

Summary of the
UK Biobank Consultation
on the
Ethics & Governance Framework

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Date: August 2003**

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1 EXECUTIVE SUMMARY

- The UK Biobank Project is the world's largest study of the role of nature and nurture in health and disease. The project will create a database of DNA blood samples, lifestyle details and will be linked ongoing medical records as well as medical histories from up to 0.5 million people aged 45 to 69. The database will be used to develop an understanding of the interplay between genes, environment and an individual's lifestyle and how these relate to multifactorial disease like cancers.
- This consultation was conducted to understand the opinions of various stakeholders in relation to the Ethics and Governance Framework that will govern the UK Biobank.
- In summary, OLR conducted two day long workshops and four depth interviews with politicians. The first workshop was held with members of the public and health practitioners and the second with various stakeholders who have been involved in consultation previously. Politicians were consulted separately as commitments do not allow them to attend workshops.
- The findings of the research are summarised below:
 - The structure of UK Biobank and workings (including appointments with research nurses, information to be given, gathering and anonymisation of data and samples, re-identification, etc) are broadly endorsed.
 - Ensuring participant confidentiality and anonymity is crucial to both public and professional confidence in UK Biobank.
 - Participation must be voluntary and based on informed and on-going consent – especially given that people will not know at the time of volunteering precisely who and how their data and samples will be used.
 - Overall, people must be given enough information without being overloaded. Participating in the study for the greater public good (i.e. donating samples and data as a gift) does not raise ethical concerns, but does raise concerns about ensuring diversity within the data gathered, as certain people may be more likely to volunteer than others.
 - Awareness-raising campaigns targeting the population cohort for UK Biobank and primary care practitioners will play an important part in enabling informed consent, but also as a potential point of recruitment.
 - Recruitment proves a particular area of difficulty. There is concern that false expectations may occur if the initial approach letter comes from the GP (e.g. in terms of levels of involvement in recruitment, feedback, and follow up, etc.). Provided awareness is raised in advance (e.g. via mass media campaigns), the public and practitioners expressed a preference for the letter to come direct from the UK Biobank. Any communications will need to clarify the role of the GP in the process.

- People must have the right to withdraw totally from the study and should be asked at the outset what they would like to happen in the event of mental incapacity or death.
- Active involvement is essential to ensure retention and the ultimate success of the project. The range of activities outlined in the draft framework will need to be explored further.
- Collaborating Centres should not have privileged access to participants, their data and samples and must be subject to the same scrutiny in terms of access as any other user of the resource.
- Concerns about the challenge of ensuring diversity and scientific basis for the project will need to be tackled effectively.
- It is imperative that an oversight body is appointed. It should be truly independent of the funders, Co-ordinating Centre and Collaborating Centres. It should include both professional and lay representatives.
- Most importantly, it should define and arbitrate for the 'public interest' in relation to all aspects of UK Biobank's workings, in particular, uses of the resource. Within this, it could combine an advisory and appeals function. Open and transparent procedures must be adopted for appointments and subsequent working of the oversight body to ensure it is open to public scrutiny in its entirety.
- To fulfil its role effectively, it may also need to work alongside, but in close collaboration with a participants' panel and scientific committee.

2 BACKGROUND

- The UK Biobank Project (co-funded by the MRC, the Wellcome Trust and the Department of Health), is the world's largest study of the role of nature and nurture in health and disease; the project will create a database of DNA (blood) samples, lifestyle details and medical histories from up to 0.5 million people aged 45 to 69
- This database will be used to develop a detailed understanding of the complex interplay between genes, environment and an individual's lifestyle that causes multifactorial diseases like cancers, heart disease and diabetes and will help researchers to devise new ways of preventing, diagnosing and treating them
- From the outset the funding partners have been acutely aware of the ethical implications of collecting, storing and using this kind of data
- Consequently, they have conducted a number of qualitative consultation exercises to understand fully the hopes and concerns of stakeholders (both public and professional) on the development, ethics and future governance of the project; these have identified a number of areas of particular concern including:
 - Consent
 - Confidentiality
 - Access
 - Commercialisation
 - Oversight / monitoring
- As the project is approaching implementation, the co-funders appointed an Interim Advisory Group (IAG) to advise on an Ethics and Governance Framework which will address these and other issues.
- In this consultation the co-funders commissioned independent consultation on a draft / outline Framework. The findings from this consultation are set out in this report.

OLR EXPERIENCE

- Opinion Leader Research has previously worked with the MRC and the Department of Health.
- Opinion Leader Research has been instrumental in developing and pioneering a range of innovative approaches and methodologies that enable stakeholders (especially Citizens / the public) to enter into an informed dialogue and arrive at recommendations based on information, scrutiny and deliberation
- In partnership with IPPR, Opinion Leader Research introduced Citizens' Juries to the UK and have subsequently conducted over 40 juries on a wide variety of projects. We have also been at the forefront of developing deliberative stakeholder consultations using forums

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(of 100 or more participants) and workshops (using comprising 14 to 16 participants); on average we would conduct 20 forums and well over 100 workshops each year

3 OBJECTIVES & METHODOLOGY

The objectives of this consultation were to:

- Consult with a range of stakeholders on the Ethics & Governance Framework for UK Biobank
- Provide feedback as to how the Ethics and Governance Framework might tackle the following issues:
 - Consent
 - Confidentiality
 - Access
 - Commercialisation
 - Oversight / monitoring

In order to do this we followed a qualitative / deliberative workshop approach to the consultation as it allowed participants more time to digest and discuss the detail of the project and the associated Ethics and Governance Framework. This approach has also enabled us to understand in depth and detail the reasoning / drivers underpinning the different stakeholder viewpoints.

A comparative approach was taken involving both those who have not been consulted on UK Biobank previously and those who have been involved in consultation before. The purpose of this approach was to bring a fresh set of eyes to the consultation and to allow deliberation during the workshops on the issues. The use of this approach allowed us to explore the differences in views held by the different interest groups and to seek resolution of conflicting views on the day.

One of the areas in which it was possible to highlight the benefit of this approach was in relation to the issue of recruitment to UK Biobank. GPs expressed a concern that their involvement in such a project would over-stretch them, whilst the public considered that this approach would provide them with reassurance. Via the discursive process there was agreement that whilst patients should be free to seek guidance from their GP it was perhaps best if the approach came from UK Biobank.

In our experience it is difficult for political stakeholders particularly to have the time to attend a daylong workshop. Therefore we have found that the best way to consult with this group is through face to face depth interviews.

In summary, we conducted two day long workshops and four depth interviews with politicians. Other stakeholders who were unable to attend the workshops were given the opportunity to provide input via a postal questionnaire.

The following workshops were conducted:

Workshop 1 – Public & Practitioner Stakeholders

- This was held on the 19th May 2003
- 39 individuals in total attended, working in the following groups:

- 9 x Primary health care professionals including GPs and practice nurses
- 20 x Members of the public within the target age range, 45 to 69 years olds, working in two groups of 10
- 10 x Members of the public outside the age range
- These groups included equal numbers of men and women, a spread of age, socio-demographics and ethnicity
- The members of the public and health care professionals had not been previously consulted on UK Biobank

Workshop 2 – Other Stakeholders

- This was held on the 27th May 2003
- All those involved in previous consultations were invited to attend
- In total, 135 individuals were approached about attending the workshop, of those 14 individuals attended on the day, working in two groups of seven
- The following stakeholder groups were represented:
 - Those involved in the development of the original protocol for UK Biobank
 - Spoke / Collaborating Centre¹ organisations
 - Scientists, clinicians, social scientists, ethicists, lawyers, health service professionals, patient groups and other civil society groups involved in previous ethics consultation work
 - Health professionals involved in previous consultation work

Respondents who attended the workshops were given questionnaires to complete following the workshops; the findings from these are summarised at appendix one.

Research Process

The Opinion Leader Research team and Dr William Lowrance, Chair of the Independent Advisory Group (IAG) welcomed participants at both workshops. Observers from the MRC, Wellcome Trust, and the Chair of the IAG were introduced and their role explained (i.e. that they could clarify points of detail, but would not actively participate in the discussion).

The Opinion Leader Research team gave a brief summary of the purpose of the consultation and outlined issues that had emerged from earlier consultation that the Ethics and Governance Framework was intended, among other things, to address. Participants were given an opportunity to ask questions in this initial plenary before breaking out into stakeholder groups.

At the first workshop, two groups of members of the public within the target age range, one group of members of the public outside the target age range, and a group of GPs and practice nurses worked separately throughout the day from the same agenda and stimulus material. At the second workshop, stakeholders worked in two mixed groups.

For both workshops, plenary sessions were held at the end of the morning and afternoon at which each of the stakeholder groups presented key learnings.

¹ The co-ordinating centre of UK Biobank, based at the University of Manchester, will have overall responsibility for delivering data management and quality assurance, computing and financial management. It will also be responsible for co-ordinating the activities of six scientific Collaborating Centres who will contribute to the design of the project and be responsible for participant recruitment and initial data and sample collection.

The same stimulus material and a similar agenda were used for both workshops. Opinion Leader Research staff facilitated all sessions and break-out groups. Participants were given notes summarising the detail of the Ethics and Governance Framework. Facilitators read through the notes to ensure comprehension.

The workshop materials and agenda are appended (Appendix II).

All sessions were flip-charted and tape-recorded. All audio-tapes were transcribed verbatim.

Responses by post

To ensure an inclusive approach those other stakeholders who were unable to attend the workshop on the 27th May were given the opportunity to respond via a written questionnaire to be returned either by email, fax or through the post. In total 121 questionnaires were sent out.

Twenty five questionnaires were returned. The content of these questionnaires is reflected in the main body of the report. The table below illustrates the response to the postal questionnaire:

Response	Number
Attended workshop	14
Postal / Email Questionnaire	15
Do not wish to respond further	8
Will respond as soon as possible	1
Holiday	3
No time	1
No response	93
TOTAL	135

In summary, this group particularly emphasised that openness and transparency is key to the project as is the establishment of an oversight body. Certain stakeholders questionnaires reflected self-interest, being concerned about why UK Biobank does not look at a particular scientific area of interest to them. One area that came up particularly was the lack of attention given to phenotyping by UK Biobank. Many of the issues raised did not specifically relate to the Ethics and Governance Framework and therefore are not reported here.

Post-workshop Questionnaires

All those who took part in the workshops were asked to complete a questionnaire at the end of the workshop. These questionnaires sought to gather opinion on the workshop format as reported at Appendix one but also gather information on the key issue, that is whether those involved in the consultation would consider being involved in UK Biobank.

Out of the 43 respondents who filled in a post-workshop questionnaire 30 said they would consider being a volunteer for UK Biobank. The reasons that were given included:

- Contributing to the development of medical thinking
- Improving the health of the nation
- Being interested in knowing more about the progress or outcomes of UK Biobank
- Participating does not appear to be demanding on time and effort
- Not concerned about anything in medical records becoming known by other people
- Understanding that it is for the public good
- Considering that outcomes might be able to help my family and friends in the future

However, some of those who agreed they would consider being a volunteer also raised concerns and stated that they would only do so if they were completely confident that all their concerns had been addressed, and that there was an easy and effective withdrawal process.

Ten of the participants would not consider being a volunteer, this was due to either concerns about UK Biobank or due to being outside the required age range. The primary concerns revolved around access to data, confidentiality of patient records and the level and nature of feedback. A minority also mentioned that they could not see any real motivation to participate (e.g. no benefit for themselves or their friends and no financial incentive).

Political Consultation

Four depth interviews were conducted with MPs at Westminster from the various health and science committees. This aspect of the research was designed to provide a sense of the issues amongst key politicians with an interest in the area of health / genetics. These four interviews were not designed to be exhaustive but rather to gain a sense of the issues amongst political stakeholders. Each of these interviews lasted approximately 30 minutes and was structured to cover the key areas of concern to UK Biobank.

In summary amongst this grouping, there was limited awareness of the detail of how UK Biobank might be structured and function and some concern that there has not yet been a debate within parliament / amongst MPs in relation to UK Biobank.

"I think there must be an opportunity for parliament itself to consider this ground breaking endeavour ... I just hope that none of this is done in a rush." (Politician)

However, there was general endorsement of it as a project despite concern that it needs to be carefully governed, that access to the data needs to be carefully managed and that protection of participants must be guaranteed. The discussion with these MPs was very similar to the discussion with all other stakeholders. To an extent the attitudes and concerns of MPs were dependent upon levels of knowledge and understanding of UK Biobank.

Those MPs more informed about UK Biobank mentioned the need to carefully manage public expectations in relation to output:

"One danger is that it's going to be over-hyped too early and everyone will get expectations which are too high too soon. I think the science will start coming out quite fast, but by and large, most people don't care a fig about the science, what they do care about is health. And I

think you're talking quite possibly a minimum of five, and more like ten to fifteen years for significant health benefits." (Politician)

4 KEY FINDINGS

4.1 Awareness and response to UK Biobank

Members of the public and practitioners who took part in the first workshop arrived at the event with no previous awareness of UK Biobank. As stakeholders, participants in the second workshop knew about UK Biobank (they had been consulted during its development). However, even among those who had previously been involved in consultations, there was a certain amount of confusion and misunderstanding about the precise nature of the project. Many had understood it to be an epidemiological study in itself, rather than a project to build a resource for future research.

Once people had an understanding of the role and nature of UK Biobank, the majority of those participating in the consultation endorsed UK Biobank and the proposed Ethics and Governance measures. Public participants who adopted such a view were willing to place their trust in UK Biobank to protect their interests.

"Isn't it a trade-off that if you're gonna give all this information to a central point you have to accept that there is a risk, [but] this is for the greater good then surely that's a good enough reason to say all right I'll go with this ... [as] this is gonna help us over the longer period of time." (Public, 45-69 year old)

A substantial minority, however, expressed:

- Cynicism and a lack of trust generally in science, medicine and public bodies
- Concerns more specifically about scientific advances in relation to DNA

Some of the other stakeholders were particularly concerned about the scientific basis of the project, the research protocol (e.g. age cohort, etc), its political ramifications (e.g. would it increase demand for genetic testing, would tests be developed before therapies, etc), and whether or not it represents good use of public funds. Members of the public also questioned the rationale for the age range chosen and how such a resource might create further debate in relation to genetic testing. Those who adopted such viewpoints as these were reluctant to place their trust in UK Biobank. Other stakeholders called for an independent scientific committee to vet UK Biobank protocol and subsequent applications for its use.

Throughout the consultation exercise considerable emphasis was placed on the need for genuine openness and transparency in all the workings of UK Biobank (i.e. opening up the resource and its uses to public scrutiny). This was thought necessary to enable participants, practitioners and other stakeholders to formulate informed viewpoints on the project as a whole and whether or not to participate / endorse it.

"Transparency is key to ensuring that UK Biobank is acting in the public interest and in protecting the rights of participants. Public declaration of proposed and ongoing projects / collaborators will be important to increase confidence and to avoid perceptions of secrecy and

conspiracy. It will also be important to demonstrate evidence of benefit and to foster ongoing dialogue between the public and Biobank scientists.” (Postal Questionnaire)

The publication of positive and negative findings was welcomed, enabling scrutiny of both the results and the use of the resource.

4.2 Main Ethics and Governance issues

4.2.1 RECRUITMENT

Concerns were expressed across all stakeholder groups about the challenge of recruiting a representative sample (especially hard-to-reach audiences). Many were concerned about the impact this may have on the study as a whole for example in relation to the ability to study rarer diseases and conditions. Any suggestions to tackle this were generally countered by corresponding concerns. Despite this the public and other stakeholders thought that the resource should be truly diverse and understood that the recruitment strategy chosen would have to reflect this (e.g. bridge language barriers). In relation to the decision that those who are mentally incapacitated should not be recruited to UK Biobank other stakeholders and the public wanted to know how mental incapacity would be defined and who would be in charge of making this decision. Some stakeholders believed that people with mental health problems can consent and that the resource could also be used to study mental illness.

All agree that participation should be voluntary and that people should be given balanced and unbiased information to enable them to choose whether or not to take part, rather than being ‘persuaded to participate’. All stakeholders agreed that recruitment should be undertaken in a way that respects cultural and religious differences.

Many called for an awareness raising campaign at both the national and local level. It is widely suggested that this could provide a means of direct recruitment (e.g. by giving a contact number). Many believed this recruitment approach would ensure widespread participation (including hard-to-reach communities). However, other stakeholders from research backgrounds thought this would have the opposite effect and would result in research biases (i.e. only more empowered audiences would come forward). (It was not discussed how links would then be made back to GP medical records.)

An awareness raising campaign was also thought important to enable informed consent. It was stressed by both the public and other stakeholders that any communications in relation to UK Biobank needs to be honest and ‘un-glossy’.

“I think you’d have to educate people as to why they should volunteer.” (Public, 45-69 year old)

It was also assumed that some direct GP involvement in the recruitment process was inevitable (e.g. providing access to their patient list). The public initially wanted the initial approach letter to come from their GP, and for their GPs to be actively involved in the recruitment interview. They assumed that their GP would be able to give them feedback and follow up on test results. Once outlined that this would not be the case and that they would be referred to a UK Biobank research nurse and that only limited feedback would be provided, the public thought the letter should perhaps come direct from UK Biobank to avoid any confusion. However, they assumed

that awareness of the UK Biobank would have already been raised and an approach anticipated.

Primary health care staff were similarly concerned that a letter from the GP might cause confusion and raise false expectations. They too preferred a direct approach from the UK Biobank.

Many public and practitioners thought direct recruitment (via PCT lists) was preferable, given the concerns expressed about GP involvement. However, practitioners and other stakeholders often expressed concerns about the legality of this option. One other stakeholder suggested PIAG approval should be sought if this option was to be used.

Either way, it was thought essential that the initial approach letter should make it absolutely clear:

- Where personal details had been obtained
- Why people had been selected
- What they were being asked to do and why
- How their interests would be protected

Indirect GP involvement was considered inevitable (i.e. that patients would seek reassurance from them, that GPs would have to provide full access to medical records, etc). Given that indirect GP involvement was considered inevitable, an awareness raising campaign among primary care professionals was considered essential.

“... Most GPs are not genetically competent. That’s the first thing. That’s my big challenge. So you’d have a huge education programme in terms of varying GPs who are participating [to allow them] to meaningfully discuss the project with their patients.” (Other Stakeholder)

Primary care professionals were concerned about the impact this project will have on their workloads (whether they have direct or in direct involvement) and requested clarification about remuneration, etc.

4.2.2 CONSENT

Raising public awareness of the project and providing relevant and accessible information in advance of any kind of face to face consultation with a UK Biobank nurse were thought essential to enable informed consent. There was agreement that the IAG had identified a comprehensive list of topics to be covered during the initial consultation. Striking an appropriate balance between openness and transparency and potentially overloading participants with information (given the perceived complexity of the project) caused concerns. Other stakeholders were concerned about the potential length of the recruitment questionnaire and/or the consent form. There is agreement across stakeholder groups that consent should be obtained in writing and should (ideally) include an expression of preferences in terms of withdrawal (see notes below). A few other stakeholders thought obtaining ‘blanket consent’ contravened MRC guidance. Overall, informed consent was considered key to retention, especially among other stakeholders and practitioners.

“It’s better that consent is one-off ... as it will get a bit too complicated.” (Politician)

“People need to give informed consent, but it’s hard to know for prospective studies like that, what they are consenting for. We don’t know what can be done in the future. Consent will have to be vague then, to ensure that it covers most things. People need to know that there are things that may develop in the future that we don’t know about.” (Politician)

On-going consent was considered essential due to uncertainty both about the precise uses of the resource and the frequency of recontact / level of inconvenience encountered by participants. While some members of the public were willing to place their faith in the project to protect their best interests, others (including several stakeholders) believed it would be important to seek re-consent for future uses of the resource (e.g. that individuals should be given the opportunity to opt out of individual studies or to consent to batches of studies).

“As it will not be possible to explain all research uses of UK Biobank, subjects will be asked to give blanket consent and consent waivers e.g. to the oversight body. However, it is crucial that the types of research that will or will not be allowed are explained in as much detail as possible.” (Postal Questionnaire)

All stakeholders considered active participation (i.e. dialogue) essential to retention. This involves providing information on the use of the resource and the value derived from their involvement as well as providing mechanisms for participants to ask questions / discuss their concerns.

Lack of specificity about the meaning of the terms such as ‘public good’ or ‘public interest’ raised concerns. Clarification is required as to who will determine whether or not uses are for the public good, and the extent to which participants / the public will be involved in the process. To this end, the establishment of an oversight body and participants’ panel is considered vital.

4.2.3 COLLECTION OF DATA FROM MEDICAL RECORDS

Many did not understand why full access to medical records was required (e.g. instead of selective access, or participant self-reporting only). Those who had concerns about the project as a whole wanted reassurance that anonymity and confidentiality would be preserved and for the implications of ‘full access’ to be covered at the point of recruitment. Primary care staff expressed concerns about the impact of full medical records on their workload.

“If they’re looking for full access to the full medical record of each participant from a doctor’s surgery, that does raise suspicion.” (Public, 45-69 year old)

Strong concerns were expressed about the variable quality of GP records, incompatibility of computer systems used, transfer of information from secondary to primary care, and the potential impact this may have on the quality of data gathered. However, there was some acknowledgement of the current programme to improve primary care information systems.

4.2.4 FEEDBACK

Feedback caused much debate. Most thought feedback should be given on any tests conducted at the time of recruitment (e.g. blood pressure, cholesterol, etc). Several practitioners and other stakeholders thought that research nurses had a professional obligation to provide such feedback, but required training and professional indemnity if they were to do so. However, respondents were divided on whether or not they should be informed about the

results of subsequent tests. The public and some practitioners thought people should be given the choice whether or not to receive feedback on predictive genetic tests. Several other stakeholders were concerned that people do not really know the implications of this and that feedback of such test results should not be given. All stakeholder groups required clarification of the precise tests to be conducted at the point of recruitment, post-anonymisation of samples, etc. before they felt able to give an informed view of the ethical and governance implications of feedback.

“If they’ve got a cholesterol of 12 and they’re going to die within the next year, are you going to tell them?” (Public, 45-69 year old)

“[Feedback] must be seen to be absolutely open to everybody.” (Politician)

“People need to know that they are only going to get feedback at the initial physical testing stage, but aren’t going to get direct feedback after that.” (Politician)

It was however agreed that if feedback is not to be given, clarification of reason for this needs to be provided to participants.

4.2.5 ONGOING DIALOGUE WITH PARTICIPANTS

Active participation was considered essential by all audiences to ensure retention, but an appropriate balance was thought necessary between keeping people informed and not being too obtrusive. The measures outlined by the IAG were considered appropriate (including a website, newsletter, public meetings, enquiry and complaints’ telephone line). The public and other stakeholders also suggested the use of open days and workshops. Feedback both on the use of the resource and the value derived from the resource was thought necessary. Many from each stakeholder group supported the formation of a participant panel, but stressed that this should allow for anonymous participation (e.g. in surveys of participant opinion).

There was also widespread agreement that an appropriately staffed enquiry and complaints line should be established.

4.2.6 EXPECTATION OF RECONTACT

Many from other stakeholder groups were concerned about the level of recontact required to make the resource a success. It was assumed that samples would need to be continually drawn to satisfy the research needs of those using UK Biobank. Many stressed the need to ensure that recontact does not become too onerous because it may lead to attrition. Those with concerns believed the frequency of recontact should be covered in detail at the point of recruitment.

“It would seem appropriate and necessary that some indication as to frequency of that contact should be outlined at the time of gaining consent. This is likely to have an impact on the uptake into the project.” (Other stakeholder)

4.2.7 RIGHT TO WITHDRAW

The right to withdraw was considered of fundamental importance to the project. There was widespread agreement that participants should have the right to withdraw altogether if they wish (e.g. if displeased with specific uses of UK Biobank) despite the fact that this might jeopardise the future of the project. Reassurance / a guarantee was required by all groupings that samples and data would be destroyed in the event of such withdrawal.

“If you’re asking people to participate in something like this then you would have to offer them a choice of how much ... - they might want to withdraw totally ... I don’t think you’d get a very good signup if you were saying you can only withdraw under this [or that] circumstance.” (Other stakeholder)

“Everything should be removed, because that information could impact onto that person’s children and relatives.” (Politician)

Given the potential difficulty of keeping track of participants it was considered pragmatic by other stakeholders to continue to use the data of an individual who had not ‘actively’ asked to be withdrawn (involuntary withdrawal). In this scenario also the use of ‘last valid consent’ was considered reassuring, as at last contact the individual would have had opportunity to withdraw.

The public emphasised that the process in relation to withdrawal needs to be made as easy as possible and considered that other options for withdrawal were also necessary (including an advance directive).

The public and other stakeholders were keen to understand exactly how UK Biobank would safeguard the confidentiality and security of participants’ data and samples after death. A number of members of the public emphasised that it would not be appropriate to contact the family of a participant who had passed away. In contrast a stakeholder suggested that in relation to incapacity and death family members make a ‘best interest’ assessment.

4.2.8 EXPECTATION OF PERSONAL FINANCIAL GAIN

Donating samples and data as a gift was considered normal research practice among many other stakeholders and practitioners. Many members of the public were similarly happy to participate on this basis, but often expressed concerns that others would not be so publicly spirited. Those who were more cynical about the project as a whole thought that they and others would not take part without a personal incentive (although this could include health benefits, in the form of feedback).

4.2.9 CONFIDENTIALITY

Given the highly sensitive nature of the data and samples gathered, reassurance that measures will preserve anonymity and confidentiality were considered paramount. The public and other stakeholders believed that the confidentiality of the data needs to be fully secured and protected. Participants wanted to know how this would work in practice.

Yet, most are satisfied with the measures outlined although admitted to not understanding the different IT implications. One stakeholder suggested that UK Biobank should look at the protocol used for clinical trials in relation to the Food and Drug Administration (FDA). The use of a package, which ensures data integrity and security, was suggested as was a common criteria for those who have access to the database such as 2FCR Part II.

The ability to re-identify data raised concerns about the process of anonymisation and the public wanted reassurance that their interests would be protected. Some stakeholders considered that there should be a separate body to oversee security and encryption and another that holds the key to re-identification. Further to this some stakeholders considered that in this case the body overseeing security should have the power to enforce sanctions and close the body down if security is not tight enough.

4.2.10 RESEARCH ACCESS TO DATA AND SAMPLES

There is concern about the lack of certainty about how UK Biobank resource will be used and how licences provided for use will be policed (e.g. will commercial companies obtain data for one purpose, but use it for another? Will they be able to develop tests that in effect compromise the anonymity of participants, e.g. for very rare conditions? Will they gain covert access to data, e.g. by funding university departments?).

“The government hasn’t undertaken an absolute exclusion on the police getting use of it. I think it should not be open to them at all. That needs to be set down.” (Politician)

There was a mixed response on the issue of providing access to commercial companies. Some public considered that profit making companies should be charged more than those who come from a non-commercial background, whilst others considered that access to the resource should be free so as not to create a financial incentive for those running and administering the resource.

“...this business of access ... to commercial companies ... that brings the money thing into it which to me rings warning bells immediately. I think anybody or virtually anybody, can be bought if there is enough money free to do it. I just don’t like the commercial bit at all.” (Public, 45-69 year old)

A minority thought using profits for the ‘community’s benefit’ too vague and open to potential abuse. Others suggested that it should be used to fund research, improve NHS service provision, etc. In general all respondents considered the term ‘public benefit’ too broad and vague. Clarification is required on who will decide this and whether or not the oversight body, participants / the public will be involved.

The public and practitioners were concerned that other interested parties may gain access to the resource (in particular, the police) and that this should be made clear to participants at the outset. Although they accepted that financial services would not gain access, many were concerned that the publication of results may encourage such institutions to insist on genetic testing to determine risk / susceptibility to conditions before therapies were available.

Other stakeholders also wanted clarification on whether or not companies will be able to patent genetic codes.

Overall, many within each stakeholder group called for all applications for use of the resource, acceptance and rejection of applications, and subsequent use and findings to be open to public scrutiny.

Respondents also generally considered that UK Biobank should ultimately become financially self-sufficient.

4.3 INTERNAL GOVERNANCE

4.3.1 The structure of UK Biobank

There were few concerns about the structure of UK Biobank. A few other stakeholders wanted clarification regarding whether or not Collaborating Centres would gain privileged access to samples and data. Most approved of the IAG suggestion that they should not. It was also generally considered appropriate that there should be some kind of oversight body that operates as a check on the Board of Directors of UK Biobank.

“Can I ask what’s in it for the Co-ordinating Centres and the Collaborating Centres? Do they get payment ... clearly they get some form of kudos, what else do they get out of this? Do they get free access to the data?” (Other stakeholder)

Ideally, both the public and other stakeholders would want to know who will and will not have access to UK Biobank as well as what uses will and will not be sanctioned. MREC approval provided some reassurance but other stakeholders were concerned that abuse of data remained a possibility, which heightened calls for independent oversight of the project and openness and transparency at all stages.

“You need not only just an NHS Ethics Research Committee, which at the end of the day is one committee, chaired by one person. You’d need a whole series of organisations keeping an eye on them.” (Public, under 45 years of age)

“It should elect its own chair. Shouldn’t be government appointed, it should be independent of government.” (Politician)

Clarification was required regarding the sustainability of the project financially, the charging structure and potential use of any profits generated, and what would happen to samples in the event of bankruptcy.

Both the public and other stakeholders suggested the involvement of participants in the governance of UK Biobank either inside or outside the structure. Other stakeholders endorsed the training of these individuals to enable them to participate effectively in any governance structures. A politician spoke of the need to set up a committee which particularly sought to represent the views of those enrolled with UK Biobank. This body could then act as the voice of the contributors and asked to give a view on decisions where necessary.

4.3.2 Oversight body

MREC approval provided some reassurance about protection of the public interest. However, all stakeholder groups considered the establishment of a truly independent oversight body as paramount to the success and safety of the project. Some stakeholders also saw a key part of the oversight body’s role to ensure that data is correctly protected and the security systems well implemented. There was also agreement that it would be appropriate for an Oversight Body to handle serious complaints.

Those who have experience of the Nolan Principles had mixed views of their value some felt they are worthwhile but others were less convinced.

*“The Nolan principles almost ensure that the people you want on public bodies don’t get on.”
(Politician)*

Most agreed that funders, the Co-ordinating Centres and Collaborating Centres should be excluded from this body. It was suggested that membership of the oversight body should include:

- Research Scientists / GPs
- Public / lay representation
- Church / Religious representation
- Ethics experts
- Legal representation – Magistrates
- Charity Commissioners

“The committee should consist of a range of people, lay people definitely. Most advisory groups do have lay people.” (Politician)

A number of stakeholders, the public and politicians emphasised that these positions should not be permanent appointments. It was suggested that such appointments should last for a limited number of years.

Almost all wanted the oversight body to have a role both as an adviser and as an arbiter. Many believed it should hear any serious complaints about Ethics and Governance issues. Several other stakeholders wanted it to set ‘public interest’ criteria and to assess whether applications for use of the resource meet them. Several suggested it should hear appeals against refusal of access. All stress the need for the oversight body to take decisions in public and publish its decisions for public scrutiny.

“And my preference, I think, would be to have it operating in public, and make it advisory, so that it was highly embarrassing, or could be highly embarrassing, for the management to go against this, and if they were to go against it, they would have to have a jolly good scientific reasons.” (Politician)

4.4 QUESTIONS FOR CLARIFICATION

Several further points for clarification were identified through the consultation work, including:

- How and who will decide mental incapacity (given its potential use to explore mental health issues)?
- What tests will be conducted and the feedback that may be possible at the point of recruitment and subsequently (to enable people to determine the desirability of feedback per se)?
- Whether people can opt out of individual studies or consent to batches of studies?
- Why full access to medical records is necessary and how will potential problems with the reliability of data gathered will be handled?
- What level of recontact and inconvenience can people expect as a result of volunteering?
- What users of the resource will be charged and how monies raised will be used?
- How will the public interest be preserved if diagnostic tools are identified long in advance of any therapies or cures?
- Exactly what is meant by the 'public interest' and 'public good' and who and how this will be determined?
- What will happen to data and samples in the event of bankruptcy?
- Will users be able to patent genetic codes?
- How will licenses awarded to users be policed (especially given concerns about covert access via university departments)?
- Participants reiterated that open and transparent working should be the guiding principle in respect of all UK Biobank's operations and decision-making.

APPENDICES

APPENDIX I

POST WORKSHOP QUESTIONNAIRES

Summary Findings

At the end of each workshop participants were asked to complete a questionnaire summarising their views on UK Biobank and the workshop itself. The comments about UK Biobank have been incorporated into this report. This note summarises participants' attitudes towards volunteering for UK Biobank and their thoughts on the workshops.

Feedback on the workshops

Participants found the workshops interesting, informative and enjoyable. A minority of participants from the public workshop found the day confusing. The table below shows how the 43 participants who filled in a post-workshop questionnaire found the workshops.

Interesting	38
Informative	26
Enjoyable	24
Hard work	20
Confusing	10
Easy	4

Participants were asked to explain what they considered to be the best thing about the workshop. There was a diverse range of answers including:

- The diversity of people attending the workshop
- The opportunity to listen to a range of views and opinions
- The opportunity to learn about UK Biobank
- Good to be involved in discussion and consultation
- The opportunity to raise your concerns and have your voice heard

Participants also commented on the professionalism and organisation of the day and the interplay between members of the public, health professionals and representatives from UK Biobank.

Participants were also asked to consider what they felt to be the worst part of the workshop. Many participants complained that the day had been long, and hard work. However, other participants had concerns that there had not been enough time to reflect adequately on all the issues. Some respondents said that they would have liked more information on UK Biobank and further clarification on the questions they had raised.

**APPENDIX II
WORKSHOP MATERIALS & AGENDA**

UK BIOBANK

COLLECTION OF DATA/ CONFIDENTIALITY

- UK Biobank will require access to the full medical record of each participant
- Data will be treated in a highly confidential manner
- UK Biobank will ensure that data and samples are linked, anonymised and stored in accordance with the highest security and encryption standards
- Data will be collated by research nurses and transmitted to Collaborating Centres in encrypted form
- From there it will be sent to a Co-ordinating Centre where data will be made anonymous
- This process will be reversible
- Bar-coded blood samples will be transported directly to the Co-ordinating Centre

Option 1:

The current preferred option is to create a relational database. This would allow data matching with specific search criteria and therefore involve extraction from flagged records. This would operate on the same basis as a search engine, extracting information from GP / PCT databases. This approach provides benefits of security, accuracy in updating information, and economy of processing.

Option 2:

Another option would be to create a regularly updated UK Biobank database, storing relevant information from the medical record. This would mean that all the information is held in one place.

UK BIOBANK

CONSENT & FEEDBACK

- Consent will be based on an understanding of the following:
 - Overall purpose of the UK Biobank to benefit the community
 - Study takes place over a long period of time
 - Lifestyle data and blood sample to be collected at recruitment
 - Ongoing link to participants' medical records
 - Procedures for access to and use of data
 - Possibility of being recontacted from time to time
 - Right to withdraw at any time
- There will also be ongoing dialogue with participants
- UK Biobank will not provide feedback to individual participants concerning data generated from their samples
 - During initial data collection, limited feedback will be provided to participants according to a clear procedure & nurses may advise participants to contact their GP for further investigation if necessary
- Results will be made available through publication of findings & through general communication with participants
- There will be a procedure in place for handling enquiries & complaints

UK BIOBANK

DATA MANAGEMENT / ACCESS

- The UK Biobank will:
 - Act as owner of the database and samples
 - Hold the samples and data in trust for the public benefit
- All proposals for use of the data will be subject to a stringent scientific and ethical review by UK Biobank and ultimately by a NHS ethics research committee
- The UK Biobank will not exclude uses 'up front'
 - But from time to time it may determine that certain types of use are not compatible with its statement of purpose
 - And certain individuals or organisations may not be given access to the database
- All approved uses will be licensed under stringent terms and conditions and safeguards will be in place to:
 - Protect confidentiality
 - Protect security of participants' data and samples
 - Ensure that UK Biobank is used in the public interest
- Access will be given to:
 - Commercial companies and other research that stands to make a profit
 - Non-profit making ventures
 - BUT UK Biobank will not provide exclusive access to the data to any single party

UK BIOBANK

WITHDRAWAL

- Participants will have the right to withdraw from the study at any time
- In the event of incapacity or death, UK Biobank will aim to:
 - Protect the interests of participants who lose mental capacity
 - Treat the wishes of deceased with respect
 - Safeguard the confidentiality and security of participants' data and samples after death

Withdrawal

Option 1 – Withdraw

Samples and identifiable data would be destroyed. Any links to medical records would be broken.

Option 2 - Discontinue participation

No more information would be collected. Any links between the participant and samples or data, including the link with the health record, would be destroyed. This would allow the samples and data already contained in the UK Biobank to be used, but no further contact with the participant would be made.

Incapacity and Death

Option 1 - Last Valid Consent

Continuing participation, on the basis that participants would have been reminded how to withdraw as part of their likely annual recontact.

Option 2 - Advance Directive

Initial consent would include asking the participant what they would like to happen to data and samples should they become incapacitated or should they die.

UK BIOBANK

RECONTACT

- All recontact will be made through UK Biobank
- The need for recontact is anticipated for 3 reasons:
 - To provide information on project developments, uses etc
 - To collect additional data / samples
 - To collect further lifestyle information

UK BIOBANK

UK BIOBANK AND PUBLIC

- Participants will not be offered any financial or material incentive, but expenses may be reimbursed. They will be participating for the public good.
- UK Biobank will ensure that all results generated through access to the database are made publicly available in due course
 - But it will allow users to keep results confidential for specific periods of time
- UK Biobank would seek to ensure that the UK community obtains the greatest possible benefit from the use of the database
- The generation of knowledge and understanding is a principle value of the UK Biobank database

UK BIOBANK RECRUITMENT

- The UK Biobank will recruit:
 - 500 000 volunteers
 - aged between 45 and 69
 - reflecting the diversity of the population
- UK Biobank will not recruit anyone who is:
 - Terminally ill
 - Mentally incapacitated
 - Unable to give consent
 - Unable to attend initial consultation
- In order for UK Biobank to provide robust data to scientists it must retain as many participants as possible

Option 1:

Recruitment via the GP – the initial approach would be made by a letter from the GP. Interested participants would be referred to a research nurse for interview.

Option 2:

Direct recruitment – participants within the target age range would be identified via the Primary Care Trust list and receive information about the resource direct from UK Biobank. If interested, they would be referred to a research nurse for interview.

UK BIOBANK

STRUCTURE AND GOVERNANCE

- UK Biobank will be centrally controlled from a Co-ordinating Centre which will have overall responsibility for delivering the project including:
 - Data management
 - Quality assurance
 - Computing and financial management
 - Formal custodianship of the data and biological samples
- It will be a charitable company limited by guarantee, jointly owned by the Wellcome Trust and the Medical Research Council
 - As such it will only be allowed to act in the public good
- It will co-ordinate the activities of 5 or 6 Collaborating Centres, which will be responsible for:
 - Recruitment of volunteers
 - Collection and storage of initial sample and data
 - Managing access by other groups to the database
- Funders will establish an independent oversight body to:
 - Ensure compliance with the ethics and Governance Framework
 - Safeguard the interests of participants and the general public
 - Take all key policy decisions in public



UK BIOBANK

POST-WORKSHOP QUESTIONNAIRE

1. What do you think are the main benefits of UK Biobank?

2. What are your main concerns about UK Biobank?

3. How effectively have the measures discussed today addressed your concerns?

4. What, if any, are the outstanding issues for you?

5. Would you consider being a volunteer for UK Biobank

YES	
NO	

6. Why do you say that?

7. How would you describe the workshop you have just taken part in? Please tick as many as you like

Interesting	
Confusing	
Hard work	
Boring	
Enjoyable	
Easy	
Informative	

8. What do you think was the best thing about the workshop?

9. What do you think was the worst thing about the workshop?

10. Is there anything else you would like to add?

Name: _____

Thank you for your help

Please return your questionnaire to Julia

Document sent by post with questionnaire

Introduction

Draft Statement of Purpose

“The UK Biobank will monitor the health of a large number of volunteers for many years, collecting high quality information on environmental and lifestyle factors, linked to biological samples. This will result in a resource that will be used for ethically and scientifically approved research, with the aim of improving the prevention, diagnosis and treatment of diseases and medical conditions within society. Every safeguard will be put in place to secure that both healthcare information and samples are held in trust for the public benefit and to ensure due respect for the rights, choices and privacy of participants.”

Recent developments in relation to UK Biobank:

There have been a number of developments in relation to UK Biobank over the last year: Dr John Newton has been appointed as the Chief Executive Officer for the UK Biobank Project. Dr Newton is a public health specialist and epidemiologist and is former Director of Research at the John Radcliffe Hospital in Oxford.

The structure of the UK Biobank has been announced. There will be a coordinating centre based at the University of Manchester plus six consortia of 21 universities called Collaborating Centres. These will be responsible for recruitment and collecting the data. The coordinating centre will be responsible for managing the database

The Ethics and Governance Framework for UK Biobank is under careful consideration. The text below summarises the key issues under discussion.

Overview of Ethics and Governance Framework

1. Governance

UK Biobank will be set up as a charitable company limited by guarantee. It will be jointly owned by the Wellcome Trust and the MRC and can only act in the public good. The coordinating centre will have a board of Directors, comprising one member each nominated by the funding bodies and six independents.

UK Biobank is also considering establishing an independent Oversight Body. The Oversight Body's overall remit might be to ensure compliance with the Ethics and Governance Framework, and to safeguard the interests of participants and the general public. Also, it is proposed that the Oversight Body will take all key policy decisions in public.

UK Biobank, and research undertaken using the resource, will comply with other governance mechanisms such as the NHS Research Governance Framework. Also a NHS research ethics committee will review the core protocol, and later proposals to use the resource. Participants will be informed that this independent review will take place before access will be provided to data or samples.

The coordinating centre will be responsible for implementing the Ethics and Governance Framework. The Ethics and Governance Framework for UK Biobank will be reviewed periodically, as will the scientific management, policy, and research output.

2. Relationship between UK Biobank and participants

A. Recruitment

UK Biobank aims to ensure that the whole population of the UK may benefit from this study, by reflecting the diversity of the population. Recruitment should be undertaken in a way that respects cultural and religious differences, and preserves the voluntary nature of participation. UK Biobank will not recruit anyone who is terminally ill, mentally incapacitated or otherwise unable to give consent or unable to attend the initial consultation.

There are two options in relation to recruitment being considered:

- Recruitment via the GP – the initial approach would be made by letter from the GP. Interested participants would be referred to a research nurse for interview.
- Direct recruitment – participants within the target age range would be identified via the Primary Care Trust list and receive information about the resource direct from UK Biobank. If interested, they would be referred to a research nurse for interview.

B. Consent

To preserve its value as a longitudinal cohort study, UK Biobank should aim to retain as many participants as possible. It is therefore important to recruit those who are likely to remain in the study.

Consent will be based on an understanding of the following:

- the overall purpose of the UK Biobank, to benefit the community, in accordance with its statement of purpose
- the nature of the project as a longitudinal cohort study and the requirements this imposes
- the data and samples to be collected at recruitment
- an ongoing link to participants' full medical records (past and future, primary and secondary care)
- the process for making decisions on access to the resource and the many safeguards that will be in place (laws, operating procedures, NHS Research Ethics Committee review, review and governance mechanisms established by the Ethics and Governance Framework)
- the intention to carry out ongoing public consultation
- the possibility of being recontacted from time to time, including who will hold personal information to allow this
- the right to withdraw at any time.

Further consent should be sought when new elements are introduced, rather than revisiting the terms of the initial consent. However, annual recontact (for other purposes) may provide a natural opportunity to remind participants how to withdraw from the study, thereby confirming their continuing desire to participate.

C. Access

Data will be treated in a highly confidential manner to protect participants.

Currently there are two options under consideration in relation to data extraction and storage. The current preferred option is to create a relational database. This would allow data matching with specific search criteria and therefore involve extraction from flagged records. This would operate on the same basis as a search engine, extracting information from GP / PCT databases. This approach provides benefits of security, accuracy in updating information, and economy of processing.

Another option would be to create a regularly updated UK Biobank database, storing relevant information from the medical record. This would mean that all the information is held in one place.

D. Feedback

UK Biobank is considering how much feedback information to provide to individual participants concerning data generated from their samples, including results of tests or analyses undertaken. During initial data collection, limited feedback could be provided to participants according to a clear protocol and nurses could advise participants to contact their GP for further investigation if necessary (e.g. because of high BP result).

Results of studies will be made universally available through publication of findings in peer-reviewed literature and through general communication with participants and the public. UK Biobank will also establish regular communication with participants by a variety of means, in order to involve participants in the study as it develops, to feed back findings from UK Biobank research, and to maximise retention of participants within UK Biobank.

A procedure for handling enquiries and complaints will be put in place to ensure that participants and users and potential participants and users have confidence in UK Biobank and a means of redress should this be necessary.

E. No personal gain

Participants will not be offered any financial or material inducement to participate, at sign-up or later. Reasonable expenses incurred through participation in the research, such as travel expenses, may be reimbursed. UK Biobank will treat samples as gifts or donations.

G. Profit making and access by commercial users

Commercial companies and other research endeavours that stand to make a profit may be allowed access to UK Biobank, as well as those that are non-profit-making, if they meet the appropriate criteria.

Safeguards will be in place to protect the confidentiality and security of participants' data and samples and to ensure that UK Biobank is used in the public interest.

All proposals will be scrutinised to see whether they comply with UK Biobank's statement of purpose (i.e. "ethically and scientifically approved research with the aim to improve the

prevention, diagnosis and treatment of disease in society”). Access for other purposes will not be granted.

H. Recontact

All recontact will probably be made through UK Biobank in the first instance (with the possible exception of contact to seek consent to conduct genetic tests of high predictive value).

Three reasons to recontact participants are anticipated:

1. to provide information on the project – this would probably be done annually, and would include a change-of-address notice and a reminder to participants how to withdraw if they wish
2. to collect additional data e.g. by linking to another database, without recalling participants
3. to collect further information (e.g. updated lifestyle information) or samples from the participants, or to conduct particular tests.

Recontact may also be made (probably with the advice of the Oversight Body) for consent to new uses.

I. Respect for incapacitated and deceased participants

UK Biobank will aim to protect the best interests of participants who lose mental capacity and will seek to treat the wishes of deceased participants with respect. UK Biobank will safeguard the confidentiality and security of participants’ data and samples after death.

Currently there are two options being considered as to how this might be best handled:

- Last valid consent - this would mean continuing participation, on the basis that participants would have been reminded how to withdraw as part of the likely annual recontact.
- Advance directive – initial consent would include asking the participant to state what they would like to happen to data and samples should they become incapacitated or should they die.

The policy adopted will be explained to participants. Those unable to give consent at enrolment will not be recruited.

J. Right to withdraw

Participants will have the right to withdraw from the study at any time. This is essential to preserve the voluntary nature of participation. It is suggested that UK Biobank could offer participants the option either to:

1. Withdraw – entailing the destruction of identifiable data and samples and breaking the link to the medical record.
2. Discontinue participation – not collect any more information and break the link between the participant and samples and data, including the link with the health record. This would allow the samples and data already contained in UK Biobank to be used, though no further contact with participant would be made.

K. Data Management

UK Biobank will comply with UK legislation and regulation relating to participants’ rights over personal information. UK Biobank will monitor developments in this field, and seek revised consent from participants if necessary.

UK Biobank will ensure that data and samples are linked, anonymised and stored in accordance with the highest security and encryption standards. Samples will not be released to third parties, other than under contract, e.g. for sequencing.

Data will be collected by research nurses and will be transmitted to Collaborating Centres in encrypted form and from there sent on to the coordinating centre, where data will be reversibly anonymised. Bar-coded blood samples will be transported directly to the coordinating centre (Hub).

3. Relationship between UK Biobank and users

A. Control & conditions of use of samples and data

UK Biobank will not provide exclusive access to the resource to any party. In law, UK Biobank will be the owner of the database and the samples, although it is unclear who will own information derived from the samples. UK Biobank views its role as that of a custodian or steward and will hold the samples and data in trust for the public benefit in accordance with its statement of purpose. Samples will not be returned to participants who withdraw, but will be destroyed.

B. Public release of findings as a condition of use

In order to maximise potential benefit from the resource UK Biobank will seek to ensure that all research results generated through access to the database are made publicly available in due course. This will include 'negative' findings. UK Biobank will permit users to keep new data confidential for specific periods of time, to enable results to be analysed and publications prepared or applications to be made for patent protection where appropriate. This will be strictly regulated.

C. Benefit to the community:

UK Biobank will seek to ensure that the UK community obtains the greatest possible benefit from the use of the database. In addition, reporting of all results, and copying of results back to the resource, will contribute to benefit sharing.

The principal value of the resource is expected to be the generation of knowledge and understanding. UK Biobank mainly will be used to test or develop hypotheses, and is not expected to return a significant income to the UK Biobank or users. Rather, it is expected to become a valuable public good.

UK Biobank Ethics & Governance Framework - Questionnaire

- 1. What do you consider to be the main strengths of the UK Biobank to be and why?**

- 2. What do you think are the main weaknesses of the UK Biobank and why?**

- 3. What things do you think the UK Biobank needs to do to ensure that it works in the public interest and why?**

- 4. What comments would you like to make on the draft ethics & Governance Framework and why?**

- 5. Any other comments?**

Thank you for taking the time to complete this questionnaire.