefit, well it should be, so either way it doesn't matter who has access to it.

F: So the university sector shouldn't have priority over the commercial sector?

EFG3: I don't think so, because if they are all reaching the same goal, trying to help

EFG4: The greater good

EFG3: They shouldn't really be a problem with who got the rights first or had priority access

Theme 2: Definition of health related research

There were various definitions given in different FGs about the meaning of 'health-related research, what it is and what it is not. In terms of what it is, observations included:

CFG1: 'If it was about blood it must be about health.

(LFG2) 'Health related doesn't have to be positive thing, it could be negative thing, could be identifying something negative, but that's still beneficial to the health of the population, like these people who live under electric pylons and things like that, they could test their blood over a series of years, that's not creating a tablet but it is health related'.

MFG2: 'I don't know if this is right, but is it diagnosable illnesses, not all depression is diagnosable, so obviously wouldn't put research into something you can't get a physical cure for.'

The LFG2 person makes an interesting point about the expectations of the kinds of outcomes UK Biobank will produce – not necessarily clinical products that can be marketed but epidemiological information that ideally shapes public policy. This is potentially much more powerful information. More generally, much of the commentary was also about how research would feed into the NHS and contribute towards the wider public benefit (see discussion of benefit sharing below).

In regard to what was seen as research that was not related to health, most FGs identified some or all of the following: cosmetic-related, insurance linked, (genetics for) 'designer babies', and 'performance enhancing drugs'. Insurance-linked research was seen as far removed from any sense of the public good, primarily because of the commercial interests of this type of company:

> LonFG1: Insurance companies are gambling companies really and they, that's how they make money, they have to stick by the rules.
>
> LonFG3: They've set up their business, that's what they want from it, medical and health related are two different, it's like different, from insurance, insurance want to gamble, medical want to find.
>
> MFG2: The whole basis I have got from this on the UK Biobank is public good, that isn't in my opinion, because insurance companies can go to a specific person.

One of the participants in the Cardiff FG made the following interesting observation about the meaning of health-related research, distinguishing the research element from simply an informational aspect:

> CFG2: I think the key word there is not actually health related, I think the key word is research, there is a difference between providing health related information and providing something that is going to health related research, I think that's the key word, is actually research for the public good, the implication something is going to come out of that which is going to help everyone, when we talked about the insurance and things like that, that's about providing information for their good, not for the public good, I think that is the key thing, is the difference between information and research.

In short, most people seemed, as in the follow-up telephone interviews, to have a relatively clear idea of what they understood 'health-related' research to be: this was research that was principally about tackling disease areas, was of broad benefit to all (even if in some contexts some groups derived more benefit than others precisely because they were suffering from specific diseases), and was research (and not merely information) based and driven. Some also commented that the work should be on both existing and new – 'groundbreaking' – areas of research, as well as both preventative medicine and 'preventative information'.

Theme 3: Meaning of the public good

This last point takes us to a discussion of respondents' understanding of the term 'public good'. In general, this was understood to imply that everyone would benefit from research even if they were not suffering from illness of disease: in later life they or their kin might, was the common view. The following extract illustrates this position:

> LFG2: It's not you personally, but eventually the research will sort this, that and the other and everyone will benefit from that.
>
> LFG3: Or even a section of society, not the whole of society, like a random section, could just be people of a certain age or live in a certain area, if they're aware of something there that is a public good, that they wouldn't have been aware of before, it doesn't have to be everybody…Even research that could stop things like down syndrome or cure cancer or stop diseases like Alzheimer's or dementia, that's for the public good, not everybody might get dementia, but the ones that do any research that is done, anything they learn from the research is good, it's for the public good.

Similar views were expressed at the Cardiff FG where respondents distinguished between research that could potentially benefit anyone from research that *had* to benefit all equally. Public good research did not imply the latter.

Theme 4: Benefit-sharing models

We next summarise the key points that emerged from a discussion of the four different benefit models that were provided to respondents in advance of the FGs.

All of the FGs believed that the compensatory model was impracticable, unworkable, and the solidaristic model[33] too vague to be deployed in any credible way. They also tended to favour a combination of the fees for access model (the model adopted by UK Biobank) and the profit sharing one (which UK Biobank has said might come into play in exceptional circumstances). Only one group Leeds, felt that the fee-for-access was clearly the best and did so because they felt it stressed the public-good nature of UK Biobank, and would attract more trust and so recruits:

> LFG1: It's the fairest one, isn't it and it's keeping things simple, saying these are our beliefs and these are our rules, this is what we will abide by, we're not trying to make a profit .
> LFG3: It's not complicated, they're not complicating the issue.
>
> LFG2: I think that, I think if you start saying we're going to give you money, were going to give you so much, like has just been said it's just going to cause, it gets away from what it is, from being a good thing to being a monetary thing.
> LFG3: Some things you just can't put a price on.

Some similar remarks were made in the other FGs especially in terms of option 2 being best designed to retain the trust of the public, but even so, many argued in favour of a hybrid fee-for-access and profit sharing arrangement.

> CFG1: I think it's absolutely reasonable a commercial company would get a reasonable profit from whatever they develop because it is hugely expensive to develop any sort of medicines, but I think there would probably be nothing wrong with putting a percentage that could be returned back.
>
> CFG3: I suppose that's what I would argue a percentage was reasonable, a bit like royalties, if it doesn't sell then no money is payable, if it does then a reasonable percentage, because you've got to allow the drug companies to make a big profit, you've got to allow them that potential to make a good return because it is so expensive and such a vast amount of input with potentially no return.

Benefit sharing was seen then in terms of a balance between UK Biobank being seen as a non-commercial, public good organisation, and one which at the same time secured a reasonable return from third parties where they made profit from using the resources of the bank. This clearly has longer-term implications for UK Biobank as it moves towards a point in time when it will be self-financing.

[33] The compensatory model presumes that an individual could be compensated for the costs (in terms of time, provision of samples and information) incurred in participating in a tissue bank; the solidaristic model presumes that the community as a whole would benefit.

Section 6: Follow-up interviews

Follow-up telephone interviews were conducted between 25th November and 4th December 2007, with 20 respondents selected from the population who participated in the CATI survey. Although we secured a proportionately higher number from minority ethnic backgrounds, we found no systematic differences in their perspectives compared to self-reported 'White British' respondents. Three main themes provided the core of the interview: third party access, the meaning of 'the public good', and views on commercialisation and benefit sharing.

6.1 *Third party access*

Overall, the majority of respondents agreed with UK Biobank's policy that third parties, including commercial organisations, should be able to access samples and information. However this is tempered by the feeling that strong and stringent restrictions, and penalties, should be in place if third parties were to violate their access agreements and pass information on to others. One interviewee even suggested that in the case of misuse individual participants whose specific information is used in this way should be compensated. Comparisons were drawn to personal information being passed on to fourth, fifth or even sixth parties in the form of telemarketing.

An important issue mentioned in more general terms about data handling was the ability to maintain anonymity in particular with respect to the electronic nature of records. Serious concerns were noted by many about the prospects of this happening. It is important to record here there was some heightened sensitivity to this issue in light of the loss of the 25 million records by HM Customs and Revenue at the time the interviews were conducted. UK Biobank reports that it has security arrangements in place to address this issue that is now, perhaps, assuming higher priority among the public than in the past because of the recent controversies.

Where concerns were raised about possible misuse of biological samples, health records, and life-style information, patient records were seen among some as the most sensitive kind of information that would be provided to UK Biobank: as one commented, this is 'personal information that is between me and my GP: my family doesn't even know that'. Even so, there was still considerable support for 'full' participation. In other words, health records and life-style information should accompany biological samples so that contributions are not 'halfway'.

In contrast to these concerns, privacy was seen as very minimal concern on the other hand among respondents with chronic conditions. Some felt that advances in medical research outweighed any potential incursions of privacy while others felt that they were 'living on borrowed time' and, as a result, their health status was of more concern than issues of privacy.

There were some respondents who made specific mention of access to UK Biobank resources for safety and security issues (i.e. non health-related research). While most others agreed with the UK Biobank's access policy which would deny third party access for non health related research, respondents did not necessarily oppose the existence of other biometric repositories for safety, security, and policing matters; rather, they simply felt that these should be separate resources. One suggested that a uniform rule should be applied and that the Home Office could have access to results of analysis done by tests

conducted in-house, but they could not access samples as 'that would be breaking the agreement'.

Respondents were asked about the nature, or foundation of the trust invested by people in UK Biobank and the assurances of privacy and anonymity. Some felt that trust was based on the fact that the bank was related to health research, whereas others felt that trust was an elusive concept – 'trust is a thing that doesn't happen much these days'.

The above suggests an acceptance of the dynamics of biomedical research in the context of UK Biobank, and certain levels of expectation that third party access will operate within a professional and well-regulated framework. At the same time this trust is contingent. Expectations are high for measures to be in place to regulate third party access and institute penalties in the event of violations. Given the contemporary high profile case of records going 'missing', trust in the provision and protection of personal information is a volatile and sensitive issue.

6.2 *Views on the 'Public Good'*

There was virtual unanimity in regard to a willingness to provide samples and related information to UK Biobank, citing reasons of improvement of health of society generally. There was no support for the provision of incentives to provide such, but if a sample helped towards research then some argued that one should have access to the medical benefits of that research more directly. This was an interesting issue with regards to privacy. People wanted privacy, but some felt that if a company had a new medical treatment that was relevant to them and their sample was a part of their research, then they should have access to results, diagnosis, and/or treatment. So there appears to be a trade-off being made here between privacy and access to benefits.

There was significant discussion with regards to the comparison between UK Biobank and blood banks, especially among respondents reporting chronic illnesses. People did not feel that incentives were necessary for UK Biobank, just as they have not been for the blood bank, and that if the bank is a public resource its benefits should be publicly accessible.

6.3 *Views on Benefit Sharing*

There was almost complete agreement that the general public – rather than any specific group - should be the recipient of health benefits resulting from research that made use of UK Biobank resources (in the vague understanding of the forms by which this may come). Public access to these benefits was likened to the national/public good nature of the NHS.

Furthermore, there was almost a complete consensus that in the event of profits some should be shared with the wider public, the NHS or "ploughed back into research". The reasoning behind this varied. Many felt that often commercialisation leads to companies making huge profits, and consequently those benefits should be distributed to the bodies that facilitated the commercialisation; others felt that benefit sharing of profits should be proportional to the size of profits as well as to the fees paid for original access (a position that broadly reflects the CATI survey).

With regards to benefit sharing in the event of commercialisation one respondent noted that benefits should be fed back to UK Biobank. For them, the reason was that one sample did not lead to an analysis or a discovery; rather, it was the group of samples that would provide for analysis and/or discovery. Consequently individuals should not necessarily be rewarded; rather UK Biobank – as the holder and organizer of the group of samples - should be the beneficiary in the sharing of commercial benefits.
The general position with regards to benefit sharing is congruent with broad notions of serving the public good: benefits resulting from research based on UK Biobank resources should be shared with 'the public' health care system and public sector researchers.

Section 7: Emergent Themes and Key Issues

In light of this discussion, there are a number of themes and issues that have emerged from this analysis of the data that bear directly on UK Biobank's policies. These relate to the following:

- Public understanding of key terms such as public good and health-related research
- Access policy and the preparedness to allow re-contact
- Access policy towards non-health related sectors
- Benefit-sharing models and the current fee-for access policy
- Concerns over security of information more than anonymity
- Distinguishing between being a 'participant' and being a 'participant-patient'
- Age-related differences in responses
- Respondents' perceptions relating to the meaning of 'blood', 'samples' and 'DNA'

7.1 *Public understanding of key terms such as public good and health-related research*

It is apparent that there is less of an immediate sense of what the term 'public good' means compared with health-related research -- the former typically eliciting responses only after prompting via an example. Such responses, across all three data collection exercises, centred on the NHS as the repository and guarantor of the public good. But there was a broadly shared view that the nature of public good research was that which serves the needs and interests of all, in principle, even though in practice its application might inevitably focus on those disease areas that are most common yet not contracted by all.

This raises far-reaching questions about the ease with which publics are able to quickly recognise the meaning of 'public good' and equally pressing questions about the discursive basis of communication about UK Biobank. In rhetorical terms, the phrase operates at a level of abstraction not easily grounded in everyday understanding and knowledge. However, it is important to recognise that respondents in the study, particularly in the focus groups and telephone interviews, were able to situate and develop the notion of public good with reference to health services, and also in contrast to exclusively for-profit commercial sector activity. Nevertheless, it is just as clear from the data that respondents are aware of the complexities and fluidity of public-private boundaries. This is particularly evident for example from the broadly shared belief that UK Biobank and by default the wider health care system is seen to benefit from the commercial development of clinical products and services.

In sum, it is likely that the concept of 'public good' will perform an important ongoing function in framing the mediating role of UK Biobank in facilitating broad public and commercial healthcare aspirations. It may also be the case that, as an abstraction, it may offer an important and new way for people to grasp the increasingly hybrid character of contemporary healthcare research.

In asking what health related research was, respondents readily and commonly identified work on disease and therapies, while there was a broad consensus across all three data sets about what it excludes, including cosmetic, insurance- and employer-related work.

These were seen to favour specific rather than general interests. This was also linked to particular concerns about the custodianship role of UK Biobank and access to its resources, especially in regard to the police, to which we return below.

In short, examination of the data suggest that when *combined* the notion of 'health-related research' for the 'public good' does evoke a reasonably well-defined set of assumptions among the people we spoke to. For many this ties in with the rationale for participating in UK Biobank in the first place – a 'gift' for the 'public good', and for some this has very clear resonance with giving blood for transfusion. We were particularly struck by the distinction made between health-related research and simply health information (which, for example, might be sought from clients by an insurance company). This distinction could help UK Biobank position its 'health-related' research by emphasising the *investigative and applied* nature of the work undertaken by third parties. This would be a useful point to stress even more fully than at present in policy documents and when securing prospective participants in UK Biobank.

7.2 *Access policy and preparedness to allow re-contact of participants*

All three data sets indicate strong support for access by third parties to UK Biobank resources, both biological and lifestyle related. There is also very strong support for the range of restrictions detailed in the access policy and especially the importance of the role of the EGC in advising UK Biobank. The various checks in place relating to consent, anonymisation of data and ethical and scientific review were seen as key to retaining trust in UK Biobank as a public good institution.

The main concerns that were expressed, which might also figure among prospective participants, related to ensuring that access by commercial third parties was seen to be both legitimate and warranted in the sense that it was clearly only for health-related research. The gate-keeping role of the various review procedures is clearly an important source of reassurance for prospective participants during recruitment. The possibility of re-contacting participants and providing more detailed information is a more contentious issue for a minority across the three data sets. Just over a third of the respondents agree that third parties should be allowed to contact individual participants, in the future (with consent), if more data is needed about them. This seems quite a low number and could potentially be a concern for UK Biobank since follow-up and re-contacting will be a vital part of realizing the value of UK Biobank for future research.

Concerns included the frequency of re-contact that might be made (which if high might be regarded as intrusive) and the signal this might send out (that the particular participant has an interesting but thereby worrying condition). Beyond this question of recontact, there was some concern over the ability to guarantee that there could be no misuse of personal data. Security of data is a more general concern heightened by recent national controversies over lost material. Continuing reassurances (through UK Biobank's website) about security (especially in guaranteeing that data loss would not occur and anonymisation not be jeopardised) may be as important to prospective participants as conditions regulating access by third parties.

One interesting observation made at a number of the FGs was that those with a chronic condition may be more happy with a higher frequency of contact from a third party (via UK Biobank) as their ill-health requires them to engage with the medical system on a regular basis, providing additional information and new samples when required. Nearly a

third of the survey sample defined themselves as suffering a 'long-term illness'; it would seem that prospective recruits with such conditions might be more prepared for more regular re-contact, but clearly it would be important to ensure that such an expectation does not lead to an overburdening of this group simply for research purposes.

7.3 *Access policy towards non-health related sectors*

All respondents endorsed the restrictions that UK Biobank has placed on research being solely for health-related work, and, in doing so, quite readily distinguish between biomedical and other requests (such as from employer organisations). There would appear to be a recognition that once UK Biobank is fully recruited, a range of organisations would like to have access to the resources, but equally a belief that these should not be permitted to do so. While it was pointed out that this was against UK Biobank policy, one FG (in Edinburgh) raised the prospect of UK Biobank favouring commercial interests (*viz.*: 'there is this cancer charity that wants access to these results, but then there is this company with 100,000 pounds, we can get 100,000 pounds, we're not going to get anything off the cancer charity'). It is, therefore, important for the bank to reiterate in its public policy statements that this scenario is impossible given the rules and procedures under which UK Biobank operates.

However, we found that, apart from one of the FGs – and there was even some ambivalence expressed there - it does appear that UK Biobank's policy of resisting police access is *not* widely shared. It is also clear, however, that at the same time respondents do not thereby advocate that police *should* have access *as a matter of course.* As we noted earlier, these contrasting views, sometimes held by the same person, reflect dilemmas that people have about the balance between protecting personal privacy against the demands of public interest. Views about where this balance lies varied quite considerably but were often framed by anxieties over the expansion of state and police interest in accessing genetic data. Whilst many respondents were in fact supportive of the wider use of police DNA forensics, respondents were also concerned about potential miscarriages of justice arising from technical mistakes and the planting of genetic evidence. It would appear that if UK Biobank in the future did have to prevent access to samples the majority public view would be to endorse this policy though there would be some who would question this if the basis of the request from the police related to a highly public incidence of criminality. Much would depend on whether such matters became an issue in the public domain and then were defined as a matter of 'the public interest'.

Given these concerns and sensitivities it will remain imperative that participants are reassured that the bank be insulated from association with the criminal justice system, notwithstanding the need to respond to an unlikely intervention from the High Court. In all such cases, the obligation of confidence can be argued as a basis for not disclosing data or personal information. However further research is needed to clarify the rights and obligations that might apply under statute and common law, for all third parties who may wish to have access to UK Biobank.

7.4 *Benefit-sharing models and the current fee-for-access policy*

There were a variety of perspectives about the differing models provided for consideration during each of the three phases of the study. However, the majority position that appears in all data sets is that some sort of hybrid fees/profit sharing model would be worth considering. Both compensatory and solidaristic models were regarded

as either impracticable or too imprecise to implement. In addition, prospective recruits are likely to share this view and indeed we found that compensatory models would be contrary to the very strongly held view that participation is based on a non-pecuniary, altruistic model. Introduction of compensatory payments elsewhere – such as in the field of stem cells – has been shown to reduce rather than increase the predisposition among women to contribute eggs/embryos to research.

From the responses collected across all three data sets it does appear that most regard the fees-for access model to be 'cleanest' but one that would prevent some legitimate profits returning to UK Biobank. There is a balancing act here between securing (what is perceived as) a just return and sustaining the non-commercial character of the bank itself (in this regard, one FG member raised the question whether UK Biobank could market the research results that have been returned to it). UK Biobank's position that it would, in some circumstances, consider seeking some return where it had made a significant contribution towards a third party's product is likely to receive wide-spread support and could be extended in the future.

7.5 *Concerns over security of information more than anonymity*

Our data suggest that there are more likely to be concerns in the future over guaranteeing the security of information than matters of anonymity and consent, which are seen to have been properly addressed. The Focus Groups (and follow-up interviews) took place during the period when the government was coping with the very public controversy over loss of national data; to the extent that there was occasional reference made to the issue, respondents' awareness of the matter of security had clearly been heightened. However, much of the commentary was of a more general nature related to concerns about personal information circulating via government-based, health-related, and commercial systems which we have seen grow over recent years. As one FG member from Edinburgh commented, 'Is there anything safe? When you look at it from the point of view that everybody is on about security, they're going to bring out these cards, ID cards, and there is a wee guy in Poland churning them out! It's as simple as that'. Or as another said: 'I know there are security issues; there's security issues in everything'. In light of this, UK Biobank stringent security safeguards when recruiting prospective participants are key to the continued successful recruitment in the future.

7.6 *Distinguishing between being a 'participant' and being a 'participant-patient'*

Almost all respondents across the different elements of the fieldwork (survey, FGs and interviews) acknowledged that UK Biobank was not 'in the business', as one FG member put it, of providing information about participants' actual health since that was not its purpose. However, many raised the question of whether, even if participants were under the medical care of their GP, the sort of information that third parties might derive from analysis may be of great importance to the participants, precisely because it may have longer-term implications for their health and well-being than the diagnoses GPs are likely or able to make. Here, there is a slippage between participants as participants and what we might call prospective 'participant-patients', whereby a clear distinction between being a participant and being a patient becomes blurred. Expectations clearly need to be carefully managed when recruiting participants to the bank to ensure that, as the resource grows in scale and national importance, those associated with it as participants do not redefine what personal benefit they might derive from UK Biobank over the longer-term.

7.7 Age-related differences

For a long-term project such as UK Biobank, the question of whether there are generational differences in attitudes towards the conduct and governance of biobanking has been of interest to both its funders and commentators. In this case, can we see in relation to matters of access, intellectual property, the role of commercial organisations, and benefit-sharing, significant differences between older and younger respondents? The data from the CATI telephone survey reveals a number of variations between the two age groups of 18-30 (n=151) and 40-69 (n=353). While we must be careful with how we interpret these variations based on such sample sizes, there are some interesting differences on a number of key questions that are worth commenting on in this concluding part of the report, albeit somewhat speculatively. However as we noted above, these differences *cannot* be seen to be statistically significant, only that they indicate some potential divergences between the two age groups, which should ideally be borne in mind as the bank's full operations get underway, and perhaps provide some pointers to future research.

UK Biobank Participation

On the issue of participation in UK Biobank, the CATI survey indicated that a notably lower percentage of the 18-30 age group reported that they would be prepared to provide a blood sample to UK Biobank (60% compared to 78% overall). A slightly greater percentage of younger respondents stated that they would be prepared to help with lifestyle research (77% compared to 75% overall), while a smaller percentage stated that they would be willing to provide access to personal medical information (58% to 65% overall). These findings indicate perhaps a greater reluctance or ambivalence towards providing blood samples for research purposes, but a willingness to share certain types of personal information. The higher percentage of younger respondents stating that they would be prepared to help with lifestyle research might reflect a greater interest in and willingness to share information about lifestyle amongst younger people. We might see this reflected in the recent phenomenon of social networking websites. On the other hand, there was more reluctance to share medical information *per se*.

Access to UK Biobank

The survey also revealed some notable variations on questions of access to UK Biobank by different organisations, as mentioned in the report of the CATI survey. It is difficult to know how to make sense of the finding that a much higher percentage of younger people reported that patient charities *should have* access to UK Biobank data (75% to 62% overall). On the one hand, there was no reported membership of patient groups or advocacy organisations in the younger age group, and there was a statistically significant difference in the report of long-term illness between the two age groups. On the other hand, similar levels of chronic illness in the family were reported in the two age groups. Arguably, in the last twenty years or so, we have seen the rise of new forms of patient groups not only funding research but also playing much more of an advocacy role, often with patients themselves at the forefront. Perhaps this is evidence therefore that older and younger respondents have different expectations about the role of patient groups and their interests in resources such as UK Biobank – that charities should have more of a role to play in funding or even conducting medical research compared with the university or commercial sectors?

On the question of access, it can also be noted that in the overall sample there was a clear consensus (94% agree) that UK Biobank should only allow access for research that is consistent with the participant's consent. Within this 21% "strongly agreed" with this statement. Amongst the younger age group, this figure rose to 31% of respondents reporting that they 'strongly agree' that access should be permitted that is consistent with participant consent. Does this indicate that younger respondents value consent more than older ones? Might this reflect changes in the cultural dynamics of trust in the medical professions related not only to recent public controversies but also the reported decline of deference to medical authority?

Issues of sharing information also came up in relation in third party access to UK Biobank. A greater percentage of younger respondents in the sample said that third party organisations should only be able to access more detailed information about participants in UK Biobank, where this is in the 'public interest' (79% to 68%). A higher percentage of younger people (51% to 40% overall) also said that third parties should be allowed to contact participants in order to gain additional information. This would indicate that greater access to information should be allowed when seen in the 'public interest', but that otherwise individuals should have the option of choosing to provide this additional information or not. This again would seem to emphasise the importance that younger respondents gave to individual consent.

Commercial and Public Good Research

On the issue of 'public good' research, it is also of note that more of the younger respondents thought that the government should benefit from 'public good' research (79% to 68% overall) and, indeed, should take priority in this regard (18% to 7% overall). Does this indicate that respondents in the younger age group associate the government more closely with notions of 'public good'? Does this signify a more positive attitude towards government than the older age group?

Finally, on the questions of access by commercial organisations to UK Biobank and their use of its resources, there were no significant differences between the older and younger people with regard to the one-off fee model, leaving commercial companies free to exploit the results of their research once the fee had been paid. Similar agreement was apparent with the idea of these companies returning profits from research to UK Biobank on an ongoing basis. Therefore, the evidence indicates the one-off fee model is broadly supported. The Focus Groups in particular seemed to favour this view.

7.8 *The perceptions of different types of 'sample'*

There are some issues that should be considered with respect to widely held conceptions about the material and symbolic differences between, for example, blood, urine, DNA and patient records. This is unsurprising given that each of the material/data sources upon which UK Biobank depends are steeped in contrasting political and moral economies bearing different meanings, histories and perceived risks.

People talk easily and repeatedly about the routinisation of 'giving blood' with the giving and voluntary donation of blood operating as a recognisable touchstone in making sense of participation in the UK Biobank initiative. A similar form of recognition is attached to urine. But this association with the familiar is less characteristic of DNA. Not so grounded in established experience, there are some indications in the data that DNA and

genetic information, in comparison to blood, is more difficult to grasp and of greater sensitivity.

Surprisingly however, whilst patient records are a regular feature of the clinical encounter for most people, the data suggests that anxiety surrounds their availability for research purposes in general, even when fully anonymised.

The survey found that blood, DNA and patient records have slightly greater sensitivity amongst younger sections of the population sample than in the older cohort. This might be construed as a purely generational response (that is, as people get older they are more prepared to provide samples) or possibly illustrates important and potentially challenging changes of culture across what we might call the 'demographics of donation'. But this issue goes beyond the scope of this study. In broad terms these we suggest that these differences probably outweigh differences in concerns between blood, DNA and other sources drawn upon by UK Biobank.

7.9 *Conclusion*

This report has begun to identify some issues which we think will be important to address as possible courses of concern and even difference of view from the existing access and benefit-sharing policies of UK Biobank, which will need to be considered in the medium term as more participants are recruited to provide samples and personal information.

Section 8: Summary, Conclusions and Recommendations

8.1 In light of the analysis above what are the main results and key recommendations that emerge from the study? From the three datasets (survey, focus groups and follow-up interviews) we have derived the following broad conclusions.

8.2 *Public understanding of key terms such as public good and health-related research*
There was a broadly shared view that the nature of public good research was that which serves the needs and interests of all, in principle, even though in practice its application might inevitably focus on those disease areas that are most common yet not contracted by all. However, respondents are aware of the complexities and fluidity of public-private boundaries. This is particularly true where the healthcare sector is seen to benefit from the commercial development of clinical products and services. When *combined* the notion of *health-related research* for *the public good* does evoke a fairly limited and reasonably well-defined set of assumptions among the people we spoke to whose views can be seen as representative of the wider UK population. (see pp 34-5; 40-1)

8.3 *Access policy and the preparedness to allow re-contact*
All three data sets indicate strong support for access by third parties to UK Biobank resources, both biological and lifestyle related. There is also very strong support for the range of restrictions carried within the Access Policy and especially the importance of the role of the EGC in advising UK Biobank on matters such as direct access to biological samples, which almost all thought should be provided only in rare circumstances. The checks in place relating to consent, anonymisation of data and ethical and scientific review were seen as key to retaining trust in UK Biobank as a public good institution.

8.3.1 Only just over a third of respondents agreed that third parties should be allowed to contact individual participants, in the future, if more data is needed about them. This seems quite a low number and could potentially be a concern for UK Biobank since follow-up and re-contacting will be a vital part of realizing the value of the resource for future research. However, we found that those with a chronic condition may be happier with a higher frequency of contact from a third party (via the bank) as their ill-health requires them to engage with the medical system on a regular basis. (see pp 31-2; 41-2)

8.3.2 *Access policy towards non-health related sectors*
All respondents endorsed the restrictions that UK Biobank has placed on research being solely for health-related work, and, in doing so, quite readily distinguish between biomedical and other requests (such as from employer organisations). There would appear to be a recognition that once UK Biobank is fully operational and recruited, a range of organisations would like to have access to the resources, but equally a belief that these should not be permitted to do so. (see pp. 37-8/papra 6.1.1; p. 45)

8.3.2.1 The potential access of the criminal justice system and police forensics was seen to be acutely problematic in terms of the bank's public credibility amongst participants, and current UK Biobank policy to resist such access is extremely important.

8.4 *Benefit-sharing models and the current fee-for access policy*
The majority position that appears in all data sets is that some sort of hybrid fees/profit sharing model would be worth considering. Most regard the fees-for access model to be 'cleanest' but one that would prevent some legitimate profits returning to UK Biobank (see pp 36-9).

8.5 *Concerns over security of information more than anonymity*

Our data suggest that there are more likely to be concerns in the future over guaranteeing the security of information more than matters of anonymity and consent, which are seen to have been properly addressed (see pp. 37; 41; 43).

8.6 *Distinguishing between being a 'participant' and being a 'participant-patient'*

Though the great majority of our different respondents recognised that UK Biobank had no clinical or advisory role for them as individuals (were they to be participants) many comments suggest that for a minority there is a potential for slippage between participants as participants and what we might call prospective 'participant-patients' whereby a clear distinction between being a participant and being a patient becomes blurred. This has important implications for the management of participant expectations *in the future*. (See pp. 26; 28; 32; 43)

8.7 *Age-related differences*

We make a number of observations related to variance across our two main age-groups included in the study. Among these two are worth emphasising: findings indicate perhaps a greater reluctance or ambivalence among the younger age set towards providing blood samples for research purposes, but a willingness to share certain types of personal information. The higher percentage of younger respondents stating that they would be prepared to help with lifestyle research might reflect a greater interest in and willingness to share information about lifestyle amongst younger people as reflected in the recent phenomenon of social networking websites. Secondly, our results indicate that younger respondents value consent more than older ones. This might reflect changes in the cultural dynamics of trust in the medical professions related not only to recent public controversies but also the reported decline of deference to medical authority. (See pp 24-7 and section 7.7).

Section 9: Key recommendations

The themes identified above provide a clear evidence base for the future engagement of UK Biobank with present and prospective participants and broadly confirm that there is a widespread support for the current policies in relation to access and benefit-sharing though with some differing interpretations of the latter in a minority of the population surveyed. Our recommendations are drawn from considerations arising throughout the survey, interview and focus group data, but also from the secondary literature on developments here in the UK and elsewhere.

9. 1 Access policy

- The reputation and legitimacy of UK Biobank is very strongly connected to its healthcare focus and, more especially, to the cultural significance given by the public to potential new treatments and clinical knowledge for health-related research only.
- It is important however to bear in mind that potential participants need strong reassurance that these restrictions will remain in place over the longer term. The information 'slippery slope' has become firmly embedded in the public image of information databases over the last decade. In light of this **we recommend that the EGC's advice in relation to access for health-related research is strengthened in light of and as a response to the perceived risks that the public sees over loss of control of access to information.** UK Biobank would be served by advice relating to public scepticism about such guarantees. The rapid expansion of the UK forensic database – and the gradual lowering of thresholds of its inclusion criteria – is frequently cited as illustrative of ever changing boundaries in the biobanking sector.
- A key element of UK Biobank's current policy is that that third parties cannot approach participants directly, but must go through the bank. We found that a quite low number of just over a third of respondents agreed that third parties should be allowed to contact individual participants via UK Biobank, in the future, if more data is needed about them. Given the need for follow-up, this would be a concern for UK Biobank. There is clearly a range of anxieties related to this that we describe in the full report, but we also note the difference in attitude about this among those with a chronic condition. **We recommend that the EGC should give further consideration to the re-contact issue and provide advice to UK Biobank about managing participants' expectations and potential anxieties over time.** We note that while there is reference made in UK Biobank Ethics and Governance Framework (v.3.0, Oct 2007) there is no explicit reference made to this within the 'Confidentiality' section of the online FAQ.
- With respect to what our respondents understand *is* being accessed, we were particularly struck by the distinction made by them between health-related research and simply health information as such. This distinction, we believe, could be deployed by UK Biobank to discriminate between the *investigative and applied* nature of the work it supports from the merely *informational* for third parties, which it does not. **We recommend that the complementary relationship between investigative and applied research and epidemiological information is worth emphasising in communication with existing and prospective participants in UK Biobank.**
- In regard to access by the police to UK Biobank, the current policy is in broad terms supported but there is some ambivalence expressed about this. Much is

seen to depend on UK Biobank's capacity to handle the ever-increasing growth and cross-referencing people see in relation to other DNA databases, a point we return to below. **We recommend that the current EGC advice to UK Biobank is kept under review as these developments continue apace (including those related to genetic ID systems) in order to retain the public confidence in UK Biobank. UK Biobank could also explore the possibility of using a mechanism such as the 'certificates of confidentiality' that are used by the NIH, in order to address this issue**

- In regard to international access to UK Biobank, there was some concern expressed about this: at present overseas organisations are not treated any differently to domestic ones in terms of the limits placed on their access, and consent provisions make this clear to prospective participants. **We recommend this issue be kept under review as it may need to be addressed in the longer term**

9.2 Security and Data

- Security is likely to be a key decisive consideration for participants and UK Biobank should consider the provision of assurances about the security of data in the light of recent high-profile instances of data loss across all sectors. **We recommend that the measures relating to security are reviewed on a regular basis and made clear in all publicity documentation, and that new approaches should be found to provide such assurances that also take into consideration the damaged reputation of large-scale data systems.** We note that this issue was raised by a minority of respondents in UK Biobank's own Pilot Survey (Nov 2006) where the security of data in the longer term was cited as a reason for non-participation.

9.3 Benefit sharing

- Whilst widely considered to be legitimate, compensatory and solidaristic models of benefit sharing are seen by most of our respondents as being prohibitively complex in their implementation.
- Compensatory or solidaristic arrangements between individual participants and end users of UK Biobank are unlikely to encourage greater participant-participation. **We recommend that the EGC and UK Biobank could strengthen reference to broader population and social benefits especially as the resource becomes fully operational.**
- Some form of fee-for-access arrangement was seen as reasonable by the majority of the respondents within the Focus Groups once the practical implications of sliding scales of profit-sharing arrangements or such-like had been discussed. Such discussions were not possible during the CATI survey. The fees were seen as important source of revenue to offset UK Biobank's running costs or related research. This is unlikely to have any negative impact on the reputational credibility of UK Biobank amongst participant populations. **Our interpretation of the responses we received would lead us to recommend the continuation of the fee-for-access model as one which will be seen by the large majority as both most equitable and practicable, though there was also support for profit-sharing where UK Biobank has made a material contribution to the IP behind new products or processes**. **Where prospective participants ask about this issue, the practicality of the fee-for-access model should be stressed.**

- Respondents in the study were clear that a fee-for-access system needs to be explicitly non-exclusive and that participant-participation is likely to depend on assurances to this effect.

9.4 Emerging Themes from the Study and Literature Review

To conclude this final part of the report we would like to highlight a number of more prospective issues that arise out of both the empirical work undertaken as part of this work and the literature review that we completed.

9.4.1 Emerging diagnostic and healthcare sectors

- It is evident that there is a growing public but especially private market in new diagnostics, many of which may be ineffectively regulated. While this might seem far removed from the immediate concerns of the EGC and UK Biobank, these developments may begin to influence when and why people decide to become participants to the bank. **We recommend that the EGC and UK Biobank take account of a rapidly changing healthcare information environment with the emergence of a growing market in online diagnostics (both genetic, conventional and lifestyle) and how these sectors are likely to impact upon the motives of potential UK Biobank participants.** Will future participants who access these other sources of information seek to redefine the use of their terms of consent from what they learn elsewhere, or not?

9.4.2 Development of common standards and international collaboration

- There is a trend across the biosciences towards greater standardization at the international level. However, it is unclear at this point what the ramifications of this trend might be in terms of *both* access and benefit sharing but **we recommend that the matter of the internationalisation of biobanking is an issue that UK Biobank and the EGC will need to prioritise in order to maximise the scientific returns from UK Biobank resources while still retaining public support**. This is especially relevant given the reservations expressed in the focus groups about making material available to third parties located overseas.
- However, the public good argument, which receives strong support in this study, could be enhanced by linking it to the idea of a *global public good* that could be realized through international collaboration amongst different biobanks.

9.4.3 Release of samples to third parties

- In regard to UK Biobank reviewing its policy on the release of physical biological samples to third parties, public perceptions with regard to what constitutes the public good, may be different than under currently proposed arrangements. **We recommend that the EGC assists UK Biobank in clarifying and publicising the arrangements for the release and processing of physical samples by third parties once the policy is in place.**

9.5 Robustness of existing UK Biobank policy

Overall, we conclude that UK Biobank's current policies with respect to access and benefit sharing resonate well with the public. There are a number of areas identified above however that need further consideration especially in the medium to longer-term as UK Biobank moves towards full operation. Some of the issues that need addressing in

sustaining the bank's continued support relate to developments in the wider society that could destabilise public trust in UK Biobank. This indicates the need for ongoing and strengthened reassurance modified in light of these developments.

9.6 Implications of the report to existing and future participants

Within our sample a relatively small number of our respondents had heard of UK Biobank (i.e. only 35 of 504 in the CATI survey). We did not disaggregate this small group from within the wider population since we could not have derived any significant results from such a small group from any possible clustering of responses we might have found across them. So it is worth considering how the results as a whole might relate to two questions: do they have any implications for *current* participants; and how might the findings provide some pointers with respect to prospective participants?

9.6.1 In regard to the first of these we think that, longer-term, existing participants may begin to raise concerns about re-contact, less to do with the matter of contact by a third party in itself, as this was understood to be mediated by UK Biobank, and more to do with the implications this is seen to have about possible ill-health (or a predisposition towards it) that has been identified by the researchers. Given that participants are not in receipt of any information about their samples, this absence of information could conceivably be the cause of heightened anxiety. This is yet to be seen since the experience of re-contact at this point of time is non-existent. Yet it would be sensible we believe to try to anticipate any such anxieties by considering further how requests to participants will be handled and in particular whether their GP might be informed that a request for recontact is being made, not least to provide reassurance (especially when contacting sub-samples of populations where information about genetic disorders is at greater risk of being revealed). Paradoxically, perhaps, anxiety might be higher among those who do not regard themselves as chronically ill. It will be especially important to stress the population-based as opposed to individual-based nature of the research conducted by third parties to ensure the participant relationship does not take on any clinical component or expectations.

9.6.1.2 Secondly, although participants are signed up for life, it is always possible for them to withdraw (as we noted in Section 2.1.b). What factors, suggested by the findings, might prompt active withdrawal? Anxiety over re-contact is one possibility which may also be linked to a participant claiming a 'right to know' about information held on them especially when they think it might help them to improve their health; another may be occasioned by participants making similar claims collectively if they are members of a patient advocacy group or charity, while a third may be related to perceived risks of loss of control over UK Biobank data through events happening elsewhere, even if no such loss has or could occur.

9.6.1.3 Both of these issues relating to re-contact and withdrawal can be mitigated by UK Biobank's policy of keeping in touch with participants through its website about the results of the work once they begin to come through, stressing their health and public good benefits based, as we noted above (9.1) on a combination of epidemiological and basic research.

9.6.2 In respect to the second question, how far might the report help in improving recruitment of prospective participants, given that while most say they would be prepared to participate in UK Biobank, in practice recruitment is hovering around the 10% mark of those contacted? We do not have any information relating to the profile of

the existing participants in order to determine whether this would indicate there to be a 'typical' participant. Other studies of overseas biobanks have suggested a particular profile of those willing to join: for example, (Kettis-Lindblad' et al, 2006[34] have shown that those most likely to participate were 'middle-aged, had children, had personal experience of genetic disease, were blood donors, had a positive attitude toward genetic research, and had trust in experts/institutions'. One limitation of the study might, therefore, be that the positive response from our respondents would not necessarily translate into practice other than for those with this type of profile, or something close to it. It may well be possible of course to improve the participation rate by translating this type of profile into the core message that is used during recruitment. One of the strongest messages that came across from the study was that engagement with UK Biobank would be driven by a desire to contribute towards the public good; inasmuch as this was often framed in terms of a gift-relationship, the register of 'donor' was as important as that of 'participant' (with its long-term implications). Indeed, the consent provisions (see para 2.1) make reference to participants 'donating' their samples. This is not to suggest that the EGC might consider a new language that combines the two – 'the donor-participant' (interesting though this is) - but to ensure that prospective recruits' familiarity with the notion of donor is used appropriately to foster a participatory engagement.

[34] Kettis-Linbald, A. et al. (2006) Genetic research and donation of tissue samples to biobanks. What do potential sample donors in the Swedish general public think?, The European Journal of Public Health 2006 16(4):433-440

Appendix 1: Literature Review

1.1 Introduction

This review opens with a brief discussion of aspects that relate to the review's main focus: access, benefit sharing and related governance arrangements. These include the complexity and terminological confusion associated with what are variously described as 'biobanks' and the importance of international trends for UK Biobank policy on these issues. This provides the background for the substantive review that follows.

1.1.2 Core Principles with regard to Access to UK Biobank resources

The purpose of UK Biobank is to learn from the collective health experience of the participants over time, in order to generate and disseminate new knowledge to benefit the health of the public in the UK and elsewhere. The core principles with regard to access to UK Biobank resources by third parties can be summarised as follows: UK Biobank is 'a managed research resource for the public good, with access managed to the extent necessary to do the following: protect participants, ensure compliance with consents, data protection etc., prioritise access where availability is limited, and manage intellectual property rights.' Subject to these constraints, access that furthers UK Biobank's stated purpose 'will be encouraged as widely and openly as possible' (UK Biobank 2005).

1.2 What type of data is being accessed?

It is important to understand what type of data is being made available. Researchers will have access, subject to controls, to the following types of data: data (in anonymised form) relating to participants' health, lifestyle and environment; data derived from analyses of samples; data and materials from investigations conducted using the resource; biological samples – but these will not generally be physically released and will always under UK Biobank's legal control. Participant identifying information will not be released by UK Biobank unless further consent is obtained (ibid).

Knoppers et al (2007) and Gibbons and Kaye (2007) and several others have highlighted the transition from genetic to genomic research, and the explosion in informatics and high-throughput sequencing technologies that have expanded the tools available to scientists. This next phase of research is likely to involve the study of 'normal' genomic variation across whole populations and complex gene-lifestyle-environment interactions, and UK Biobank will provide a suitable resource for such studies. But such studies will require highly sophisticated database infrastructures, shifting the emphasis from (merely) questions about access to 'samples and data' located in relatively small, often localised, repositories to issues of collaboration and benefit sharing, often across borders as calls to 'internationalise' biobanks gather pace. As Gibbons and Kaye comment:

'Population genetic databases are intended to be accessed and used over the course of several decades by any number of different researchers, potentially located anywhere around the globe, whether based in the public, charitable or commercial sectors, and who may engage in as yet unknown and entirely unforeseeable kinds of research' (Gibbons and Kaye 2007, p202).

Multiple, integrated 'virtual' datasets will be interrogated across national boundaries, particularly for genome-wide association studies (Majumder 2005), and a major player in developing international collaboration between national biobanks is the Public Population Project in Genomics (P3G) – a non-for-profit international consortium to

promote collaboration between researchers in the field of population genomics. P3G has been launched 'in order to provide the international population genomics community with the resources, tools and know-how to facilitate data management for improved methods of knowledge transfer and sharing. Its main objective consists in the creation of an open, public and accessible knowledge database. The motto is transparency and collaboration' (http://www.p3gconsortium.org/ accessed 22/02/08).

According to Knoppers *et al*, 'a review of existing norms at the international level—in particular, around benefit sharing and access to data—and their application in different countries, reveals areas of both convergence and divergence. But, most of all, it reveals the need for international harmonisation in order to secure interoperability and the public participation, trust and investment in such large initiatives that are crucial to their success' (Knoppers et al 2007). The development of common standards and international collaboration is a trend noted across the biosciences. However, it is unclear at this point what the ramifications of this trend might be in terms of both access and benefit sharing but it is an issue that UK Biobank and the EGC will need to prioritise in order to maximise the scientific returns from UK Biobank resources.

1.3 Definition of a biobank

The definition of what constitutes a biobank is very wide and a number of definitions are in use. The precise nature of a biobank affects access and benefit sharing policies and wider governance issues as well. Among the terms used besides 'biobank' are: genetic database, DNA bank, genetic databank, population databases or population collection, tissue bank, and tissue repository and increasingly 'genome-wide association databases' (Lewis 2004; Gibbons and Kaye 2007). Importantly, biobanks also have a twofold character comprising both samples and data – what Parry has referred to as 'corporeal' and 'informational' characteristics (Parry 2004). This 'two-fold' character may affect public perceptions about privacy and data security and hence influence public attitudes to access arrangements.

Overall, there are many thousands of tissue repositories in the world, from large formal biobanks like UK Biobank to small informal storage of blood or tissue specimens (Eiseman and Haga 1999; Eiseman et al. 2003) Knoppers et al (2007) and others (see e.g. Gibbons and Kaye 2007) have underlined the need for clarification of the terminology used to describe different types of biobanks on the grounds that agreement on what is being referred to is a necessary condition for rational discussion of appropriate arrangements for issues such as access and benefit sharing (Knoppers et al 2007).

Adoption of a particular definition has implications for policy including third party access. The House of Lords Science and Technology Committee Report (2001) on 'human genetic databases' defined them as 'collections of genetic sequence information, or human tissue, that are, or could be, linked to named individuals', which is a very narrow definition (House of Lords 2001). Others argue that genetic databases specifically involve the integration of genetic data with medical and perhaps other information (such as 'lifestyle' information), and that it is this integration that makes them different from other collections which may comprise tissue only for example, or exist as repositories for treatment or monitoring rather than for research purposes (Martin 2001; Lewis 2004). The linking of health data with bio-specimens or conversely, the linking of bio-specimens with other information provides the most robust definition of a biobank (UK Biobank EGC 2007).

The significance of definition for access arrangements is that a biobank's contents (samples only; samples plus data; data only) decides what resources third parties can access and hence, how access arrangements may be viewed by the public – and indeed the level of demand for access because the type of accessible information will determine scientific value. For example, in the case of UK Biobank, analysis of samples is to be conducted 'in-house' and samples themselves will not be distributed to third parties. If samples were to be handed over to third parties, public perceptions with regard to what constitutes the public good may be different than under currently proposed arrangements. However, what constitutes 'in-house' may require qualification if experiments and data generation are conducted by external parties such as contract research organisations on behalf of UK Biobank because they could themselves be viewed as third parties.

Finally, many definitions in the literature have tended to define biobanks by ownership or location (whether public or private; and for 'internal' use or available to third parties). But biobanks can also be defined by access arrangements and the extent to which constraints are placed on use and, perhaps most important, identifiable links to participants (Wylie and Mineau 2003).

1.3.1 Different protections for different types of data?

The accessible data and materials can be classified according to three types, each with different degrees of protection necessary: so-called Protected Material (e.g. anonymised data relating to individuals; samples); Open Data (e.g. research results already in the public domain); Proprietary Material (e.g. proprietary tests protected as a trade secret). Within these categories, Protected Material is considered the most significant for both researchers and participants (UK Biobank 2005).

1.4 Recent legislation and potential impact on UK Biobank access arrangements

New legislation relating to human organs, tissues, and bodies has been introduced in the UK, largely as an outcome of the 'retained organs' scandal at Bristol and Alder Hey (although similar retention practices were widespread at the time) (Bristol Enquiry 2001; Royal Liverpool Enquiry 2001). The new laws, the Human Tissue Act 2004 and the Human Tissue Act Scotland 2006, apply to a wide range of activities including the use of human tissue in research. Although the original problems arose largely from pathology practices, the new legislation applies to research activities involving human derived samples such as UK Biobank samples, except in Scotland where the powers are somewhat different (Human Tissue Act 2004; Human Tissue (Scotland) Act 2006; Clark 2007).

1.5 The Human Tissue Acts

The Human Tissue Act (2004), which came into effect in September 2006, provides a legislative framework for England, Wales and Northern Ireland within which those who handle human tissues have to operate. The Human Tissue Authority (HTA) established under the Act oversees implementation of the legislation and requires all organisations holding or banking tissues for research purposes to register each collection or tissue bank with them. The HTA began licensing under the EU Tissues and Cells Directives in April 2006 and the Directives came fully into force in July 2007. According to Clarke, the introduction of these measures 'were intended to redress the balance from a doctor - or researcher-centric culture, to one in which the rights and autonomy of the patients were central' (Clarke 2007, p219).

In the case of UK Biobank, its responsibilities do not extend beyond obtaining consent and the relevant licence as a Research Tissue Bank (RTB) from the HTA.[35] Repositories such as UK Biobank apply to the HTA for Research Tissue Bank status, which means they do not require approval from a Research Ethics Committee (REC) so long as their research fits the purpose of a RTB (which UK Biobank research does). The Act itself does not apply to extracted genetic material, as generally speaking, it only applies to material that consists of or includes human cells (s. 53(1) of the Human Tissue Act 2004). The Act therefore does not apply to genetic material once it has been extracted from tissue samples. The Act and the Human Tissue Authority regulates the DNA extraction process itself, if it is undertaken for a scheduled purpose (such as research). However, subsequent storage and use of extracted DNA are not covered. In the case of UK Biobank, it may be the only physical matter that is held in long-term storage. If UK Biobank had made any tissue collections before the Act came into force in 1 September 2006, these also would not be covered by the Act.

We understand that according to current policy UK Biobank may expect to distribute tissue samples to external researchers. If consent has been given to use the tissue for research, as is the case with UK Biobank, there is no legal requirement to obtain ethical approval for research carried out on licensed premises. Also, given that UK Biobanks holds a Research Tissue Licence it has no legal obligation to seek ethical review for research. However, under the Act if a bank plans to distribute tissue to external researchers, it can apply to a REC for "generic ethical approval" for these research programmes. This would confer ethical approval for projects receiving tissue from the bank within the conditions agreed by the REC (for example, tissue is supplied in anonymised form and projects have received appropriate scientific critique). The National Research Ethics Service (NRES) has published model approval conditions for tissue banks, although RECs have the discretion to vary these conditions in discussion with applicants (NPSA/NRES n/d). However, whether such exemptions apply in the case where samples are physically, but not legally, transferred to other parties such as to contract research organisations in order to undertake DNA analysis for example, is unclear.

The Act applying to Scotland was developed with the same intentions as the Human Tissue Act 2004, but does so through a more restricted scope and a less complicated and pragmatic piece of legislation. According to Clarke, the key differences are: (1) the positive act of giving by participants is referred to as 'authorisation' rather than consent (but should be considered as equivalent); (2) the Act only regulates samples derived from deceased participants, and (3) there is no regulatory body with statutory powers equivalent to the Human Tissue Authority in relation to research and tissue banking,' although the Scotland Act does cover activities involving a person's DNA (Clarke 2007). We therefore interpret the Scotland Act as imposing no additional requirements on UK Biobank.

As Clarke notes, and in line with other studies, many of those offended by tissue and organ retention did not fundamentally object to the use of organs or tissues in research and would have been happy to allow the retention of tissues from themselves or their deceased relatives if only they had been asked beforehand. Other work suggests this

[35] In the case of UK Biobank, the HTA licence covers 'establishments storing human organs, tissues and cells for research purposes other than for a specific ethically approved research project.

approach to the act of donation applies equally to other types of donation such as to UK Biobank [36] (Dyer 2000; Clarke 2007)

Discussion of consent procedures is outside the remit of this report. However the EGC and UK Biobank have both recognised that the establishment and maintenance of appropriate consent procedures is crucial to building long term public trust. The latter is a critical element in public acceptance of third party access. UK Biobank will therefore need to ensure that access arrangements, including consent procedures, are transparent, credible and robust. The connection between consent and access has been emphasised by the Human Genetics Commission (HGC) in a 2003 report which suggested that consent 'needs to be based on the explanation and understanding of the access and financial arrangements' for UK Biobank.

Specifically, these would include arrangements for the participation of industry, particularly the point that although commercial entities may apply, no one will get exclusive access to data. Also that research will always be confined to work on data and UK Biobank will not pass on DNA; and benefit sharing (by means of making information publicly available and charging licence fees at appropriate levels for those who may make financial gain) will be adopted. However, this statement does not help define what these 'appropriate levels' might be. The Commission also believed that the potential for police access, while referred to under II B Research Access to Data and Samples, needs to be clearly spelt out from the outset, as UK Biobank has subsequently done (Human Genetics Commission 2003).

This question of access to data raises other issues for the EGC and UK Biobank related to the Data Protection Act 1998. This Act (which is UK wide) does not cover all the activities and aspects of research in a biobanks. The Act applies to all identifiable data that relates to a living individual. Over time, UK Biobank will increasingly hold the personal data of the deceased people, yet once individuals have died, this data will no longer be covered by the Data Protection Act (DPA). In many biobanks, records will be stripped of personal identifiers when passed to third parties for research purposes, which also takes much research activity outside of the provisions of the Act. Under the DPA, if the third party researcher could not identify an individual from the data, then the secondary research would be considered outside of the Act (even though there would still be a need to fulfill the research ethics committee requirements). This is in contrast to the provisions of Directive 95/46/EC, (from which the DPA in the UK is derived), which suggest that if *anyone* could relink the data and identifiers, then the data could not be considered anonymous. As national legislation should implement the provisions of the Directive, this potentially could be problematic for biobanks in the UK. (Beyleveld,2007). Moreover, '[b]oth the DPA and the HTA enshrine consent as the foundational element that legitimizes and legalizes regulated activities. However, both also allow for numerous exceptions to consent; not least, for research purposes. Where the HTA and DPA overlap – for example, in relation to consent or the effect of anonymization - they impose varying standards, procedures, and requirements.' (Gibbons *et. al*, 2007).

In regard to consent as such, the basic principle within the DPA is that 'explicit' consent must be obtained for the processing of sensitive data, but the specific requirements for this are also not laid out in the legislation. Under the Act there are a number of exceptions to the requirement for consent. The most significant one for biobanks is laid

[36] The new legislation makes *consent* (or *'authorisation'*) a central element prior to the retention of human materials and it is a criminal offence to analyse DNA for research purposes without consent.

out in the National Health Service Act 2006 ss. 251- 2, which allows PIAG to give approval for the use of identifiable information without consent.

1.6 Other key governance documents

A key document relevant to UK Biobank governance and access arrangements is the report released by the Medical Research Council (MRC) and the Wellcome Trust in March 2006, entitled Access to Collections of Data and Materials for Health Research, which reviews '…various issues surrounding research access to population-based collections of data and materials in the UK.' The report was commissioned to provide information on the extent to which current access arrangements for a number of UK collections including UK Biobank were standardised; whether there was scope for greater standardisation; the possibility of a model governance structure; and if there was scope to develop guidelines in this area. The collections examined included UK Biobank, the Southampton Women's Survey and Generation Scotland, as well as many more (Lowrance 2006).

The Lowrance report found that current access arrangements for the different repositories were not standardised but did have much in common, and concluded that there is scope for greater standardisation, such as for example in standardising core terms of access and material transfer agreements. This suggests that careful consideration of other arrangements might be useful since a model governance structure might be built using a range of existing models as exemplars or templates.

The report also highlights the need for 'clarification and revised guidance … on aspects of consent, confidentiality and anonymisation,' and proposes that other guidance is also needed. With respect to this study, it may be that these recommendations have been considered and implemented as considered necessary. However, since no further information is publicly available via online sources with regard to actual arrangements for either the Southampton or Generation Scotland projects, a full discussion of the governance possibilities raised by the Lowrance report and their suitability in the context of UK Biobank would require further research.

The report also advances several arguments on why increased access to UK Biobanks and other collections would be valuable. These can be summarised as follows: input from other researchers could add informational value to collections, increasing the return on investment and increasing the possible health benefits. Access can also promote scientific openness, enabling replication of studies while reducing duplication of effort. The need for new samples may be minimised as existing ones can be better exploited. And as collections are used, their 'richness' increases as they are analysed in new and different ways.

However, the report argues that if access is to be increased, the following must be done: the original promises made to participants must be kept; the public and scientific integrity of the project must not be jeopardised; the interests of the developers and custodians of the resource must be protected and their hard work and goodwill rewarded; developers and custodians must be fairly compensated for costs incurred in providing access; and intellectual property must be managed judiciously (Lowrance 2006; PGHF 2006).

1.7 Previous studies on public trust and UK Biobank

The Wellcome Trust (WT) and the MRC commissioned People Science & Policy Ltd to conduct a public consultation about the ethical and management issues surrounding 'the

proposed BioBank UK project'. Three sessions were held in 2002 in Hertfordshire, the West Midlands and Glasgow. Each session involved around 20 people aged 45-69.[37] The results of this consultation were structured around the main issues identified by participants including: recruitment; access to the data, the samples and confidentiality; uses to which the data will be put; governance; value for money. The report recognised that addressing these 'will be critical for the success' of UK Biobank (PSP Report 2002).

The 2002 report examined access and confidentiality with reference to access by both non-commercial and commercial bodies; participants and their families; GPs; the police; insurance companies and employers; as well as illegal access. These are all areas referred to in the present study and the earlier study's findings may be valuable for comparison purposes.

The 2002 work found that:

- Complete confidentiality at the individual level is important to potential volunteers.
- The need to re-link data with names in order to up-date data was understood.
- There was little discussion about the role of academic researchers. However, there was a general assumption, despite some explanations to the contrary, that most of the research would be conducted by UK Biobank staff.
- The idea of access by commercial organisations raised concerns. After some thought however, most participants realised that this is the only way medicines will be developed. Nevertheless, there remained concern that companies should address major healthcare issues and not just focus on 'profitable diseases'.
- Some participants were looking for ways in which they would benefit from taking part in the study. Access to personal health information that they might not otherwise have was the most obvious direct benefit. Some were also keen that their descendants should have access to the samples in case it could help with future family diseases that are found to be genetic.
- Many did not want their GPs to have access to the lifestyle data and everyone was clear that employers and insurance companies should not have access to individual data. However, many realised that the general findings will be published and therefore accessible to anyone and that this might indirectly affect insurance premiums.
- There was some ambivalence about whether the police should have access to the information. Where groups explored this in more detail they seemed content that if a court order was obtained access would be granted.
- The report notes that 'the generally pragmatic attitudes to illegal access were summed up by the quote: "You don't have to wait for [UK Biobank] to exist for people to hack into data about you"' (PSP Report 2002, p3)

On governance matters, participants generally recommended that some form of oversight body should be established and that the body should be capable of acting independently of the users and sponsors. Of the two main models that emerged ('traditional' stakeholder representation model and lay-based panel with no direct interest in UK Biobank), the latter being the one broadly adopted subsequently in the form of the

[37] Participants were split into two groups of 10 for an introductory session of 1.5 hours on a weekday evening, and reconvened the following Saturday for a four hour interactive workshop session with PSP moderators and two members of the project team, one from the Wellcome Trust, the other from the MRC.

EGC (although participants in the 2002 study perhaps wished for EGC powers to extend beyond being advisory) (PSP Report 2002).

1.8 International dimensions to access arrangements

Whilst access arrangements are often viewed from a national perspective, the arrangements adopted for UK Biobank are likely to have significant regional and international implications because of the trend towards building international networks of biobanks (see e.g. EU Workshop in 2003) (EU 2003). Many other commentators have noted this trend and highlighted its importance with regard to arrangements adopted by UK Biobank (see e.g. Gibbons and Kaye 2007)

In terms of trends and governance perspectives, four types of biobank can be distinguished in the literature:
- clinical case/control biobanks based on biological specimens from patients with specific diseases and non-diseased controls (with pathology archives typical of this type);
- longitudinal population-based biobanks that contain biological samples from (parts of) the general population with or without disease (e.g. UK Biobank and the Estonian Biobank Project). Subjects followed over a long period of time are expected to develop different diseases with a certain frequency and these are related to environmental factors.
- the third type are 'population isolate biobanks', characterized by the homogenous genetic and environmental features of the population represented (e.g. Icelandic Biobank).
- finally, twin registries, such as GenomEUtwin, which contains samples from monozygotic and dizygotic twins and is therefore particularly suited to distinguish between the genetic and non-genetic basis of diseases (Gottweis and Zatloukal 2007).

These different types of biobank are complementary in the sense that the longitudinal population-based cohorts depend on end-points from clinical case (disease-oriented) biobanks, both for precise delineation of phenotypes and for molecular characterization, while the latter require control subjects and biological material from longitudinal cohorts which the former can supply. Recognition of the complementary nature of different types has resulted in the establishment of international networks of bio(tissue)banks being given a high strategic priority (see e.g. Gottweis and Zatloukal 2007; Hagen and Carlstedt-Duke (2004); Boucher 2004; Kaiser 2002)

However, as Clarke (2007) has pointed out in relation to pathobiology repositories, even if similar governance structures can be agreed across jurisdictional boundaries, any local differences that remain could make effective cross-border collaboration difficult in practice (Clarke 2007, p22. See also: Brand and Probst-Hensch 2007; Riegman, Dinjens and Oosterhuis 2007).

Whilst focusing on repositories containing diseased tissue, Riegman et al (2007) raise a number of important issues that may apply in the case of UK Biobank. The authors note that it takes a long time to build up a collection and failure to reach sufficient size may significantly degrade the value of the collection. Collections also need long-term dedication to goals and proper funding. In many cases benefits from tissue banks can be improved by starting work on experimental design within a multidisciplinary team, although it is unclear how such a model might operate within the context of UK Biobank since it operates as a resource that encourages research that is conducted by third parties rather than 'in-house'.

1.9 Examples of public-private collaboration in tissue banks

Womack and Gray were responsible for establishing (one of) the first human tissue banks in a NHS hospital in 1996 (Peterborough NHS Trust), based on established links with local contract research organisations. The repository was aimed at supplying the needs of the pharmaceutical industry for well-documented samples and at the same time generating an income stream to maintain 'in-house' pathology services. Ten years later both authors moved to the pharmaceutical industry, establishing a supply of human tissue and cellular pathology services for cancer research and drug development at AstraZeneca (Womack and Gray 2007; Gray, Womack and Jack, 1999).

Womack and Gray maintain a 'persistent and underlying principle that there is no monetary value attached to human tissue samples', which is in line with current European recommendations and generally accepted internationally (Council of Europe 1997). The authors argue that: 'When using human tissue samples, ethical considerations must affect business decisions irrespective of whether funded in the public or private sector' (Womack 2002).

2. Consent and confidentiality – what does the public think?

Public perceptions of the benefits or otherwise of allowing personal data to be used in health research are important because they are likely to impact on public views towards third party access. Both the MRC and Wellcome Trust (WT) have called on researchers, funders and medical charities to do more to convince the public of the benefits to society of allowing personal health information to be used in important medical research.

The MRC commissioned a survey to look at public attitudes to and awareness of the use of personal health information in medical research. A separate study by the University of Surrey for the Wellcome Trust looked more broadly at the public's attitudes towards the governance of medical research. Their findings have shown that public support for research is strong, but more needs to be done to understand people's concerns in areas such as consent and confidentiality.

People taking part in the WT study indicated 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. But the report found 'this confidence could be undermined by the involvement of particular actors: GP receptionists, insurance companies, and other non-health or non-research agencies' (Hansson, 2007).

2.1 Public attitudes to participation and its relation to access arrangements

A study conducted by the Sheffield Health Economics Group in 2004 on public preferences for design and use in context of appropriate design for optimum recruitment using a discrete choice methodology experiment. The study sampled the public at 180 points across the UK. The research found the some 34% were willing to take part in UK Biobank, with the most preferred scenario including access to the data by the NHS and Universities but not other third parties. The single most important attribute was access to data. If individual's insurance companies were to be given access to the data this would be the largest single impediment to recruitment to the study. Extra resources are likely to be needed to counter the reduced recruitment rate if pharmaceutical companies are allowed access to the data.

The conclusion was that the general public do have clear preferences regarding the design of biobanks. Whilst designing the study to meet the most preferred scenario may not be practical within available resources, biobanks can use the type of information

provided here to compare the costs and benefits of different study designs. The 'price' of discounting public preferences in terms of reduced recruitment should be an important part of the 'weighing' process. Pilot studies of recruitment under alternative study designs may be justified (Hapgood, McCabe and Shickle, 2004).

The politics of legitimation with regard to UK Biobank has been examined by Salter and Jones, who highlight the recognition by its founders of the importance of public trust in ensuring its success. Legitimacy can be defined as 'the capacity of the system to engender and maintain the belief that the existing political institutions are the most appropriate ones for the society'. If this belief is not present, or if it exists in only tenuous form, a government's ability to formulate and implement policy will be inhibited by its citizens' lack of trust in its institutional processes and outcomes. Citizens may decide not to cooperate, to cooperate partially, or actively to oppose a particular policy initiative. The maintenance of the legitimacy of the relevant institutions is therefore a sine qua non of any new policy development and has an acute significance in initiatives such as UK Biobank which are heavily dependent on the active cooperation of citizens. Access arrangements will of course be an important component of this trust.

Civil society opposition to the creation of such databases is often couched in concerns about the allegedly unique nature of genetic information and the resulting implications for privacy, surveillance, discrimination, and commercialisation. The extent to which a governance framework can effectively protect such powerful information from abuses directly impacts on public trust in this regulatory field. At the same time one should not forget that whatever form of regulation is adopted also has to be seen as legitimate by science and industry.

To take one dramatic example, the collapse of the Swedish biobank company UmanGenomics despite its much vaunted ethical foundations was due to a failure to work through both the requirements of the scientists involved and the intellectual property requirements (IPR) of a successful market venture in this field (Rose, 2003). Where industry is content with a regulatory framework that facilitates its economic interests, civil society may feel that certain citizenship rights have been compromised in the interests of commercialisation. Alternatively, civil society stakeholders may be content with ethical arrangements that industry may regard as a constraint on its activities. Thus, and as UK Biobank has clearly recognised, scientific advance in genetics is dependent on the construction of novel forms of regulatory legitimacies (Salter and Jones 2005).

2.2 International dimensions of access and benefit sharing

Kaye et al (2004) have compared the way in which the law in the UK, Estonia and Sweden deals with the issues of ownership, consent, feedback, genetic counselling, benefit sharing and access to the database in each jurisdiction through specialist legislation and how these issues challenge existing legal precedents. The conclusion they reach is that these issues are not currently addressed in a coherent manner and that there is some way to go before achieving a uniform legal structure for population genetic databases across Europe (Kaye et al 2004).

The issue of benefit sharing in genetic research has been an issue of debate since UNESCO adopted the Universal Declaration of Human Genome and Human Rights in 1997. The concept of benefit sharing encapsulates the sharing of the benefits of the

research at a community level (Kaye et al 2004).[38] The concept of benefit sharing, particularly in the international context, has developed significantly over recent years from a focus on simply proposing exact numbers for distribution of profits to more sophisticated recommendations, ending with the Article 19 of the Draft International Declaration on Human Genetic Data which requires that there should be: special assistance to the persons and groups that have taken part in the research; access to medical care; provision of facilities for new treatments or drugs stemming from the research; support for health services; capacity-building facilities for research purposes; development and strengthening of the capacity of developing countries to collect and process human genetic data, taking into consideration their specific problems; and finally, any other form consistent with the principles set out in the declaration.

From a legal perspective there is little mention of actual benefit sharing arrangements in national legislation relating to existing biobanks such as those in Iceland, Sweden and Estonia, and similarly no provision in UK law though this has been discussed in relation to UK Biobank (Kaye et al 2004 p27). Thus, all these states would have to take steps to introduce benefit sharing principles into domestic law. However, agreements have been entered into between public or at least publicly controlled authorities in each of the Nordic examples, to provide for a set of payments (although some of these arrangements may have been adjusted to account for changes in the respective national biobanks).

An earlier article by Knoppers (2000) examined international or national guidelines specific to human genetics and found that they concentrate on actual or potential clinical applications. In contrast, the Ethics Committee of the Human Genome Organisation (HUGO) has attempted to provide guidance to bench scientists engaged in fundamental research in genomics prior to any clinical applications, and hence may provide guidance with regard to UK Biobank.

HUGO's ultimate goal is to assist in the worldwide collaboration underpinning the Human Genome Project. It is an international organisation with 1,229 members in approximately 60 countries, and presented a 'Statement on Benefit-Sharing', in April 2000, which examines the issues of defining community, common heritage, distributive justice and solidarity before arriving at its conclusions in benefit-sharing. The question according to Knoppers (2000) is: how to avoid both commodification of the person through payment for access to DNA and biopiracy with no return of benefits to the families or community?' (Knoppers, 2000, p.212).

The HUGO Ethics Committee's 1996 Statement on the 'Principled Conduct of Genetic Research' recommended that: 'inducement through compensation for individual participants, families, and populations should be prohibited. This prohibition, however, does not include agreements with individuals, families, groups, communities or populations that foresee technology transfer, local training, joint ventures, provision of health care or of information infrastructures, reimbursement of costs, or, the possible use of a percentage of any royalties for humanitarian purposes' (HUGO 1996).

Similarly, the 1997 UNESCO Universal Declaration on the Human Genome and Human Rights proclaims in article 12a that: 'Benefits from advances in biology, genetics and

[38] Reimbursements made to participants to cover direct expenses and income forgone are not viewed as benefit sharing but usually dealt with within the context of prohibiting financial gain from participation in biomedical research (Kaye et al 2004).

medicine, concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual' (UNESCO 1997).

In the section on solidarity and international co-operation, scientific co-operation is encouraged (article 10) as well as the free exchange of scientific knowledge and information in the areas of biology, genetics and medicine (article 19iv) (UNESCO 1997).

According to the 11 April 2000, HUGO Statement on Benefit Sharing (HUGO 2000), there are three fundamental arguments in favour of benefit sharing:

'First we share 99.9% of our genetic makeup with all other humans. In the interest of human solidarity, we owe each other a share in common goods, such as health. Second, starting with Hugo Grotius's law of the sea in the 17th century and proceeding to international law governing air and space in the 20th century, such global resources have been viewed as common: equitably and peacefully available to all humanity, and protected in the interests of future generations. International law may therefore set a precedent for regarding the human genome as a common heritage. Third, when there is vast difference in power between an organisation carrying out research and the people providing material for that research, and when the organisation stands to make a substantial profit (albeit taking a risk of investment), concerns about exploitation arise that benefit sharing can address. Considerations of justice require action to meet basic health care needs'.

As Knoppers (2000) notes, based then on the recognition that: the human genome is part of the common heritage of humanity; that there is a diversity of communities (and of concepts of community); that precedents for benefit-sharing can be found in the areas of food and agriculture and finally, that genetic research should foster health for all human beings, the HUGO Ethics Committee maintained that we need to recognise participation in genetic research. Furthermore, the HUGO Ethics Committee stressed the importance of prior discussion and consultation with communities and populations, that benefits not be limited to those who participated, that some form of appreciation and information regarding research outcomes, that even in the absence of profits, community needs be met and finally, that 'profit-making entities dedicate a percentage (e.g. 1–3%) of their annual net profit to healthcare infrastructure and/or humanitarian efforts'. Even prior to this Statement certain efforts were under way in the area of population genetics, efforts that recognised the equitable nature of benefit-sharing, such as the Iceland case where products emerging from the Icelandic biobank would be provided free of charge to the Icelandic people (although as noted previously, the Iceland situation has changed drastically since these HUGO Statements).

2.3 International dimensions of third party access

The issue of third party access can be conveniently examined in terms of family access, scientific/commercial access, police and forensic access, and access by organisations such as insurance companies. The study by Kaye et al (2004) of legal arrangements for the Nordic and UK biobanks found that the dominant principle underpinning legal frameworks is that of individual rights, particularly in the UK and Sweden where all regulation targets individuals and the only rights attributable to family members are derived from the original individual participant (as providers for proxy consent for example). As Kaye et al (2004) note:

'There have been no measures introduced to recognise that genetic information also has implications for other family members. This is despite the fact that information within the population genetic database will contain DNA samples, family histories and genealogies that place the individual within a network of relationships. It is only in Estonia and Iceland where these issues have been specifically addressed.'

In the latter two cases, the views of relatives can be solicited, if the use of biological samples is deemed to '*impact important interests*' of the relatives' (Iceland). Whilst Estonia recognises the familial nature of genetic information, it provides a way to protect individual interests at the same time. Thus the authors note that:

'The Estonian population genetic database contains the names, dates of birth and blood relationships of the ascendants and descendants of a gene participant. These genealogies may only be used within the genetic database for organising biological samples, descriptions of DNA and descriptions of state of health on the basis of blood relationships. Family members have no right to access this information or any other information about the gene participant. Gene participant's rights cannot be transferred either.

When we turn to the scientific community, the foundation of legislation is that scientific research is a public good and to be encouraged, which is, of course, a 'core principle' of UK Biobank. In both Nordic countries and the UK, benefits are also viewed in terms of employment generation, stimulating the economy and providing a centralised health record system, although the latter is not emphasised in the UK case, perhaps because other legislation is establishing such a system.

With regard to police access to UK Biobank, international comparisons show that the Nordic examples practice a clear legal distinction between criminal and clinical genetic databases, a practice that UK Biobank has adopted (although police have gained access to research samples via a search warrant in Sweden, New Zealand and in Scotland) (Kaye et al 2004, p29;Kaye, 2005, 2006). The question of police access to samples and other information held by UK Biobank has also concerned the HGC (HGC 2002)

With regard to access by employers and insurance companies, the UK has not implemented the safeguards regarding genetic information in the European Convention on Human Rights and Biomedicine. But the issue is under investigation in the UK, with the voluntary moratorium agreed by insurers that ended in Nov. 2006 extended for another five years until 2011.

As of 2004, employers' possibilities to ask for or use genetic information existed in a grey zone. As Kaye et al (2004) note, the question is whether the interest the employer wants to protect is proportionate to the violation of the integrity of the employees or not. In the UK, the Human Genetics Commission has found no evidence that employers so far are using genetic data for recruitment or occupational health purposes. However, there have been calls to consider whether current law should be extended to include genetic discrimination, as a safeguard against future misuse and possible discrimination. However, interest may of course grow as the usefulness of such material increases.

2.4 Models for benefit sharing and data sharing

Winickoff has made a series of important contributions with regard to property in context of biobanks, most notably his examination of the possible benefits from

adoption of a charitable trust model for biobanks (Winickoff and Winickoff 2004; Winickoff 2007). Winickoff makes the following points: biobanks server to unsettle relations between genes, tissues, medical records and persons (both individual and collective). But also these relations are increasingly being restructured by new rights of control, access and 'property' both material and intellectual. And bioethics scholarship on governance has comparatively ignored property over issues such as informed consent and privacy. In other words, the literature has focused on individuals and not collectivities. Possible benefits to society as a whole, and how to protect collective interests as well as those of individuals have been ignored relatively. These interests may not of course be the same and in fact may be in contention, such as when it comes to benefit sharing issues. The key issue emerging according to Winickoff is: "how can societies incentivise private capital to construct the mega-experimental apparatus of genomic databanks in order to help drive knowledge and economy forward, even as they remain deeply concerned about the penetration of markets into the personal domains of genome and body, health, and personhood (Winickoff 2007, p440).

Winickoff and Winickoff (2004) propose new legal-institutional vision for negotiating a middle path for genomic resources between commodification and inalienability: the "Charitable Trust Model". This model is critiqued by Boggio; and Winickoff and Neumann (2006) have responded to this critique. There are a number of other attempts to articulate a potential 'third way' for treating ownership of personal information, data, tissue, DNA and IP in biobanking, and many calls for some form of profit sharing and benefit sharing with research participants – whether by contract, regulation, taxation, to ethical standards, to remedy problems of distributive justice. But Winickoff argues these are merely suggestive until real attempts to negotiate such as 'third way' – which he believes may be emerging in the case of UK Biobank on the grounds that is has forged a 'form of "partnership" between funders, biobank participants, and future users – a system of shared property rights' (Winickoff 2007, p441). This has been a process of leaning from the Iceland experience and the political and ethical critiques that emerged from that project, of which the key policies were granting a single commercial licensee the right to build the Health Sector Database and adopting the 'presumed consent' clause. This re-opened old debates about the commodification of biomedical research.

Reporting the results from a project on 'Human Genetic Databases: Towards a Global Ethical Framework' (http://www.ruiggian.org/research/projects /project.php?ID=17), Boggio (2008) focuses on three areas in addressing the commercialisation debate, which he conceptualises as the difficulty of reconciling general objection amongst ethicists to payment to participants for samples whilst researchers are encouraged to commercialise their research in order to develop new treatments and techniques. These are: the obligation to put data in the public arena; the issue of patenting rights and publicly funded research; and the admissibility of fees imposed on researchers using a repository (Boggio 2008, p2).

Foster and Sharp (2007) also examine how the scientific and social benefits of genomic data should be shared. The US National Institutes for Health (NIH) and the Wellcome Trust are formulating policies for sharing large amounts of genomic data generated by projects they have sponsored (see below). A policy of rapid access to sequence data was agreed at a meeting convened by WT and NIH in 2003 with the specific purpose of establishing a consensus about 'community resource' projects (which UK Biobank is now described as) that provide shared infrastructure data for the global data community - i.e.

rapid release of data into community. The aim of this policy is to equalise access between those who are funded to generate data and other researchers who require access. Data sharing policies can impact on how disease susceptibility and drug-response research (i.e. pharmacogenomics) will be pursued by the scientific community and who will benefit from the resulting medical discoveries. They suggest that a complex interplay of stakeholders and their interests, rather than single issue and single-stakeholder perspectives, should be considered when deciding genomic data sharing policies.

The NIH is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease. For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition (DHSS/NIH 2007). As noted above, whole genome information, when combined with clinical and other phenotype data, offers the potential for increased understanding of basic biological processes affecting human health, improvement in the prediction of disease and patient care and UK Biobank will increasingly be used for such research.

One of the key questions is how long should third parties have sole access. Foster and Sharp (2007) suggest that data sharing policies should be developed in a manner that reflects the full range of stakeholders and the multiple ways in which their varying interests intersect. In other words, this is an approach that does not focus on single-issue and single stakeholder perspectives, such that a more balanced and contextualised evaluation of data sharing takes place. The conventional focus on individuals tends to encourage a privileging of the issues of informed consent and privacy (Foster and Sharp 2007, p634).

But this raises the issue of who are the stakeholders? These consist of first party producers of genomic data: participants have an interest in the confidentiality of their own genetic information, privacy and protection of data – but they may also have an interest in encouraging research (such as if family member has a disease). They may also have altruistic interests in supporting research for collective or societal benefit (Kohane and Altman 2005). Depending on the nature of access and proposed research, researchers also have a dual interest in both restricting access by others, so as to maximise potential scientific and financial gains, whilst also wishing to access data already available in the furtherance of their own research. This body of work demonstrates the complexity of stakeholder interests.

A limited number of studies have examined public attitudes towards community engagement in genetic research. A survey on public attitudes towards the Quebec CARTaGene project and whether public is receptive to project was undertaken to establish dialogue with public (Godard, Marshall and Laberge 2007). The study involved 23 Focus Groups of 7-8 participants undertaken in Nov 2001, Aug 2003 and Sep 2003 in four Quebec regions and various population segments. The study found that while there were high levels of support for research, equally as important was a concern for confidentiality and respect for the individual. Respondents were also concerned about transparency, the participants' right to feedback, and governance issues.[39] Other literature

[39] In the Quebec CARTaGene survey the focus groups were conducted first, followed by the quantitative survey – i.e. the opposite to the present study.

on this subject which may be useful in the UK Biobank case includes an examination of community engagement with the HapMap project (Rotimi et al 2007).

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Appendix 2:

Information that accompanied the postal survey is reproduced below.

<Address>

<Date>
Dear <name>

UK Biobank Study

I am writing to you to ask if you would be prepared to take part in a short telephone interview in connection with a national study that we have been asked to undertake in connection with the UK Biobank by the Wellcome Trust. The Wellcome Trust is an independent charity that funds medical research in the UK.

The UK Biobank, located in Manchester, is to be a national depository for biological samples provided by 500,000 people in the UK. These samples and related information will, it is hoped, eventually help researchers find out about the cause of illness and disease and so provide the basis for future treatment.

The Ethics and Governance Council (EGC) has been established as an *independent* body to oversee access to UK Biobank data. The ECG is keen to learn the public's views about who should have access to this information. Your opinions are vital to inform the future policy of the ECG, and the advice it gives to UK Biobank itself, so we hope you will give a little of your time to assist us with this important study.

I have provided some additional information with this letter giving some background to the study, who we are and more specific details about some of the key issues we will be exploring in the research and how findings from the study will be used.

Following receipt of this letter, colleagues from QA Research who are assisting us with the national survey, will be contacting you by telephone to see if you are able and willing to help us.

Yours sincerely

Professor Andrew Webster (on behalf of the survey team)
Director SATSU

UK Biobank Study: Summary

The study has been commissioned by the Wellcome Trust acting on behalf of the Ethics and Governance Council (EGC) of the UK Biobank in order to discover the public's attitudes towards access to and use of the UK Biobank's material and information. The results of the study will be used by the EGC to help shape its developing policy in this area. The survey seeks people's views on the following: how access to the UK Biobank should be managed; whether they have concerns about the ownership of information and whether these concerns vary between different groups in society; and how best to ensure the maximum benefit from research based on the UK Biobank's material.

The study

The study is being conducted over a three month period (October –December 2007) by the Science and Technology Studies Unit (SATSU) located in the Department of Sociology at the University of York. Our partner in the study, York-based QA Research, will be inviting up to 500 participants from across the UK to take part in a telephone survey. These interviews will establish the views of people across the UK, from a variety of regions, occupations and between two age ranges, 40-69 and 18-30.

Your participation

You will receive a telephone call from a researcher from QA Research and will be asked to take part in the survey. The interviews will take between 20-30 minutes of your time. We will ask you about your views on the sort of access public and private organisations should have to the UK Biobank and how the benefits of research might be shared between public and private interests. Your responses will be entered directly onto a computerised database by the researcher and will not be tape-recorded.

Some key terms

- **What is the UK Biobank?**

The UK Biobank has been recently established by the Department of Health, the Medical Research Council and the Wellcome Trust. It is one of a number of similar initiatives that have been established in other countries. It is a 'bank' that will contain blood and urine samples provided by 500,000 volunteers aged 40-69 who are being actively recruited via UK GPs over the next three years. The UK Biobank will also carry other information about the participants' general health (including their health records) and lifestyle and participants may be contacted from time to time throughout their lives to update the information held in the bank. The information in the Biobank must be identifiable to individual participants to link up the different types of information. However, personal information on participants will be protected by a number of security safeguards and researchers will not have access to the names and addresses of the participants or information that could identify them, as all samples and information will be given a unique code. Genetic analysis of participant samples will be undertaken and over time the relationship between their genes, the environment and any disease(s) they contract should be better understood. The participants themselves will not receive any treatment or medical advice resulting from their participation in UK Biobank. Rather, the information is used instead for 'the public good' and longer term health improvements in society as a whole.

- **What is meant by researchers having 'access' to samples in the UK Biobank?**

Once UK Biobank is operating fully, medical researchers working for different organisations such as universities, medical charities, teaching hospitals or private companies will be able to apply for access to coded samples and information. These organisations and individuals are the 'third parties' referred to in the study. Access to the samples and related information will allow them to carry out studies that will contribute towards our understanding of health, illness and disease. However, such access will require a formal application that meets certain requirements set down by UK Biobank and its Ethics and Governance Council. Moreover, access will only be permitted for research use that is ethically and scientifically approved by appropriate bodies. Finally, access may depend on the payment of a fee to cover administrative and related costs to help towards the financing of UK Biobank.

- **What is meant by 'benefit sharing'?**

The phrase 'benefit-sharing' is used to describe different ways in which the benefits of research are shared or distributed among the different parties or groups that might claim to own, or have an interest in, the results of the research. There are a variety of benefit-sharing models. For example, one model argues that those who provide samples are owed a share in any gains (monetary or otherwise) that result from the research. Other models place more stress on any gains or benefits being shared throughout the community, such that everyone (weak or strong) gains from the research. A further model suggests that if private companies gain from the research they should pay some of the income they receive back to the public organisation (such as the UK Biobank) on which such profits depend.

- **What is meant by the term 'intellectual property'?**

The term 'intellectual property' is used to refer to the ownership rights that someone or some organisation, has over ideas or inventions that have been made or created through their own efforts. Copyright, for example, is a form of intellectual property, as are patents and trademarks. Research that is undertaken using samples and information obtained from the UK Biobank could produce findings that give those doing the research intellectual property rights which can be used to gain financial reward (through royalties, licensing income and so on). The potential for these types of benefits, therefore, raises questions about how best they might be shared between commercial enterprises and the wider public good. The Biobank insists that, once any commercial interest has been protected (through an intellectual property rights agreement) the results of the research must be publicised and be freely available to other researchers and users.

- **What is the role of the EGC and the Access Committee within UK Biobank?**

In 2004 UK Biobank established an *independent* Ethics and Governance Council (EGC) to help guide the biobank's development and ensure that UK Biobank will meet the commitments and standards laid down in its Ethics and Governance Framework. The positions on the EGC were advertised and candidates selected according to the standards required for public appointed positions. The ECG advises the Biobank on various ethical matters including guidance to ensure that samples are only used for scientifically and ethically approved research, and for research that is consistent with participants' consent. The Access Committee of the Biobank has

been established to handle and decide on the approval of research applications to use the Biobank after independent assessment of the application by the ECG.

Your contribution to the study

Your personal details will be kept separately to your responses to the survey. All information you provide to the survey will be anonymised, held in a secure database, and will not be used for any purposes other than for this study. Survey data will be managed according to the requirements of the Data Protection Act, will be held centrally and securely by SATSU on a secure server rather than on free-standing PCs, and will require authorised access via user ID and password protection. The study has been reviewed by the University of York's Social Science Ethics Committee. In addition, the University has public liability and insurance that covers its researchers in respect of this study.

Your contribution is immensely valuable and before the start of the telephone survey you will be asked to give your consent to your participation in the study. However, if, at any point during the course of the project, you wish to withdraw from the study, we will respect your decision immediately.

Outcomes from the study

The findings of the study will be written up as a report for the Ethics and Governance Council of the Biobank, overseen by the Wellcome Trust in London. Study findings may also be used for the preparation of academic papers and may include quotations from the interviews, but individuals will never be named.

Further information

Further information on the study is available online at **www.york.ac.uk/org/satsu**
Further information on the Wellcome Trust is available at www.wellcome.ac.uk/
Further information on UK Biobank is available at www.ukbiobank.ac.uk/

Appendix 3: CATI Telephone Questionnaire

1.1 Background material

1.2 Survey instrument

Introduction

Good morning /afternoon / evening. My name is ……. calling from QA Research. We sent you a letter earlier this week from the University of York about the UK Biobank Study.

Is now a convenient time to undertake a telephone interview?
If yes, go to introduction
If no, when would be a good time for me to call back?
Make appointment and arrange to call back. Thank and close

S1. Have you had an opportunity to read through the letter and information leaflet we sent you about this project?
Yes
No - can I arrange a time when it would be convenient to call you back once you've had a chance to read through the letter and further information about the UK Biobank Study?
If yes, go to S2
If no, make appointment and arrange to call back

S2. Can I also make sure that we have your consent to use the information we receive from you in our report? (I can confirm that the information will be completely anonymised and there will be no reference made to any personal views or statements you may make during this interview).
Yes
No
If yes, go to Section 1
If no, thank and close

Section 1: Background
S3a. The telephone interview will last approximately 30 minutes, depending upon your views and answers, but I will try my best to keep it as short as possible. Firstly, I just need some basic information about you to ensure that we have spoken to as wide a range of people as possible in this survey.
Can you please tell me how old you are?
Below 18
18-30
31-39
40-69
70 and over
If 'below 18', '31-39' or '70 and over', go to S3b
If '18-30', '40-69', go to S4

S3b.Is there anyone else in your household, between the age of 18-30 or 40-69, who has read about the UK Biobank survey and who might be willing to undertake the survey?
Yes
No
If yes, can I speak to them now or when would be a good time to call them - Continue interview with other person within specified age range from introduction onwards OR take details of person to contact, best time to call, etc. If no, thank and close

S4. And you are:
Male
Female

S5. Which of the following would you say best describes your day to day situation?
Employed
Self-Employed
Student
Retired
Unemployed/Long Term Sick

S6. What is (or was) your main job?
Occupation: ……..
Never worked
If 'never worked', go to S8

S7. And what type of industry / firm do / did you work for? (Probe 'manufacturing' , 'finance', 'retail', public service', etc.)

S8. And in terms of your ethnic background, could you please tell me which of the following groups do consider you belong to?
White British
White Irish
White Other (please specify)
Black or black British Caribbean
Black of black British African
Black of black British other (please specify)
Mixed - White & black Caribbean
Mixed - White & Black African
Mixed - White & Asian
Mixed – Other (please specify)
Asian or Asian British – Indian
Asian or Asian British – Pakistani
Asian or Asian British – Bangladeshi
Asian or Asian British – Other (please specify)
Chinese
Other (please specify)
Prefer not to say

Q1a. Had you heard of the UK Biobank before receiving our letter?

Yes
No
If yes, go to Q1b
If no, go to Q2

Q1b. What was the source of your information about the Biobank? (Tick all applicable)
Newspaper or magazine
TV
Radio
Internet
Other, please specify

Q1c. Have you already been recruited as a participant to the Biobank?
Yes
No
If yes, go to Q3a
If no, go to Q2

Q2. I'd now like you to tell me if, at some point in the future you would be prepared to help the UK Biobank with their research – please tell me if you: would be prepared; might be prepared or would not be prepared … to allow UK Biobank to …
Would be prepared
Might be prepared
Would not be prepared
Unsure

Take a blood sample?
Undertake genetic analysis with that sample?
Allow access to your medical records?
Undertake research about your lifestyle for health-related research?
Provide information about you to other organisations?

Q3a. As you will have read from our information leaflet, UK Biobank is currently gathering samples from volunteer participants. It is hoped that genetic and related research using the Biobank samples will provide long term health benefits for society.
Just to remind you, the samples and related information held by UK Biobank will eventually be available for use by researchers from both the public and commercial sectors. These are called 'third parties'. (if asked, they are referred to in the leaflet sent out). However, all access to, and use of, the information is overseen by the Biobank's Ethics and Governance Council.
So, now that is clear, I would now like to ask you first a few questions about use of UK Biobank material and how it should be controlled.
First of all, what kinds of 'public sector' organisations do you think might want access to the Biobank? Unprompted

Q3b. Which of the following do you think might want access to the UK Biobank? (Prompt)
University research groups

Medical researchers
Patient charities
The NHS
The Department of Health
Other, please specify

Q3c. And which of these organisations do you think SHOULD have access to UK Biobank? (Prompt)
University research groups
Medical researchers
Patient charities
The NHS
The Department of Health
Other
Show for 'other', the response given at Q3b

Q4a. And what private sector organisations do you think might want to access UK Biobank information? Unprompted

Q4b. Which of the following do you think might want access to the UK Biobank? (Prompt)
Pharmaceutical companies
Private insurance companies
Employers
Other, please specify

Q4c. And which of these organisations do you think SHOULD have access to UK Biobank? (Prompt)
Pharmaceutical companies
Private insurance companies
Employers
Other
Show for 'other', the response given at Q4b

Q5a. Are you familiar with the term 'public good' research?
Yes
No
Not sure

Q5b. What do you think 'public good' research is or might be?

Q6a. READ OUT: Public good research means that results are freely shared and available to everyone, and are not held exclusively by any party.
I'm now going to read out a list of organisations and people. Please tell me if any of them should benefit from 'public good' research?
Yes
No

Government
Society in general
The NHS

Patients
Medical science
You personally
Your family

Q6b. Which, if any, of the following organisations do you think should take priority in benefiting from 'public good' research?
Yes
No

Government
Society in general
The NHS
Patients
Medical science
You personally
Your family

Section 2: Access
Q7. I'm now going to read out a series of statements about UK Biobank and its Ethics and Governance Council. For each one, please tell me if you: strongly disagree; disagree; neither agree nor disagree; agree; or strongly agree.
Strongly disagree
Disagree
Neither agree nor disagree
Agree
Strongly agree
Unsure / don't know

"UK Biobank material and related information should in principle be available to 'third party' organisations, both public and private, for research purposes."
UK Biobank's Ethics and Governance Council should allow 'third parties' access to additional information held by UK Biobank.
UK Biobank's Ethics and Governance Council should permit access to UK Biobank for research that is ethically approved.
UK Biobank's Ethics and Governance Council should permit access to UK Biobank for research that is scientifically approved.
UK Biobank's Ethics and Governance Council should permit access to UK Biobank for research that is consistent with the participant's consent.
UK Biobank's Ethics and Governance Council should not allow any particular 'third party' EXCLUSIVE access to samples or information.
UK Biobank owns the samples held in the bank, but should accept that research conducted by 'third parties' creates new commercial rights to be held by those 'third parties' themselves.

Q10. UK Biobank is expected to operate for the next 25 years. Do you think that in earlier stages of its development access should be open to …
Yes
No

Public researchers

Universities and the NHS
All 'third parties' public or private

Q11. Do you object to, or have any reservations about, a commercial company accessing data given by participants to UK Biobank?
Yes
No
If yes, go to Q12
If no, go to Q13

Q12. Can you please tell me what the objections or reservations you have about commercial company accessing data are?

Q13. Do you disagree or agree with the view that commercial firms should pay a fee to access UK Biobank?
Disagree
Agree

Section 3: Benefit sharing
The term "benefit-sharing" is used to describe how the results of research could be shared to benefit different interests, such as those of the wider community, UK Biobank itself, and public or commercial researchers accessing the bank.
Q14. I'm now going to read out a series of statements, and for each one could you please tell me if you strongly disagree; disagree; neither agree nor disagree; agree; or strongly agree.
Strongly disagree
Disagree
Neither agree nor disagree
Agree
Strongly agree
Unsure / don't know

The interests of the 'wider community' should be given priority over others
The interests of the 'public research' should be given priority over others
The interests of the 'private research' should be given priority over others
The interests of UK Biobank itself should be given priority over others

Q15. I'm going to read some statements about the benefits from research. For each one, could you please tell me if you strongly disagree; disagree; neither agree nor disagree; agree; or strongly agree.
Strongly disagree
Disagree
Neither agree nor disagree
Agree
Strongly agree
Unsure / don't know

As the efforts of the pharmaceutical industry make long term benefits possible, the industry be rewarded from the income that comes from this research

The financial and scientific benefits of research undertaken by the pharmaceutical industry, using UK Biobank material, should not remain entirely with the pharmaceutical industry
The financial and scientific benefits of research undertaken by the pharmaceutical industry, using UK Biobank material, should be shared with the community at large and the National Health Service

Q16. The long-term benefits of the research could be shared in different ways between the wider community and commercial organisations. Could you please tell me if you strongly disagree; disagree; neither agree nor disagree; agree; or strongly agree with the following statements.
Strongly disagree
Disagree
Neither agree nor disagree
Agree
Strongly agree
Unsure / don't know

Commercial organisations should be free to exploit the result of their work using UK Biobank material once they have paid a fee for accessing it
Commercial organisations should be asked to return some of their profits from the research back to UK Biobank on an ongoing basis
Profits from research should be shared equally between UK Biobank and that company

Q17. And now can you please tell me if you strongly disagree; disagree; neither agree nor disagree; agree; or strongly agree with the following statements about potential benefits of UK Biobank.
Strongly disagree
Disagree
Neither agree nor disagree
Agree
Strongly agree
Unsure / don't know

UK Biobank participants should not enjoy any special benefit from donating their blood samples
Users of UK Biobank's information must return the results of their research to UK Biobank for future use by other users
Limits should be placed on access to UK Biobank's information by overseas public or commercial organisations
If 'agree' or 'strongly agree' to the last statement (i.e. 'Limits should be placed … commercial organisations'), go to Q18.
All other options, go to Q19

Q18. In your view, what limitations would be appropriate?

Section 4: Longer-term developments
Q19. Again, I'm going to read out some statements about longer term developments of UK Biobank. For each one, could you please tell me if you strongly disagree; disagree; neither agree nor disagree; agree; or strongly agree.
Strongly disagree

Disagree
Neither agree nor disagree
Agree
Strongly agree
Unsure / don't know

Third parties, whether public or commercial organisations, should be able to access more detailed information about those people whose data is on UK Biobank database
Third parties, whether public or commercial organisations, should ONLY be able to access much more detailed information about those people whose data is on UK Biobank database - IF THIS IS SEEN TO BE IN THE PUBLIC INTEREST
Third parties should be allowed to contact individual participants, in the future, if more data is needed about them

Q20a. Do you currently have a long-term illness?
Yes - please specify nature of illness
No

Q20b. Is there any family history of chronic illness?
Yes - please specify nature of chronic illness
No

Q21. Do you belong to a patient self-help or advocacy group? (If required, provide some examples if interviewee is unclear about question – e.g. Alzheimer's Society, MIND, MS Society etc. – but not e.g. Age Concern, Shelter etc.)
Yes - please record name of group
No

Q22. Would you be willing to help with further research in the future?
Yes
No
If yes, take down details for someone to ring back, name, telephone number, best time to call, etc.

Q23. As part of our quality control procedure, a research supervisor may contact you in order to confirm the accuracy of the interview and to ensure you were happy with the way the interview was undertaken. Would you be prepared to give your contact details for this purpose?
Name
Telephone/Mobile
Prefer not to be contacted

Q24. Can I ask you if you were happy with the way I have undertaken this interviews with you today?
Yes
No

Q25. Finally, are there any further questions you might have, for example about the background to the project, why the work is being done, and what will happen to the results of the study?

Appendix 4: Focus Group Vignettes

Vignettes for UK Biobank Focus Groups

The material in the vignettes is based on the current provisions made by the UK Biobank but is entirely fictitious of course.

Vignette 1: Explores attitudes to Intellectual Property and benefit sharing arising from commercial access to UK Biobank

An academic research centre which has a commercial spin-off company in the health sciences area seeks access to physical samples of biological material as well as lifestyle and health-related data from UK Biobank. This request for the release of samples falls within the 'Protected Materials' category and is therefore considered by both the Access Committee and UK Biobank's independent Ethics and Governance Council, and then referred to its Board for a final decision. The application is subsequently approved by Board since the request meets the ethical principles of UK Biobank and its objective of supporting health-related research. The firm is required to pay a Data Access Fee, set at a level higher than equivalent requests from purely academic researchers.

Subsequently the company uses this information to develop new products for sale worldwide. The terms of access allow the company full commercial (intellectual property) rights over these products, but no rights over the original samples held by the bank. Five years later the results of the work produce a highly profitable cancer drug with annual sales of £300m.

In light of the success of the drug, a cancer charity challenges the UK Biobank's policy that all profits can be retained by the firm, and argues that some should be returned to the public sector. The UK Biobank reminds the charity that the company made available the full results of its original research to the bank for future use by other researchers.

Questions

1. In general, researchers have full rights to the products they create that in part depend on access to UK Biobank material. Do you consider this to be a reasonable policy and if so, why and if not, why?

2. Do you think that even if they do have full rights to these products the benefits they bring in broad terms with respect to public health balance any particular financial reward that comes through commercialising the results?

3. What is your opinion about the UK Biobank's response to the charity? Does full access to the results ensure that the public good benefits of the research are maximised?

4. On what basis do you think UK Biobank should manage competing access by different users to the resource? Should, for example, public researchers have priority access to UK Biobank's resources than strictly commercial organisations or not? Might there be circumstances when this might not be appropriate - for example where public university researchers are collaborating with commercial partners?

Vignette 2: Explores access to UK Biobank samples by a research consortium and follow-up access to additional participants' information

It's 2012, and the UK Biobank is receiving requests from researchers for access to information about participants' samples and personal health information. The participants' samples and personal information have been completely anonymised. The research consortium is exploring the way in which diabetes develops over the longer term and are interested in following up their initial study with further information from the participants.

The Biobank's Access Committee considers the application and whether it meets its requirements that the research is health-related, whether the request for follow-up is justified and whether this raises concerns relating to privacy and the rights of participants. In considering the proposal, the Committee asks the Ethics and Governance Council to review it and identify any issues it considers need to be addressed before access is granted. The EGC notes that the request is made by a consortium made up of a number of research groups from the UK and overseas, and recommends that Access be granted only if the applicants can demonstrate that the consortium as a whole conforms to the ethical requirements of UK Biobank.

The Committee decides to grant access to the information but future access is only possible through UK Biobank itself who will re-contact the participants to find out if they are willing to be approached by the consortium. Only some of the participants agree to this, so the consortium decides to withdraw its request.

Questions:

1. Do you think that third parties should in principle be able to have access to biological (including DNA-related), lifestyle and health-related data? In addition, in what sort of circumstances/for what reasons do you think access to participants by third parties could be permitted?

2. The Access Committee has as one of its key priorities that any research linked to it must be 'health-related'. Do you have a clear idea what health-related research means and if so, how might this restrict the use of resources held by UK Biobank to particular purposes?

3. Can you envisage any situation in which access to UK Biobank for purposes other than health-related research should be permitted?

4. Do you think the access procedures with respect to follow-up are appropriate?

Vignette 3: Explores issues relating to privacy, the public good and the safeguards that have been put in place by the Biobank

Mary Evans is contacted by the UK Biobank inquiring whether she would be prepared to become a participant. She agrees, after being informed that her personal information will be anonymised, that, normally, samples themselves, will not be made available to public or private sector researchers, and that she is being asked to give a broad consent for her information and samples to be used for any research that will lead to the improvement of the health of society. Also, UK Biobank will only allow research to be carried out if it is approved by a research ethics committee and UK Biobank's scientific committee.

When Mary signed up she agreed that she could be contacted by the UK Biobank on a periodic basis to provide updated information about her general health. Mary's information continues to be added to UK Biobank over 20 years, documenting the development and treatment of her breast cancer.

Questions

1. Do you think that the safeguards that UK Biobank has in place, such as anonymising all data, are strong enough? Would you be happy to have your anonymised personal health and life-style information made available to third party users?

2. As a participant to UK Biobank, do you think Mary's willingness to provide regular updates on her health might raise for her concerns about her personal privacy in the long term? If so, what might these be?

3. How do you think people who become participants understand the idea of the research contributing to 'the public good'? Who do you consider the 'public' to be that benefits from the UK Biobank research?

4. Does it make a difference to the meaning of 'public good' if Mary were contacted by a research group who were not based in the UK?

Finally, UK Biobank has stated that if the police were to request access to personal information (say to Mary's), they would resist such a request and indeed refuse it without a court order.

In these situations, the requirement that the request be considered by a court shows how the individual's personal privacy and the importance of the public trust in the bank is given precedence by UK Biobank over, say, police claims to the information being released 'in the public interest'. Do you think that UK Biobank's priority to protect the participant in this way is one that you would support?

Appendix 5: Follow-up Interview Schedule

Introduction:
1. Good afternoon/evening, my name is Conor Douglas and I am a researcher based at the University of York. You recently participated in a telephone survey concerning the UK Biobank, and agreed to a follow-up interview to explore some issues in more depth. Do you recall the interview?

[If yes]
I was wondering if you had some time now to discuss some of the issues raised in the previous interview in more depth?

[If interviewee does NOT recall the telephone survey, terminate the interview. Thank interviewee for their time.]

[If time not convenient]
OK, when would be a good time to do so?

[If yes...]

2. Before we get started I would like to assure you that any views and comments that you provide are completely anonymous. What this means is that anything you say cannot be traced back to you personally in any report or publication we produce for the study.

I would also like to confirm that I have your permission to record this interview so that we have an accurate record of your views and opinions. Are you happy for me to do this?

[If no – conclude the interview. Thank the interviewee for their time]

[If yes]
As you may know we are a university based research team that is exploring people's views about the UK Biobank and, in particular, issues concerning commercialisation, access to samples and data held by the Biobank, and 'benefit sharing' or how the benefits that may flow from research conducted using UK Biobank resources, such as biological samples and health information, should be distributed.

We sent you some background information on what we mean by 'benefit-sharing', and also what we mean by 'the public good'. Did you have a chance to read this information?

[If "yes", continue… If "no" quickly go over definitions using info sheet and then decide whether to continue with interview]

I am going to ask you some questions about these issues, and would like you to answer as openly and honestly as possible. This is not a test, and so there aren't any right or wrong answers; rather, we are simply interested in your views and opinions.

Questions:
I am going to ask you for your views on three topics: benefit sharing, public good and the related issues of access and privacy..

The topics all relate to the conditions - or rules, if you like - that you think should apply to how access to UK Biobank resources is managed . The resources include biological samples and health and lifestyle information provided by individual participants to the Biobank.

You may recall that the original telephone survey asked for your views on 'benefit sharing'. This refers to the idea that anyone who benefits from the use of Biobank resources, such as an individual researcher or a company, should share some of those benefits with others. This is what we mean by 'benefit-sharing'. Such benefits may be financial, such as a share of the profits generated by a new product, or they could take other forms.

1. In the telephone survey, we asked your opinion on whether, and if so, how, benefits might be shared between different parties and your feelings about access to UK Biobank resources. I would like to explore the issue of benefit sharing in more detail.

Question 1.1 What do you think might be the 'benefits' from the research undertaken using the resources of UK Biobank such as biological samples and health and 'lifestyle' information?

Question 1.2 Given your understanding of the benefits resulting from research based upon these resources, who do you think those benefits should go to?

[Prompt if required…]
In other words, do you feel that the benefits should remain with the organisation undertaking the research? Or should they be shared with others, such as the participants or perhaps the wider community in some way, such as through the NHS?

Question 2. In your view, should persons who provide samples and their health and 'lifestyle' information to UK Biobank be rewarded in any way for doing so?

[If no] Can you say why you feel this way?

3. Some people believe that since the benefits from commercialisation come, at least in part, from using a resource to which many members of the UK public have contributed (UK Biobank) then some, or possibly all, of the benefits should be returned to the individual participant or perhaps to the wider public in some way.

Question 3. Would this be something you would agree or disagree with?

[If agree] How do you think people who provide should be rewarded? And how does the idea of a reward sit with your understanding of 'the public good' and solidarity?

[If disagree] Do your reasons for not providing incentives or rewards for donating samples and personal information have anything to do with your understanding of 'the public good' or ideas of 'solidarity'?

[Prompt if required with definitions…] By **'public good'** we mean the idea that the results of research should contribute towards the broad health and welfare of society.

By **'solidarity'**, we mean the idea that the collective interests of a society should take precedence over separate, competing interests.

4. I want to ask you about your views on the potential commercial benefits resulting from research conducted on the resources held at the UK Biobank.

Question 4. Assuming that there will be profits for companies who access UK Biobank material (provided biological samples and related health and lifestyle information), do you think that any, some, or perhaps all, of these profits should be shared with the Biobank - or perhaps with the wider community more generally, such as through the NHS?

5. We are interested in finding out whether such arrangements are likely to influence people's willingness to provide samples and personal information to UK Biobank.

Question 5. Would your own willingness to provide a sample to the Biobank be influenced by the sort of arrangements put in place for what we are calling 'benefit sharing'?

6. UK Biobank keeps both biological samples (e.g. blood and DNA information) and data (patient records and 'lifestyle' information – such as smoking, drinking and eating habits). Under present policy, it is unlikely that the actual samples would be provided to outside researchers. Instead, UK Biobank would conduct any analysis required and then provide the results.

Question 6.1 What are your feelings about third parties, such as university researchers or companies, having access to the results of analysis of your biological samples (such as blood and your DNA)?

Question 6.2 What are your feelings about third parties, such as university researchers or companies, having access to anonymised health records which will be held by the Biobank?

Question 6.3 What are your feelings about third parties, such as university researchers or companies, having access to anonymised 'lifestyle' information which will be held by the Biobank?

7. I now want to ask you about your views on the commercialisation of research and the contribution such activities make to your own health and to the wider society

Question 7.1 What contribution do you think is made by the commercial sector with regards to your own health, and to that of the wider society?

[Prompt if required…] By 'commercialisation of research', I mean companies developing a new drug or diagnostic product, for example – or perhaps offering a commercial service such as genetic testing to determine whether an individual might benefit by changing their lifestyle.

Question 7.2 What are your feelings about such contributions?

Question 7.3 Do you think health improvements in society are especially dependent on the research that is done by public organisations – or by commercial organisations – or both types of organisation?

8. I want to ask you for your views on the provisions that should be made for privacy by UK Biobank, particularly in the context of access by academic researchers or commercial organisations, to samples and information stored by the Biobank.

Question 8.1 If you were to provide biological (i.e. blood) samples and other data (including health and lifestyle information) to UK Biobank, what would your feelings be with regards to the privacy of the information held about you?

Question 8.2 For you personally, are there differences between UK Biobank sending external researchers your biological samples (with safeguards in place with regard to your identity) compared to other kinds of personal information, such as health-related information?

[Prompt if required…] The safeguards include anonymisation of biological samples and other information, so that this cannot be linked to an individual participant by a third party who has been allowed to use these resources for research. Also samples will rarely be distributed to outside organisations; rather UK Biobank will undertake any analysis requested and supply the results only to the third party concerned.

[If yes] Can you explain why you feel they (biological samples and health and other personal information) are different?

[If no] Can you explain why you feel they are the same?

9. The purpose of UK Biobank is to set up a resource to support a diverse range of research intended to improve the prevention, diagnosis and treatment of illnesses and the promotion of health throughout society. I want to ask whether you feel there should be any limits placed on the type of research undertaken using UK Biobank resources.

Question 9.1 What restrictions, if any, do you believe should be placed on research undertaken using UK Biobank resources?

Question 9.2 In what circumstances, if any, do you think access to UK Biobank materials for purposes other than health-related research should be permitted?