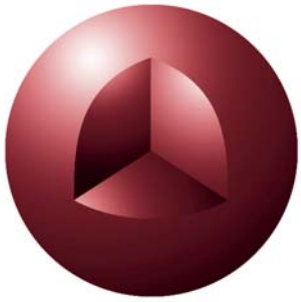

People Science & Policy Ltd

BioBank UK: A Question of Trust:
A consultation exploring and addressing questions of public trust

Report prepared for

The Medical Research Council
&
The Wellcome Trust

March 2002
01/022/sk

People Science & Policy Ltd
Hamilton House, Mabledon Place, London WC1H 9BB. Tel: 020 7554 8620
E-mail: info@peoplescienceandpolicy.com
Web: www.peoplescienceandpolicy.com
Registered in England and Wales, no. 3891609

Contents

1. Executive Summary

Introduction

The Wellcome Trust (WT) and the Medical Research Council (MRC) commissioned People Science & Policy Ltd to conduct a public consultation about the ethical and management issues surrounding the proposed BioBank UK project.

Research Method

Three sessions were held in January 2002 in Hertfordshire, the West Midlands and Glasgow. Each session involved 20 people[1] in the age group 45-69 (the proposed age of volunteers for BioBank UK). They were split into two groups of 10 for an introductory session of 1½ hours on a weekday evening. The groups were 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.

Everyone actively participated. People were willing to discuss the issues and all had thought about the project between the two sessions. Some useful practical ideas to support the development of the project were generated.

Issues

The results of this consultation can be structured around the main issues identified by participants. Addressing these will be critical for the success of BioBank UK. The five questions Genewatch suggests potential volunteers ask before agreeing to take part are subsumed within these. This report is structured around the issues identified by participants:

- Recruitment
- Access to the data, the samples and confidentiality
- Uses to which the data will be put
- Governance of BioBank
- Value for money
- The name "BioBank UK"
- Further consultation

Recruitment

Motivation

Participants were very supportive and the great majority said they would take part on the basis that research was *"a good thing"* and that valuable information would come out of the study. However, the project team should be wary of participants over-claiming their altruistic motivation in a group setting.

[1] Only 19 people took part in Glasgow.

Potential barriers to participation

While most of the barriers to participation are practical, some have a more philosophical basis. For some participants the practical barriers were sufficient justification for not taking part. Others said that they would not take part because they were ethically opposed to the idea. Yet others may justify their inertia by citing ethical concerns or by saying that the study has not been thought through and will not provide reliable data.

Respondent burden

This consultation identified that inertia and apathy, lack of motivation, some reluctance to give blood and, for some, unclear benefits, are likely to reduce the response rate. There was general acceptance of the content of the initial examination and lifestyle questionnaire. Some participants recommended that lifestyle data should be up-dated more regularly than proposed.

The location, timing and content of the initial data collection are important factors in whether people will take part. Participants were also concerned about the time involved for monitoring, although it was understood that it was entirely through records and that *"you would probably forget you were in the study"*.

"Isn't this already being done/known?"

There was a general sense that more is known about genetics than is actually the case. Some participants were therefore sceptical that BioBank would add anything to existing knowledge or current research.

Scale of the study and representativeness

Questions were asked about the scale of the project and why so many people were needed. Once there had been more discussion there was a feeling that perhaps it was not large enough.

There was concern about differential response rates. Participants suggested that those from poorer backgrounds, the obese, those with unhealthy lifestyles, etc. may be reluctant to come forward. Conversely, those who see themselves as healthy may not realise that they are still very important to the study.

Questions were also raised the about how honest people would be in giving lifestyle data.

Age

There is limited understanding about the rationale behind the age group selected.

Impact on general practitioners

Some participants were concerned about the burden on GPs and the implications of this for healthcare delivery. Others looked for assurances that their GP would not have access to their lifestyle data.

Value for money

The question of whether or not this is the best use of the money was raised. The majority view was that it would be if it delivers what it promises.

Feedback

For many this is a real potential motivator. Participants saw the initial examination as an *"MOT"* and had high expectations of the feedback. They initially believed that their sample would be tested to ensure that they are well. The limitations of any testing must be made very clear.

Access and confidentiality

Under this heading we include access by users (both non-commercial and commercial); volunteers and their families; GPs; the police; insurance companies and employers; as well as illegal access.

It is clear 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 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 generally pragmatic attitudes to illegal access were summed up by the quote:

> *"You don't have to wait for BioBank to exist for people to hack into data about you."*

Uses

Participants were keen to know how the data would be used. Questions such as *"Will certain diseases be given priority?"* were asked.

There was little interest in whether the information might be used to study the genes of behaviour or personality, even though the moderators raised it with participants. This does not mean that use of the data is not an issue. This is what might be termed a second order issue that is likely to be discussed in more depth once more immediate concerns, such as confidentiality and general purpose, have been dealt with.

Arguments about the emergence of a "genetic underclass" were not picked-up either, although the impact on insurance premiums was an issue raised spontaneously. There was some concern that if direct access to samples, rather than just data, were to be allowed, that individual volunteers might be cloned.

Governance

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. Two main models emerged.

The first was a fairly traditional stakeholder panel with users, funders, volunteers and the medical profession represented. Participants proposed that it should be headed by a well known person, maybe a retired judge. The individual members would be nominated or recruited through advertising. A role was also identified for people not directly involved in the project, and *"with no financial interest"* such as lawyers, clerics, etc.

The second model involves proactively seeking lay members with no vested interest in BioBank. They would be supported by professional staff and have the ability to consult more widely on specific issues as they saw fit. Some participants believe that *"no one who wants to be on it [the oversight board] should be"*.

Participants said that this oversight body should agree the rules for access, use, royalty payments, guarantee destruction of sample for those who wish to withdraw, and set sanctions for those who abuse their right of access. Generally, any such body should ensure that standards of behaviour and ethics were maintained and continued to reflect the public mood as the public consensus changes but within the original terms of the consent given by volunteers.

There were two minority views expressed. One held that *"if it is that important the Government should be doing it"*. The other was that as *"the Wellcome Trust and MRC are reputable bodies, why can't they do it?"*.

"BioBank UK"

The first session began by briefly exploring how participants reacted to the name "BioBankUK". For those who remembered that the recruitment had mentioned medical research this may have coloured their responses.

The name appears to describe any database or storage facility. It generally left participants with a somewhat negative impression and there was rarely an immediate connection to disease, medical research or therapy. The word *"bank"* introduced ideas of *"commercial involvement and making money"* to some.

Further work

This exercise has worked well as a public consultation. The groups thought through the issues put to them, discussed them with the project team and made recommendations on how problems might be addressed. However, in the five weeks available for this research it was not possible to ensure sufficient representation from social groups D and E (semi-skilled workers and those wholly dependent on state benefits).

The development of BioBank will benefit from further engagement with the people who have taken part in this exercise. They are now fully briefed on the proposals and are aware of the issues. Many of these issues would benefit from further discussion, especially if the sponsors are to be able to address the concerns of critics of BioBank UK.

Recommendations

Recommendation 1: The details of the helpline must be clearly stated on the initial contact letter. Helpline staff must be able to answer questions and discuss concerns with callers.

Recommendation 2: Taking part must be made as easy as possible. People may look for excuses to justify their inertia.

Recommendation 3: Setting out how this study adds value to existing work will sway some waverers. This needs to be clear in the initial recruitment material.

Recommendation 4: There must be clearly set out answers to questions about the size and make-up of the sample. It must also be clear how and why that individual has been selected as well as why they are important to the study. This should sent with the recruitment letter but might be contained in a separate leaflet. Such information will also be crucial to support the telephone helpline staff.

Recommendation 5: It must be clear from the initial documentation sent to potential volunteers why healthy people are important to the study and how their data will be used. It was more obvious to participants why less healthy people are relevant.

Recommendation 6: The role of GPs must be clarified and publicised.

Recommendation 7: Communications should focus on the need for the research and the role the individual will play, rather than on potential benefits, which are long term and will not accrue directly to the volunteers.

Recommendation 8: The communication strategy will need to ensure that volunteers understand that they are still responsible for their own healthcare. Some participants initially thought that their health would be monitored, although it is not clear how they thought that this would be done.

Recommendation 9: That consideration be given to providing more individual feedback as a way to potentially boost the response rate.

Recommendation 10: Recruitment should be carefully piloted to identify the most effective method or methods but should still allow flexibility. Participants were clear that one model may not motivate everyone.

Recommendation 11: The central staff who hold the key to the codes and those who use the data and samples should be required to sign appropriate confidentiality contracts.

Recommendation 12: There should be a scale of fees payable for access depending upon the nature of the requesting organisation, commercial and foreign researchers paying more than UK academics.

Recommendation 13: Where there are revenues accruing to organisations that have used BioBank data to develop drugs or tests, a mechanism should be established to provide on-going funding for BioBank. The oversight body should put suitable guidelines in place.

Recommendation 14: It should be made clear on the consent form which categories of user have access to the data, the samples and any conditions attached to access for specific groups of users.

Recommendation 15: It must be clear to potential volunteers that whilst there is no direct personal advantage in taking part in the study, there is no individual disadvantage either. Health information held by BioBank will still be accessible to their doctors. It will have been copied, not transferred.

Recommendation 16: There must be mechanisms that ensure that GPs cannot access personal data as well as those that ensure researchers cannot identify individuals.

Recommendation 17: BioBank will have to demonstrate that it is being set-up with the most rigorous security standards in mind. This is likely to be sufficient to reassure the vast majority of potential volunteers.

Recommendation 18: That further consultation is undertaken to more effectively explore the issue of the nature of the research that might be undertaken. This will enable discussion of responses to these concerns.

Recommendation: 19 That there should be a Governing or oversight body.

Recommendation 20: A strapline should clearly associate BioBank UK with medical research or improved public health and should always be used on all literature.

Recommendation 21: That three more consultation sessions be convened. One in each of: rural Wales, the north-west and the north-east of England and that participants be recruited to balance the overall sample socio-economically.

Recommendation 22: That the six groups be consulted on various issues, perhaps in smaller groups and following despatch of additional information, throughout the development phase of BioBank UK.

2. Introduction and Background

The Wellcome Trust (WT) and the UK Medical Research Council (MRC) commissioned People Science & Policy Ltd to undertake a public consultation on the ethical and management issues surrounding the proposed BioBank UK project. This report sets out the findings from this consultation and makes recommendations based on the findings.

BioBank UK

BioBank UK is a proposed resource that will enable medical researchers to study a number of diseases, including the principal UK killer diseases – cardiovascular diseases and cancers. The major purpose is to enable the study of diseases where genes, or combinations of genes, interact with lifestyle and the environment.

In summary, the proposed medical research project will collect blood samples, health and lifestyle information from a sample of 500,000 adults resident in the UK aged 45-69. These individuals would be tracked for ten years, mainly through their National Health Service (NHS) records. Ongoing information will therefore need to be added to individual records as the project progresses, including data from NHS records and further interviews or questionnaires.

The data collection protocol and the structure of the project is still being developed and can be found at http://www.wellcome.ac.uk/en/1/BIOvenPOPprt.html

Other consultations

The WT and MRC have undertaken two previous consultation exercises. The first was structured as a series of focus groups with the general public where the researchers fed into the group key features of BioBankUK, to elicit reactions and identify concerns. That project also included interviews with representatives of groups that were thought to have specific concerns about this type of medical research resource. These included representatives from minority ethnic groups, pressure groups and medical personnel. The report of that first consultation is available from http://www.wellcome.ac.uk/en/1/BIOvenPOPeth.html

Most of the concerns identified in that first consultation were around the security and management of the databank. The genetic nature of the research clearly coloured the general public's reactions to the proposals.

The second consultation exercise specifically explored the views of medical personnel. This group need to be committed to BioBank for it to be successful as they will be essential to the data collection process as currently envisaged. That report is available from http://www.wellcome.ac.uk/en/1/BIOvenPOPeth.html [2]

[2] Another project is being conducted with a grant from the WT to Sheffield University. Conjoint, or trade-off analysis, Likert scales and qualitative research are being compared as methods of public consultation. The results should provide information on public views, concerns and preferences and will be available later in 2002.

Issues

Genewatch, a UK pressure group, has identified five questions that potential volunteers should ask before agreeing to take part. These are:

- What research is going to be carried out on my sample?
- What are the benefits and dangers of this research?
- Will my sample ever be used for research I don't agree with?
- Will any of my genes be patented and will I be informed about it?
- Can I change my mind?

The Secretary of State for Health has made a commitment to providing answers to these questions before BioBank goes ahead. Genewatch has produced a document, available at www.genewatch.org, which raises other, more detailed questions.

The WT/MRC project team wanted to explore issues that would affect recruitment and the propensity to volunteer. This involved covering the practical issues around the recruitment process as well as deeper concerns that potential volunteers would want answered once the practicalities of taking part have been covered and the process made as easy as possible. Consequently, this consultation encompasses Genewatch's questions but also covers a much wider range of issues.

The results of this consultation have been structured around the main issues identified by participants. Addressing these will be critical for the success of BioBank UK. The remainder of this report is structured into seven sections:

- Burden on respondents of taking part
- Access to the data, the samples and confidentiality
- Uses to which the data will be put
- Governance of BioBank
- Value for money
- Reactions to the name "BioBank UK"
- Further consultation

Research Method

Three separate but similar events were held in January 2002. These were in Hertfordshire, the West Midlands and Glasgow. Each session involved 20 people[3] split into two groups of 10 for an introductory session of 1½ hours on a weekday (Tuesday) evening. The whole group was 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. The Hertfordshire exercise was run as a pilot and some changes were made as a result of the experiences there.

The objectives of the first sessions in this public consultation were:

- to brief the participants about the proposed BioBank UK;

[3] Only 19 people participated in Glasgow.

- to gather initial views on the project; and
- to identify the questions that participants, as potential volunteers, would want answered before they would decide whether or not to take part.

At the end of the first session participants were given a two page leaflet about the study and information about both the WT and the MRC. They were encouraged to read the handout and to discuss the issues with their family and friends before reconvening. All of the participants had done this to some extent before the Saturday session.

The second sessions were designed to answer the questions raised in the first session, discuss the issues participants wanted to raise and debate acceptable solutions to the issues with members of the project team. These second sessions began with a discussion of thoughts since the first session. The majority of respondents commented positively, unprompted, on the content of the leaflet and felt that it had answered their questions. However, this did not stop in-depth discussion of these issues during the second sessions and it was clear that not all the participants had key aspects of the study clear in their minds.

At the end of the second session most participants said that they had enjoyed the discussions. Most of these comments were received as people left and were not recorded. However, in one location the participants recorded their views before the end of the session.

> *"I've found it extremely interesting how different people have thought about things and how we've worked it out. It's been a complete eye opener for me."*

> *"Absolutely. I never thought I'd be talking to a scientist about science. ..... Thank you."*

More details of the materials used and the sample are available in the Annexes.

3. Recruitment

The one primary motivating force that stimulates people to volunteer, namely altruism. However, while there are some key "top level" demotivators such as how easy it is, physically, to take part, there are also some "second level" issues that will deter some people from taking part or which people will feel able to use to justify inertia. These include: how the information will be used; who will have access; and how secure it will be. This section sets out these issues and identifies some misconceptions that the recruitment process should address in order to maximise participation.

Motivation

Once they were introduced to BioBank and given the details of the proposed project, the majority were supportive and some were sure that they would take part. There was a group who were supportive of BioBank and who understood that they would be participating *"for the human good"* rather than for any direct personal benefit. For some this was seen as a way of *"giving something back to society"* by those who felt that *"we have benefited from previous generations"*.

> *"I think it's going to be fantastic for the generations to come, and I think if we can help, we should."*

We cannot draw definitive conclusions from the sample in terms of which groups might participate, because it was not representative. The study was designed to include a cross-section of the population in the age group that would be recruited. The objective was for participants to identify and discuss issues with the project team, rather than to have a representative sample that could be scaled up to represent national attitudes. Nevertheless, there were indications that those who were better educated and those with previous experience of medical research were most likely to say that they would take part. Those who had previously taken part in research studies had a better grasp on the idea that they would not get anything back personally. Gender, may have been coming into play. Some of the women thought that they would be more likely to take part than men, and some of the men reported that their wives were more positive than they were themselves. There were also indications that the older participants were less positive. However, it was difficult to untangle this because of the size and composition of the sample and the nature of the discussion process.

For those who were in favour, the benefits outweighed the risks, or as one participant summed it up at the end of one of the second sessions:

> *"The advantages outweigh the disadvantages."*

The driving force behind those who were definite in their commitment was altruism on their part. Those who had no doubts understood the nature of medical research and that there would be no direct personal gain from taking part.

Nevertheless, there is a need for a free helpline that potential volunteers can contact for more information, to discuss their concerns and to have their questions answered. As one participant put it:

> *"It's just a certain hesitancy before you commit yourself to this kind of thing."*

Recommendation 1: The details of the helpline must be clearly stated on the initial contact letter. Helpline staff must be able to answer questions and discuss concerns with callers.

This support for BioBank in principle must be distinguished from the likely response to "a call to action" and people actually signing-up. In research people often over-estimate their altruistic behaviour because they do not want to admit in public that they would not give up the time to take part in something most believed to be *"for the benefit of mankind"*.

Recommendation 2: Taking part must be made as easy as possible. People may look for excuses to justify their inertia.

Potential barriers to participation

The great majority of participants supported the idea of BioBank UK. Their reasons for this were simple and altruistic, as has been discussed. Reasons that would make potential volunteers hesitate or that would prevent some, at least initially, from taking part, were explored in some detail.

The main "barriers" to participation emerged as inertia and apathy, general lack of motivation and unclear benefits to individuals and society. The burden on respondents including the location, timing and content of the initial data collection were cited as major factors in whether or not people will take part. There were also concerns about what long term commitment was involved.

Respondent burden

Even the most positive respondents admitted that ease of access to the location for the initial examination and the frequency of monitoring would colour their decision as to whether or not to take part. It would certainly affect whether or not individuals actually present themselves following the initial contact. The content of the examination, the data required and the frequency of monitoring, would also have an impact on willingness to take part. At least one woman who had taken part in a medical research project on ovarian cancer admitted to dropping out after a couple of years because the journey to the hospital was over an hour each way.

Once it was explained that the monitoring would be through health records rather than volunteers needing to take action the response of some was that:

> *"You'd probably forget you were in it."*

There was a feeling that 40 minutes was not a lot of time to commit, although another group thought that the time commitment, with travelling, was closer to two hours.

Some remained concerned about the medical examination and the lifestyle questionnaire, even after they had been fully explained.

"Isn't this already being done/known?"

The first reaction of some potential volunteers was to ask how BioBank is going to add to what is already known, given that there is already a great deal of research going on.

> *"Aren't there other bodies already set-up to do this type of research….and it doesn't actually say they're going to cure anybody does it?……..It would appear that no matter what illness you've got at the moment there's always a body set-up to try to look into it. So, if they're trying to reinvent the wheel, with public money, half public money, there may be a bit of resistance to it."*

There was a general sense among participants that far more is known about genetics than is actually the case. Another participant was confused, and potential volunteers might also be. She could see no point in the study. "*They already know what people die of."* To address how this study adds to such basic information, which is currently available, by linking health, lifestyle and disease data, will be an important function of the communication strategy.

Recommendation 3: Setting out how this study adds value to existing work will sway some waverers. This needs to be clear in the initial recruitment material.

Scale of the study and representativeness

Half a million people sounded like a massive project to participants and questions were asked about why so many people were needed. For some, this large number provided an excuse *"You don't need me"* if there are so many others.

However, once participants were given more information about the nature of the study and how the research would be conducted, there were questions about whether the sample was large enough.

> *"I think I'm going to contradict myself now, but is half a million enough?"*

A "concept board" was used to set out visually the key features of BioBank UK. The phrase on the board "reasonably representative" led to some confusion. Participants were concerned about whether the study would be valuable if it was not truly representative. The project team explained that the results would not be used to provide national estimates of disease incidence. Rather, the study is designed to be large enough to include sufficient individuals with specific diseases and a suitable number of "controls" to allow the identification of links between genetics, lifestyle/environment and diseases.

There was also confusion about how people would be identified for the study, in some cases despite repeated explanations.

Recommendation 4: There must be clearly set out answers to questions about the size and make-up of the sample. It must also be clear how and why that individual

has been selected as well as why they are important to the study. This should sent with the recruitment letter but might be contained in a separate leaflet. Such information will also be crucial to support the telephone helpline staff.

Participants voiced concern about differential response rates, in particular they were worried that those from poorer backgrounds, who often have the worst health, would not come forward. Questions were also asked about how too many volunteers coming forward would be handled.

Participants felt that the obese, those with unhealthy lifestyles, etc. may be reluctant to come forward for personal reasons. Conversely, those who see themselves as healthy may not realise that they are still very important to the study.

> *"I don't see what you'll learn from me. I'm very healthy."*

Recommendation 5: It must be clear from the initial documentation sent to potential volunteers why healthy people are important to the study and how their data will be used. It was more obvious to participants why less healthy people are relevant.

Participants also raised the issue of how truthful people would be in answering lifestyle questions. This was given as one reason why the data collection, as well as its storage, must be confidential. One group suggested posting back questionnaires in an effort to encourage people to be honest.

Age

Despite being informed that the data would be used to study diseases of older and middle age, such as heart disease and cancer, participants returned to the question of why younger people, "*who could be studied for longer"*, were not to be included.

> *"I think they're looking at people who are too old actually because by the time you're 15, your diet has affected your health."*

The impact on general practitioners

A few individuals were concerned about the impact on GPs. There seemed to be a consensus that currently the waiting time for an appointment with a GP is about two weeks. Any increase in workload, especially one that might impact on the availability of GP appointments, worried people. This included any time GPs might have to put in to the study as well as use of their resources, whether rooms in which to conduct recruitment or nurses to undertake it.

Questions were also asked about *"What the doctor is getting out of it"*. If doctors are to be paid per volunteer it was thought that this would disrupt their normal workload. Moreover, if GPs are prepared to take on this extra workload, participants believed that there must be *"something in it for them"*.

By raising awareness of health issues, especially in the older part of the age range, participants felt that BioBank might prompt visits to GPs that would not otherwise have occurred.

Recommendation 6: The role of GPs must be clarified and publicised.

Value for money

A few participants said that *"we should concentrate on getting the basics right in the NHS"* before spending £60 million on research. When probed, they cited cleaning the wards and other such *"basics"* as needing attention. This view was countered by others who believed that this amount of money would make very little difference to the NHS. Moreover, some recognised that the results could save the NHS money in the long term.

More in-depth discussion of these questions in small groups resulted in participants agreeing that *"there is no better use of £12 million per year"* and a recognition that it might lead to longer term savings.

> *"It will save money by allowing early identification of problems so then they can be treated earlier and therefore more cheaply."*

Conversely however, some participants were sceptical and were looking for an ulterior motive. For this group, savings were seen in the context of *"another money saving scheme", "they wouldn't be doing it if it wasn't going to save money."*

On balance, most people were convinced that BioBank was good use of the money.

Too much data or not enough?

Once it was understood that monitoring would be through NHS records some participants were reassured by the lack of effort required on their part. Others were concerned that this would mean that not enough information was being collected. In discussion it was agreed that changes in lifestyle may result in the data being unreliable and that this information may need to be up-dated more frequently than proposed. The use of non-prescription medicines and therapies might also have an impact on health and susceptibility that would not be recorded by simply using NHS records.

Participants were aware that there are inaccuracies in some individual's NHS records and there was some discussion of how this would be taken into account.

Feedback

Some participants were aware that there was not usually feedback at the individual level from research projects and for this group the question of individual level feedback did not arise. There was also an acceptance that the scale of the project prohibited any individual feedback. Indeed, there was some concern that providing this level of feedback would be a waste of money that could be better used.

For others this was much more of an issue and is a potential barrier to participation. The discussions revealed that some participants were looking for direct personal benefits. Indirectly they asked whether they would have privileged access to information about their health, as a result of taking part in the study.

Some saw the initial examination as *"an MOT"* and therefore had high expectations of the feedback. Initially participants believed that their sample would be tested to ensure that they are well.

> *"I would [take part] because I'm sure they'd give you some sort of general health check when you started. So I'd be very happy to."*

Participants generally over-estimated the health information that could be learned from blood alone. There was also little understanding that, in order to diagnose specific illnesses specific tests must be run on blood; and that the decision on which tests to use is made on the basis of health history and symptoms. This misunderstanding of testing regimes was reflected in the comment:

> *"Aren't there certain things that would show up in your DNA immediately?"*

The project team explained that BioBank research would help to develop diagnostic tests that cannot be done today. Nevertheless, not identifying illnesses from samples donated to BioBank could lead to complaints in the future, unless the limitations are made very clear.

It was pointed out by the project team that, in effect, information about health status will be no different for those in the study from those outside the study. The exception is that those in the study will receive information about the BioBank-based research and findings in advance of other people probably in a newsletter or on a website - which was preferred by some. This may mean that they are able to seek medical advice for specific concerns before other members of the general public have become aware of the findings.

Other participants highlighted that there is not a direct pay-off from taking part in research of any kind. The returns are more general and longer term. As one participant said:

> *"I think we're looking at it at a very personal level. I think the two questions are, it's all research. Once it's done forget about it. The onus is on you, if you're not well, to go to the doctor, not wait for the doctor to find out from reading a paper, seeing it on television or wherever he gets his information from. The onus is on you if you're not well. He can't know from sitting in his surgery, not having seen you, in my case for about 10 years, that I've got something that I should know about. This is just for research, not on a personal level."*

There was a clear view from some that one had to take responsibility for one's own health.

> *"At the end of the day it's down to the individual. If you know, like, you've got hereditary problems in your family. I know my family history and the problems that have been had. We've got history of diabetes, blood sugar, heart disease and so on. Most of my family have died young, so I take it upon*

myself to go to my doctor every year just to have a health check…. You don't just sit and wait."

Nevertheless, some participants believed that many potential volunteers would ask:

"What's in it for me?"

One participant asked whether, once findings began to emerge, the study would identify all the volunteers with certain high risk features and give feedback to the relevant GPs. Others had a different view.

"By that time the doctors would be aware of what you've [BioBank] *found out and the doctors would go to their own set of patients, surely, and follow it up on a personal basis because they will have had that feedback. If your study is successful and information goes out to all these doctors on what they can look for and what works, then they will come back if they're in that bracket. Won't they? Regardless of whether they've taken part in the study."*

The project team supported this view saying that the research results would be made available to the NHS so doctors can assess who generally is at risk because data might be equally valid to those not in the study.

In response to these concerns it was felt that the study:

"needs to make it clear to people that there will be no feedback. Then that is part of the contract you're entering into with the study."

I think you have to make it very clear that these statistics will be used purely for research…the original information we were given, may have led us to think that it could be a personal feedback for ourselves because of our family history problems."

However, a *"moral case"* was put that:

"Ultimately the health service has a responsibility, that's one of the rationales you gave for carrying out the research, that you're trying to look after us all, so ultimately if you picked up something in this research, which would be material use to individuals that are participating in it, then people are saying, well, hang on, isn't there a moral responsibility at that point to go back to the participants?"

Recommendation 7: Communications should focus on the need for the research and the role the individual will play, rather than on potential benefits, which are long term and will not accrue directly to the volunteers.

Recommendation 8: The communication strategy will need to ensure that volunteers understand that they are still responsible for their own healthcare. Some participants initially thought that their health would be monitored, although it is not clear how they thought that this would be done.

Recommendation 9: That consideration be given to providing more individual feedback as a way to potentially boost the response rate.

Solutions

During the workshop phase participants recommended a number of approaches that would increase the response rate. These included:

- having a national information campaign so that people are aware of the study before they are contacted to take part;
- being clear about the outputs and possible outcomes in the introductory letter to potential volunteers;
- holding local recruitment sessions to facilitate access;
- providing flexibility of appointment times to cater for a variety of lifestyles and commitments;
- encouraging companies to release staff for recruitment sessions as they currently do to give blood;
- visiting people at home to undertake the recruitment;
- developing localised strategies to ensure that those in disadvantaged areas participate, including nurses proactively contacting individuals and supporting their individual needs;
- accommodating those who have low levels of literacy or whose first language is not English by providing information in a variety of media and languages;
- identifying other groups with specific needs and concerns and targeting them appropriately;
- allowing participants to post back lifestyle questionnaires so that they cannot be seen by GPs to encourage volunteers to be truthful;
- bar coding data at the recruitment interview to guarantee confidentiality;
- establishing a helpline for potential volunteers to ask questions and discuss their concerns;
- making it clear to volunteers that there will be no feedback at an individual level and that this is part of the contract with the study; and
- adopting a health education approach whereby community leaders are engaged and other benefits to individuals are identified.

Recommendation 10: Recruitment should be carefully piloted to identify the most effective method or methods but should still allow flexibility. Participants were clear that one model may not motivate everyone.

4. Access and confidentiality

Under this heading we include access by:

- users (both non-commercial and commercial);
- volunteers and their families;
- GPs;
- the police;
- insurance companies and employers; as well as
- illegal access.

When asked who they would expect to have access to the data participants said the Wellcome Trust and the Medical Research Council. First reactions were that commercial companies should not have access, although some participants were quick to realise that the results would be published and therefore widely accessible to anyone. Further debate brought the realisation that if medicines are going to be developed, pharmaceutical companies must have access.

It is clear that complete confidentiality at the individual level is important to potential volunteers. However, the need to re-link data to names to up-date the information was explained and understood by participants. Participants accepted that this has implications for the security that can be accorded to the data, as it will be essential that new data is ascribed to the correct individual. The records cannot therefore be permanently anonymised as there must be some form of identification to enable the addition of new data to existing records.

The solution put forward by one of the project team reassured participants. It was proposed that GPs would replace the names of volunteers with reference numbers and provide the "hub" with data by reference number and that the hub would then replace that reference number with another code number.

Although confidentiality was an issue for the majority, several people thought that the information being collected was not very sensitive.

> *"There's nothing on there* [the concept board describing the data to be collected] *that I would feel bad about telling someone."*
>
> *"I'd be happy to have my data published with my name on it."*

One area of confusion was the "assessment of mental well-being". Participants were unsure what this meant and who would undertake the assessment and this tended to result in low levels of discussion of the issue. Understandably, there was concern about being *"typecast"*. There was no awareness of standard tests and measures for mental well-being.

There is some potential for confusion with the 30 year rule on access to public records and the information which is publicly accessible via death registrations.

Non-commercial researchers

Participants tended to assume that the research would be conducted at BioBank by BioBank staff. It was explained that researchers from different places would apply for access to the data. If the research was not for profit and the researchers were bona fide, there was little concern about access. Some participants were confident that individual level data would not be of very much interest to researchers.

Recommendation 11: The central staff who hold the key to the codes and those who use the data and samples should be required to sign appropriate confidentiality contracts.

Commercial companies

The idea of access by commercial organisations raised concerns and generally the first reaction was to reject the idea. There was some feeling that companies were getting something for nothing and the "donors" or "volunteers" would gain nothing. As one participant said:

> *"By the time they've gone through investigating what happens to the genes and the lifestyle, everybody who took part will be dead anyway."*

After some thought however, many participants realised that only with the involvement of pharmaceutical companies will new medicines be developed. They therefore became resigned to their involvement. Some, nevertheless, remained very suspicious of any commercial involvement.

> *"It's obviously costing them some money so it's obviously being used for commercial gain."*

Most participants wanted to find a way forward that enabled medical progress while preventing profiteering by companies. Some saw a positive role for pharmaceutical companies who, by paying for access, would provide more funding for the study. One sub-group, focusing on issues of commercialisation, came up with the idea of a sliding scale of charges for access, with UK academics being charged the lowest rates and commercial companies and overseas researchers charged higher fees. They proposed that if patents result from BioBank data, 25% of the subsequent revenues should go back to BioBank to help future financing and reduce the amount of public sector funding required to maintain BioBank in the long-term.

They proposed that a similar structure should apply for the identification of therapies, with private companies paying more than the NHS. They also thought that the results of any research or drug testing data should be fed back to BioBank but were split on whether BioBank should be charged for this information.

Giving pharmaceutical companies access to the data was more acceptable than allowing them access to the samples. A few people raised concerns about whether the DNA could be used to clone people. This led into discussions about why companies would want access to the samples and not just the data. The project team explained that they originally proposed that the samples would not be released and that in-house

staff would undertake analysis on the samples and provide organisations with the resulting data. However, some companies have very specialised and expensive equipment that would allow them to do experiments that BioBank could not undertake. These companies would like access to the samples themselves.

One sub-group thought that the benefits of private sector involvement were clear.

> *"Commercial involvement will produce products which will benefit people, profits which will enable further investment and the regular publicity of medical advances demonstrates that this sort of activity gives positive results."*

There were questions raised about whether companies could sell the data on. However, participants thought that it would not be in the interests of the Wellcome Trust and MRC to let this to happen. The project team assured participants that terms and conditions could be put on the use of the data to prevent this.

> *"They're* [MRC and WT] *not going to take any risks. It would tarnish their reputation."*

Participants also thought that private companies would want exclusive rights to the data that they purchase but again the project team assured them that this would be out of the question. One member of the project team explained that the only case for exclusive access would be:

> *"If they pay to have a certain set of tests done centrally by Biobank. …Then they would have a short period in which to work out what the data means. Then that data would become available to everybody. No one can have the data collected on day one, no one can buy bits of it. It's what they do to it that makes it valuable. They hope they've had an idea that no one else has had."*

There remained concern that companies should address a range of healthcare issues and not just focus on *"profitable diseases"*. Discussions briefly touched on the relevance of the diseases to be studied to the developing world and there was some disquiet that only developed world diseases were to be examined. However, this was not a major issue and tended to be accepted.

Recommendation 12: There should be a scale of fees payable for access depending upon the nature of the requesting organisation, commercial and foreign researchers paying more than UK academics.

Recommendation 13: Where there are revenues accruing to organisations that have used BioBank data to develop drugs or tests, a mechanism should be established to provide on-going funding for BioBank. The oversight body should put suitable guidelines in place.

Recommendation 14: It should be made clear on the consent form which categories of user have access to the data, the samples and any conditions attached to access for specific groups of users.

It was not possible to address the issue of patenting within the time constraints of the consultation sessions because of the number of other topics that needed to be covered. It was thought that patenting was too complex an issue to be thoroughly explored and discussed in the time available. Participants raised the issue in the context of companies profiteering and proposed methods for transferring some of the profits to BioBank. Questions of ownership and restricted access that can result from patents were not raised.

Volunteers and their families

As has been discussed above, some potential volunteers were looking for ways in which they personally would benefit from taking part in the study. Access to personal health information that they may not otherwise have was the most obvious direct benefit. Many participants wanted access to their own records and the ability of volunteers to see their own records under the provisions of the Data Protection Act must be made clear.

It became clear that one participant had thought that she and her descendents would not be able to access what might be described as "standard health information" about herself. Her questions revolved around her descendants being able to access information about her if they discovered they had a genetic disease. As the data was to be held confidentially, and the project team had made it clear that individuals would not have access to the data about their own health, she felt that her family would be disadvantaged. However, the project team pointed out that the data is being *copied* not *transferred*. Health data will still be available to doctors in the usual way for healthcare.

Recommendation 15: It must be clear to potential volunteers that whilst there is no direct personal advantage in taking part in the study, there is no individual disadvantage either. Health information held by BioBank will still be accessible to their doctors, it will have been copied not transferred.

General practitioners

The first public consultation identified GPs as the obvious point of access and a trusted contact. This exercise has uncovered some scepticism about doctors. Many participants did not want their GPs to have access to the lifestyle data. Indeed, in one group participants went as far as identifying ways in which the lifestyle data could be sent by post directly to the central hub to ensure that doctors could not access it, even by accident.

Recommendation 16: There must be mechanisms that ensure that GPs cannot access personal data as well as those that ensure researchers cannot identify individuals.

Police

There was some ambivalence about whether the police should have access. Some felt that those who break the law give up their rights to privacy and saw no reason why the police should not have access. The following exchanges illustrate this sentiment.

Participant 1 said: *"If you're a burglar you're not particularly, not very… well what's the word? Umm…"*

Participant 2 cut in with a tone of irony: *"You've got no human rights, or privacy whatever."*

To which the firs participant responded: *"No, no, but if you go through someone else's property…."*

"You've got the right to pay for your mistakes", a third participant contributed.

Where groups explored the question of police access in more detail, the project team explained that a court order would be needed for the police to be granted access and that BioBank would always challenge any court order. It was accepted that if this was the procedure then it was probably right to grant access in those circumstances. The project team also pointed out that traditional methods of mass screening of the population in crime cases have been established and that the police would need to have some grounds for believing that the perpetrator of any crime was part of the study.

Insurance companies and employers

All the groups raised the question of access by insurance companies spontaneously. Some participants dismissed this on the basis that: "*you have to declare any medical condition anyway"* while others were wary of higher premiums and some people being unable to obtain insurance. Several participants quoted what had happened with AIDS and insurance companies, where merely taking an AIDS test barred people from getting life cover. There were somewhat subdued fears that a similar situation might arise.

There was some confusion about at what level insurance companies would have access and whether or not they would be conducting tests, accessing individual data or drawing on the overall results. Everyone was clear that insurance companies should not have access to individual data.

Only a very few participants mentioned access by employers and this was not discussed in any detail.

The project team emphasised that insurance companies and employers would not have access to individual data. This reassurance was accepted and prevented longer discussion of the issue. However, *"information leaking out to insurance companies"* was cited as one reason for people possibly wanting to withdraw, which could lead to the collapse of the study.

> *"The only way I can see* [it being] *detrimental is insurance companies."*

Illegal access

Illegal access by "hackers" was seen as a real, but relatively minor, risk. One participant, who worked in IT, revealed how difficult hacking is and other members of the groups felt that:

> *"You don't have to wait for BioBank to exist for people to hack into data about you."*

Recommendation 17: BioBank will have to demonstrate that it is being set-up with the most rigorous security standards in mind. This is likely to be sufficient to reassure the vast majority of potential volunteers.

5. Uses

This section explores how the data would or might be used and participants' reactions to different uses. Understanding the proposed outcomes from the project is a very important motivator for many potential volunteers. In this style of event the pace is to some extent determined by participants. It is for them to identify issues of concern to them and for the project team to respond accordingly. Given the deep interest in the motivation behind BioBank and the practicalities of recruitment and access, the complex issue of the types of research that might be undertaken was not as fully explored as it might have been. To some extent this was because participants focused on how BioBank would be used to study the diseases of middle and older age, that is, heart disease and cancer. There was little interest in whether the information might be used to identify or otherwise study the genes for behaviour or personality, even though the facilitators raised it with participants, in line with the project brief.

This does not mean that use of the data is not an issue. However, it is a second order issue that is likely to be discussed in more depth once more immediate concerns, such as confidentiality and general purpose, have been dealt with. With more time and more information we believe that participants would have been able to contribute effectively to the debates on this issue. Hence the recommendation to reconvene these groups rather than recruit new people for future consultations as these participants are now fully briefed and have worked through their more obvious concerns. (See section 8.) New recruits would have to go through the same "learning curve". Nevertheless, some important points can be made about the uses of the data.

Participants were keen to know how the data would be used. Questions such as

> *"Will certain diseases be given priority?"*

were asked.

There was little understanding of how the data will be used to identify connections between genes, diseases and lifestyle. While this may not appear to be essential to the project we suggest that it might influence recruitment as shown in the discussions about whether this project will add value to research already being conducted.

In terms of the type of research that might be undertaken, two main concerns arose. These were whether people could be cloned from their blood sample and whether the results would be used for genetic engineering or *"putting genes in and taking genes out"* leading to the creation of *"designer babies"*.

The project team assured participants that cloning is illegal in the UK and that the technology to clone humans is not fully developed. There was some debate about whether the law might be changed if cloning becomes practical, but the existing legal framework reassured most participants.

With respect to genetic engineering the participants who raised the issue were reassured by the project team's commitment that this was not part of the research agenda for the project.

Nevertheless, some participants remained uncertain about possible future uses of the information held by BioBank and thus continued to be hesitant in committing to taking part if contacted.

Recommendation 18: That further consultation is undertaken to more effectively explore the issue of the nature of the research that might be undertaken. This will enable discussion of responses to these concerns.

Arguments about the emergence of a "genetic underclass" were voiced by one participant but this was not picked-up by others in the group. There was, however, concern about the impact on insurance premiums.

6. Governance

This section looks at the control that should be exercised over the management and use of BioBank resources. It sets out models proposed by participants for providing the control they felt would be necessary to give potential volunteers the confidence to take part and to ensure that the data is used appropriately to improve health. As with the issue of data and samples usage, with more time this issue could have been explored in even greater depth.

Oversight body

In one of the six sub-groups the idea of some sort of oversight body was initially dismissed as a waste of money and unnecessarily bureaucratic. This group of fairly middle class women could see no reason for such a body and the project team had to push them to recognise the potential concerns that have been raised. The view of this group was very much that the research will benefit mankind, the researchers are reputable people and the project is being organised by two reputable organisations, so there should not be any problems. However, after the project team had set out the arguments that they are facing, especially from lobby groups, about the need for some independent overseeing body, participants in this location accepted that such a body would usefully add to the structure of the project.

In the other two locations the idea for some form of controlling body emerged naturally from the conversations.

Participants generally recommended that some form of oversight body should be established and that ultimately the body should be independent of the users and sponsors. Two main models emerged.

The first model was a fairly traditional stakeholder panel with users, funders and volunteers represented. Participants recommended that the committee or panel should be headed by a well known person, maybe a retired judge. The individual members would be nominated or recruited through advertising. This model would also include religious representatives, academics, ethicists, accountants and other professionals with relevant expertise. A role was also identified for people not directly involved in the project *"with no financial interest"* such as lawyers, clerics, etc.

The second model involves proactively seeking lay members with no vested interest in BioBank who would be supported by professional staff and the ability to consult more widely on specific issues as they saw fit. This included consulting relevant experts. This move away from a "stakeholder" model was reflected in the quote: *"no one who wants to be on it should be"*. To some extent a group that included a prison officer built this lay model on the prison visitor model for overseeing prisons. Other groups had similar, if less deeply considered, approaches in mind.

In both cases participants saw the need for ethnic and gender balance and a publicly known individual as Chair. A consensus emerged on the size of the "standing committee" of about 20 people. Generally participants felt that members should not be paid beyond expenses. It was realised that this would impact on the frequency

with which the body could meet, as unpaid members would probably have jobs as well.

The role of Government was contentious. Some participants felt that such an important project should be the responsibility of Government, probably through the Department of Health. Others wished to see a clear distance from the possibilities of political interference. A few people thought that as *"the Wellcome Trust and MRC are reputable bodies, why can't they do it?"*

Remit

This body would agree the rules for access and use, establish a payment structure for access to the data and the samples, guarantee destruction of the sample for those who wish to withdraw and set sanctions for those who abuse their right of access. Generally any such body would ensure that standards of behaviour and ethics were maintained. However, there were two schools of thought on the most appropriate way of maintaining standards. One group felt that as the public consensus changes the oversight body would and should reflect the public mood, while a second group felt that the original terms of the consent given by volunteers should be maintained.

Recommendation: 19 That there should be a Governing or oversight body.

7. "BioBank UK"

The first session began by briefly exploring how participants reacted to the name "BioBankUK". This was done at the start of the sessions once people had been given some information about the structure of this consultation but before any details were given about the proposals. However, respondents had been informed at the recruitment stage that the discussion would be about medical research. For those who remembered it, this may have coloured their responses.

A "word trigger" exercise was conducted whereby participants just called out words and phrases that the term BioBank UK (written on a flip chart) brought to mind. In the main this was a device to start the session and introduce the project.

The name appears to describe any database or storage facility. For some groups the "bio" element led them to focus on the implications of the prefix, whilst for others "bank" seemed to have stronger connotations. However, it generally left participants with a somewhat negative impression and there was rarely an immediate connection to disease, medical research or therapy.

Comments included: *"basically a repository of stuff", "storage of genetic information"* or *"a gene pool"*. The name conjures up images of *"spare parts", "blood bank", "sperm bank", "genetics", "biotechnology"* and *"GM food"*.

The word *"bank"* introduced ideas of *"commercial involvement and making money"* to some.

To at least one participant the "UK" suffix gave it an *"American"* tone. In his mind this had negative associations with multinationals and commercial usage.

Recommendation 20: A strapline should clearly associate BioBank UK with medical research or improved public health and should always be used on all literature.

8. Further work

This exercise has worked well as a public consultation. All the participants actively engaged with the subject and contributed to the discussions. The groups thought through the issues put to them, discussed them with the project team and made recommendations on how problems might be addressed. However, in the five weeks available for this research it was not possible to ensure sufficient representation from social groups D and E (semi-skilled workers and those wholly dependent on state benefits).

Recommendation 21: That three more consultation sessions be convened. One in each of: rural Wales, the north-west and the north-east of England and that participants be recruited to balance the overall sample socio-economically.

The development of BioBank will benefit from further engagement with the people who have taken part in this exercise, especially if the sponsors are to be able to fully address the concerns of critics. These participants are now fully briefed on the proposals and are aware of the issues. Many of these issues would benefit from further discussion, most notably the issues of consent, ownership and the use of the data and samples and the development of sanctions for those who abuse their access. Starting again with a new group will involve several hours of briefing and taking them through the basic issues that participants first identified around recruitment and feedback and other, more personal concerns.

It is unlikely that more issues could have been covered in two sessions even if they had been longer. This is because participants need time to digest information and reflect on it. Moreover, sessions of much longer than four hours as used in this study, even with a break, tend to become counter-productive.

Recommendation 22: That the six groups be consulted on various issues, perhaps in smaller groups and following despatch of additional information, throughout the development phase of BioBank UK.

Appendix 1 Recruitment questionnaire

Good morning/afternoon/evening, my name is …….. and I am from Facts International, a market research company. We are looking for people to come a to a group discussion about medical research. Could I ask you a few questions?

	CLASSIFICATION		
Q1a	Which member of your household, either yourself or related to you, would you say is the chief income earner? That is the person with the largest income, whether from employment, pensions, state benefits, investments or any other source? Self Spouse/partner Other adult (WRITE IN)	 1 2 3	
Q1b	Is the chief income earner: Working full or part time Retired/not working with PRIVATE PENSION/MEANS Unemployed less than 6 months	 1 2 3	 ASK Q 3
	Unemployed more than 6 months Retired with only state benefit/pension Not working with state benefit only	4 5 6	CODE "E"
	Student	7	CODE "C1"
Q1c	Occupation of chief income earner Job title……. Job description…….. Industry…….. Size of company……. Qualifications……. If manager/supervisor/self employed No. people responsible for (WRITE IN) IF RESPONDENT NOT CHIEF INCOME EARNER ASK Q1d		
Q1d	What is your own occupation? (WRITE IN)		
Q2	***CODE SOCIAL CLASS*** A B C1 C2 D E	 1 2 3 4 5 6	
Q3	***MARITAL STATUS*** Single Married/living together Other	 1 2 3	REFER TO QUOTA
Q4	***GENDER*** Male Female	 1 2	REFER TO QUOTA
Q5	***AGE*** 44 or under	 1	CLOSE
	45-55 56-69	2 3	REFER TO QUOTA
	70 or over	4	CLOSE

Q6	***WORKING STATUS*** Full-time (30+ hours per week) Part-time (8-29 hours per week) Not working	 1 2 3	ENSURE SOME FROM 1
Q7	***PRESENCE OF CHILDREN IN HOUSEHOLD*** None Aged 0-5 Aged 6-10 Aged 11-15 Aged 16-18	 1 2 3 4 5	
Q8	***ETHNIC ORIGIN*** White Black (including British, Caribbean and African) Indian sub-continent (India, Pakistan and Bangladesh) Other Mixed	 1 2 3 4 5	REFER TO QUOTA
Q9	Have you ever attended a group discussion or depth interview before Yes No	 1 2	 Q10 Q14
Q10	Have you ever been to a group discussion or depth interview in the last 6 months? Yes No	 1 2	 CLOSE Q1
Q11	How many group discussions/depth interviews have you been to in the last 2 years (ie 6 months to 2 years ago)? None 1-3 More than 3	 1 2 3	 Q13 Q12 CLOSE
Q12	Did you go to any group discussions/depth interviews between 2 and 7 years ago? Yes No	 1 2	 CLOSE Q13
Q13	What was the subject of the discussion you took part in in the past? (WRITE IN) IF ABOUT HEALTH OR MEDICAL RESEARCH		 CLOSE

IN A NUTSHELL

- At least one-third of each group/set of depths must be brand new recruits
- The remaining two-thirds can have attended up to a maximum of 3 groups/depths in the last 2 years (i.e. 6 months to 2 years ago)
- Those who have been to 3 groups/depths in the last 2 years must have had a 5 year gap before that
- None to have attended any group/depths in the last 6 months
- None ever to have attended a group/depth on the same subject matter
- None to work in or have family who work in any of the excluded occupations listed on showcard A

Q14	SHOWCARD A Do you or any of your close family or friends work in The healthcare sector/medical profession Medical or biological research	 1 2	 CLOSE CLOSE

	Journalism Market research	3 4	CLOSE CLOSE
	Teacher Shop assistant Transport	5 6 7	Q15 Q15 Q15
Q15	Which of the following apply to you? CODE ALL THAT APPLY I am a member of a wildlife organisation I am a member of an environmental organisation I am a vegetarian/vegan I am opposed to GM foods	 1 2 3 4	 RECRUIT RECRUIT RECRUIT RECRUIT
	I have taken part in campaigns on animal rights I have taken part in campaigns on environmental issues	5 6	CLOSE CLOSE
	Signed: Interviewer		

Quotas

These are reconvened groups. At each location the group that meets on the week night reconvenes the following Saturday.

Week night groups are 1.5 hours and the Saturday groups are 4 hours.

We would assume that the evening groups will start at 6.30 pm or 7 pm.

The Birmingham Saturday sessions should be 10 a.m. to 2.30 p.m. We will give these people lunch.

The other 2 Saturday sessions should be 1.30 p.m. or 2 pm starts and run for 4 hours. These people should have a reasonable snack of sandwiches etc.

Location	**Date**	**Group**	**Composition**	**Age**
Hertfordshire	15 January	1	10 women	45-55
Hertfordshire	15 January	2	10 men	56-69
Hertfordshire	19 January	1	10 women	45-55
Hertfordshire	19 January	2	10 men	56-69
Glasgow	22 January	3	10 men	45-55
Glasgow	22 January	4	5 Opposite sex couples	56-69
Glasgow	26 January	3	10 men	45-55
Glasgow	26 January	4	5 Opposite sex couples	56-69
Birmingham	22 January	5	10 women	56-69
Birmingham	22 January	6	5 men and 5 women – not related	45-55
Birmingham	26 January	5	10 women	56-69
Birmingham	26 January	6	5 men and 5 women – not related	45-55

Each location to include at least 3 people whose ethnic origin is either Black (including British, Caribbean and African) or Indian sub-continent (India, Pakistan and Bangladesh).

Appendix 2 Topic guides

BioBank UK Topic Guide for Session 1 INTRODUCE HERTFORDSHIRE GROUP AS A PILOT TO THE PARTICIPANTS	
Briefing Notes	**Questions and Techniques**
Purpose This topic guide should be used by facilitators in conjunction with the Q&A developed by the MRC and the Wellcome Trust and *"Giving your genes to BioBank UK: Questions to ask"* published by GeneWatch UK in December 2001. The purpose of this session is to identify the issues the group is concerned about, especially those that might stop them from taking part in BioBank UK. The second session will be run as a workshop for the group to work with one of the people working on the BioBank project at the MRC or the Wellcome Trust to identify acceptable solutions and key messages for the communications strategy.	There may be other places to those indicated below where visuals or other techniques would help stimulate participants. We need to make sure we identify them and possibly improvise in these sessions so that the remaining sessions flow as smoothly as possible.
Group introduction Go round group doing usual ice-breaking introductions e.g. first names, job, family status.	Make clear the objectives, clients, methods (session 1 is a discussions and session 2 a workshop) and session lengths. Give usual reassurances about confidentiality, request tape recording. The introduction should make it clear that people do not have to answer all the questions and are free to leave before the end of the session. Introduce CH/EM as from WT/MRC but not scientific staff. Very interested to hear first hand their thoughts and to help prepare for the Saturday session.
Introduce BioBank UK	BEFORE SETTING OUT MORE DETAIL GET FEEDBACK ON WHAT THEY THINK THIS MIGHT BE FROM THE NAME.
BioBank UK is a proposal for a research study aimed at establishing how genes, lifestyle and environmental factors interact to affect people's health. It is thought that this type of research could lead to important improvements in the ways we can treat and prevent ill health.	USE CONCEPT BOARD 1 TO TALK THROUGH THE PROPOSALS.
If it goes ahead it will be funded by the Medical Research Council and the Wellcome Trust, working in partnership with the health service. Explain what MRC and WT are, leaflets are available for all participants.	
The current proposal is that half a million adults aged 45-69 will be invited to join the study. They will probably be recruited through General Practices (GPs/family doctors) in certain selected areas of the country. The aim will be to get a reasonably representative sample of the UK population in that age groups in terms of, for example, sex, ethnic group and sate of health.	
Volunteers will be asked to give a blood sample from which DNA will be extracted. The results from this sample will be put together with their NHS record and probably also some lifestyle information collected using a questionnaire when they join the study.	
It will take about 5 years to set-up and recruit participants to BioBank and this will cost about £60 million.	

It is envisaged that the health of those who have contributed to samples will be monitored for at least ten years. Participants will be recontacted at least once for more information but most monitoring will be via NHS records and routine health databases (NB This is information specific to the individual. This will give the project enough time to research the effects of the interactions between genes, environment and lifestyle. The actual samples may be needed for longer.	
Explore initial responses How do people feel about this idea?	Get people to discuss in twos Do you think it's a good idea? Would people take part? Would they take part? If so, why? If not, why not? LIST OUT ON FLIP CHART What are the key barriers and motivators to participation? PROBE WHETHER THIS IS PERCEIVED INITIALLY AS ONLY SOMETHING FOR SICK PEOPLE
Questions that must be covered	
Recruitment Practicalities It is likely that people would be recruited by a letter from their GP/family doctor. They will receive a letter inviting them to take part and enclosing the lifestyle questionnaire.	BRAIN STORM Key areas are: information and motivation What information would people want before making a decision on whether or not to take part? Would this motivate them? Would they actively make the appointment? LIST OUT ON FLIP CHART PROBE AFTER ALLOWING TIME FOR PARTICIPANT REACTIONS Would they want to talk to someone before making a final decision? Who, besides professionals might they "consult" or talk about it with? Would they take part? Is one letter enough to get them to enrol? What would actually get them to the recruitment centre? What are the advantages/benefits of the study and taking part? Explore general practical problems and issues that people would want to see overcome. What would motivate them to take part? What needs to be in the letter, what sort of support should there be in terms of people to talk to and ask questions of when deciding whether to take part?
In addition to the blood sample and access to their NHS records there will be a lifestyle questionnaire. The sorts of things that questionnaire will cover include:	

MAIN STUDY ***self-administered questionnaire and interview*** basic demography- age, sex, postcode, educational level, marital status, ethnicity occupational exposures habits/lifestyle- tobacco exposure, alcohol consumption, physical activity diet- general dietary questions and seven day diary reproductive history family history and past medical history of specific conditions medication use assessment of disability and impairment, including Rose angina questionnaire assessment of mental well being ***examination/interview*** height, weight, waist/hip ratio two measurements of blood pressure resting pulse blood sample	USE CONCEPT BOARD 2 TO GO THROUGH WHAT STUDY WILL COLLECT AT INITIAL INTERVIEW/EXAMINATION General reactions to this? How do they feel now they know more about it? PROBE Is the proposed burden too much? Is there too much to do for not enough payback? What about the need to give blood? Do people ask "Why all this?" PROBE ESPECIALLY assessment of mental well being TRY TO ESTABLISH CONSUMER LANGUAGE
Feedback Some people have asked whether individuals will get feedback if the study finds that they have a medical condition. This obviously raises logistical issues, could compromise confidentiality and would increase the costs of the study. Moreover, for the most part there will not be the medical knowledge to provide this type of feedback until the end of the study. Feedback from the initial recruitment session will be give to the GP who will contact the person. No feedback on genetic status can be given.	*It is important we identify whether not having this information or not having it is a barrier to people agreeing to take part.* *Do they think this will be valuable? Would this encourage them or others to take part?* *Does this sufficiently address people's desires? Or would they want on-going information?*
At the project level, the sponsors plan to provide volunteers with regular updates on how the samples are being used.	How often would people like to get this sort of information? What format would they expect/want it to come in? What would they want it to cover?
Ownership The study will be in 'public ownership' through an independent enterprise set up by the MRC, the Wellcome Trust and the health service. The data will only be available to medical researchers. It will be available to scientists in both the public and private sectors. At the moment it is proposed that management of the databases and access to them will be overseen by some sort of monitoring or oversight body. In the second session we want to explore how this might work, who might be involved and how your questions can be answered. *MRC is a Government funded organisation and so ultimately accountable to the public and the WT is accountable to the charity commissioners*.	DON'T SPEND TOO LONG ON THIS OR PUSH IT HARD UNLESS IT STRIKES A CORD WITH PEOPLE Who do they think will own the databases? Who should own the databases? MAY NEED TO PUT FORWARD SOME OPTIONS Eg MRC/WT DoH "The Government" Private company Charity Some new organisation – what should it's status be? Is this an issue? It could be for any management body – who should it be accountable to, if anyone?

Consent There will be a consent form to sign once the project has been explained to potential volunteers. People will have to give their consent for their samples to be used for ever, including after they die. It will be important to use their data after they die. People who cannot give consent will not be asked to take part.	EXPLORE BEFORE GIVING INFORMATION IN THIS SECTION: Do people feel they have enough understanding of what they are being asked to do? What would people expect or want to happen to their sample and records when they die? AFTER INFORMING Would they be happy to relinquish all rights?
Type of research There has been concern about some types of genetic research, especially to do with behaviour and psychological traits and creating a genetic under class.	Are people concerned about the research that is conducted using the samples, that is with respect to specific diseases or conditions studied? PROBE for concern about research into behaviour and mental illness as well as "traditional" genetic diseases (e.g. cystic fibrosis) and more common diseases such as heart disease and cancer. Would people want to be asked for consent for their sample and data to be used for particular research or would they be happy to give general consent?
Confidentiality The samples and data will be securely coded to protect the confidentiality of the individual participants. Scientists using the data for research will not be able to identify the individuals to whom they relate. BUT in order to study the interactions between genes, environment and health the study organisers will have to be able to add follow up information on participants' health to the individual records at a later date. It is critically important to know which individuals stay healthy and which develop (or die of) particular diseases.	TO MAKE SURE EVERYONE HAS UNDERSTOOD THIS GET PEOPLE TO PAIR UP AND EACH PAIR TO ANSWER THE QUESTION: Does anonymity matter to you? If so why? If not why not? PROBE How do people feel about this? Would this be a barrier to them taking part? IN THE NEXT SESSION WE WILL EXPLORE HOW THEIR CONCERNS CAN BE MET SO THIS SHOULD BE COVERED IN SOME DEPTH.
Security The samples and related data will probably be stored in two separate locations for security purposes. The information will probably be stored centrally on one big database, although it is likely that there will need to be separate databases for genetic and other information.	DON'T SPEND TOO LONG ON THIS How do people react to this? Is it secure enough? Are there any other options? Does it matter? Why? Why not? Is the issue of theft or unlicensed access an issue of concern for people?

Developing drugs and treatments	IF TIME: Explore how people currently think these findings will be turned into actual drugs and treatments. OTHERWISE MOVE STRAIGHT TO EXPLANATION
Focusing on drugs, explain, if necessary, that drug companies undertake research that is closer to having a final drug than academic researchers of the type likely to be funded under this programme. Point out if appropriate that people take part in clinical trials for drug companies now to test drugs before they are put on the market. While the companies sometimes pay people for this they do not always.	Explore how participants feel about drug companies using their samples to produce drugs, which while useful to mankind, will also profit the companies financially. USE FLIP CHART TO IDENTIFY KEY CONCERNS
Access to records and samples In particular, one issue that is frequently raised in the press and by other groups is access by insurance companies, employers (current or potential), schools, the police, other Government agencies or family who might also be affected. DON'T ASK THIS DIRECTLY	EXPLORE Who will/should have access. Who should definitely not have access? Why? Do people have any concerns about how the results might be used and who might have access to them? Do they think that BioBank UK could/would provide information on their individual DNA profile? If so, why? How? [We will come to what safeguards they would want to see in the second session.]
To make best use of specialist research techniques there will be occasions when it is would be helpful to give samples of DNA directly to the researchers to work on.	Do people realise that researchers will be given access to the actual sample? Or do they think it is just data/information?
Withdrawal from project	What sorts of things might make people withdraw later? Is it important that people can withdraw from the project? Will they expect to have their entire record deleted or will they be content just to stop giving further information?
Closure When we meet on Saturday we will be exploring how the management of BioBank can be structured. We will have someone from the team developing the project to work with. In the meantime you might like to consider the current proposals but MRC and the Wellcome Trust want to hear your ideas on the management structure.	

MAKE SURE EVERYONE IS CLEAR ABOUT DATE, TIME AND VENUE OF NEXT MEETING.

HAND OUT LEAFLETS ABOUT WT AND MRC

HAND OUT LEAFLETS ABOUT THE PROJECT AND SAY THAT WE WILL BE ASKING FOR REATCTIONS TO THIS ON SATURDAY

THANK AND CLOSE

FOR THE FOLLOWING DAY WE NEED A LIST OF QUESTIONS THAT MUST BE ANSWERED AT THE SECOND SESSION AND A LIST OF KEY POINTS THAT PEOPLE WILL WANT FOLLOWED UP/TO DISCUSS FURTHER

ANY THOUGHTS ON HOW TO STRUCTURE THE SECOND SESSION AND TECHNIQUES THAT MIGHT BE ESPEICALLY RELEVANT TO BOTH SESSIONS SHOULD ALSO BE CONSIDERED

Further information

Questions participants might ask

- the nature and purpose of the research;
- potential benefits to others and to science;
- why you are being asked to participate;
- the exact nature of any procedures (e.g. giving a blood sample);
- how your sample will be stored and for how long;
- the nature of possible risks and discomforts for either you or your family;
- whether you and/or your family will be told of the results of the research;
- reported back to you;
- how your records will be kept confidential;
- who is responsible for the custodianship of the database to ensure
- confidentiality is protected;
- who will be given access to the BioBank and who will be denied access –
- other researchers, health professionals, your relatives, your employer,
- your insurance company, the police?
- whether commercial companies will have access to the BioBank;
- whether the results of the research will be patented;
- whether or how any commercial benefits of the research will be shared with the community that takes part;
- how you will find out about new research directions before studies begin;
- confirmation of your right to withdraw at any time and how to withdraw;
- confirmation of your right to unrestricted healthcare even if you withdraw from the study;
- a point of contact for further information.

Pilot Topic Guide –Day 2, Saturday 19 January 2001

Start 2p.m

ON ARRIVAL PARTICIPANTS TO BE GIVEN NAME BADGES, BADGES WILL ALSO HAVE A LETTER AND A COLOUR CODE FOR LATER DIVISION INTO PAIRS AND SUB-GROUPS. [PSP TO PREPARE BADGES IN ADVANCE]

2:00 – 2:20 Session 1 – Original groups of 10 split by Gender (TAPE)

Moderators: Women SK, Men AM

The purpose of this session is to reintroduce the groups to one another and to explore any thoughts, conversations or observations that participants have had since the introductory session.

USE ROUND TABLE FEEDBACK SUGGESTING THAT EACH PARTICIPANT TAKES A COUPLE OF MINUTES TO SAY WHETHER THEY HAVE NOTICED ANYTHING RELEVANT TO BIOBANK SINCE TUESDAY OR HAD ANY THOUGHTS OR CONVERSATIONS ABOUT THE TOPIC. MODERATORS SHOULD LOOK PARTICULARLY FOR ANYTHING THAT PARTICIPANTS SAY HAS INFLUENVCED THEIR OPINIONS.

AT THE CLOSE OF THIS SESSION ASK PARTICIPANTS TO COMPLETE THE ANONYMOUS VOTING FORM PROVIDED. THIS ASKS WHETHER THEY PERSONALLY WOULD SIGN UP FOR BIOBANK AND ASKS FOR TWO REASONS WHY (OR WHY NOT).

2:20 – 3:00 Session 2 – Tuesday's Questions (TAPE)

SK to introduce session and AD FR who will be answering questions. Questions collected on Tuesday will be displayed on flipcharts for participants. [PSP TO PREPARE FLIPCHARTS IN ADVANCE]

SK to remind participants of general concept of BioBank USING THE CONCEPT BOARDS and that Tuesday's session was principally about gathering questions. Then introduce AD and FR who will be addressing the questions. WE SUGGEST THAT ONE TAKES THE "RECRUITMENT AND SCIENCE" QUESTIONS AND THE OTHER THE "BACKGROUND AND MANAGEMENT" QUESTIONS. Table 1 shows the suggested grouping of questions.

After Tuesday's questions have been addressed SK to seek any new questions for AD/FR.

At the close of this session, the results of the participation vote will be revealed. [AM/MD TO PREPARE FLIPCHART SHOWING VOTE AND SUMMARY OF REASONS DURING SESSION]

3:00 – 3:10 Session 3 – Pairs work

SK to introduce session. Whole group to split into pairs, each pair must have one person from each of Tuesday's groups and a different letter (Y or N) on their name badge.

They will be asked to role play as two people who have just received letters inviting them to participate, they can assume any relationship they like (could be husband/wife, brother/sister, neighbours, friends, partners or simply met on a train while both reading the letter). One of the pair will have to argue that they should participate (the one wearing a badge with Y on it), the other will have to argue that they should not participate. Each pair will be asked to feedback the 2 or 3 main arguments that they have made both for and against participation.

3:10 – 3:30 Session 4 – Feedback from pairs (TAPE)

AM to lead session. Each pair to feedback key pros and cons of participation while a master list of each is constructed.

3:30 – 4:00 Tea Break

DURING TEA BREAK SK/AM TO BRIGADE CONS INTO FIVE KEY THEMES AND PRODUCE FLIP CHART SHOWING THESE.

16:00 – 16:15 Session 5 – Opposition perspectives
AD/FR to lead this session focusing on the five key areas identified and introduce viewpoints that have been presented to WT/MRC from groups opposed to BioBank and briefly explain the responses [THIS WILL LEAD INTO A BRIEF DESCRIPTION OF THE PROPOSED OVERSIGHT BODY].

4:15 – 4:30 Session 6 – Mini-group discussions
SK to introduce session. Whole group to divide into five mini groups (using colour coding on badges). Each group to discuss the arguments presented against BioBank on one of the five areas and their views on these arguments. Each group will be asked to prepare a short feedback saying what they thought of the arguments against BioBank. Are they reasonable or should they be ignored. If they are reasonable should BioBank respond by changing the way it works and how?

SK/AM/AD/FR/MD TO CIRCULATE ROUND THE GROUPS LISTENING TO CONVERSATIONS AND ANSWERING QUESTIONS IF REQUIRED.

4:30 – 5:00 Session 7 – Two groups (TAPE)
AM/AD to lead one group and SK/FR the other. Three of the mini-groups will join together to make one larger group and the other two will combine (the precise combination will be decided once the five key areas have been identified to bring together areas sharing common features).

The purpose of this session is to allow participants to present their initial views on how they feel about criticisms of BioBank and how it might be run in order to satisfy any concerns that they have. Each group will need to prepare a short feedback note.

5:00 – 5:15 Session 8 – Feedback from Two Groups (TAPE)
AM to lead session. Each of the two groups to feedback their aggregated views on concerns raised about BioBank and how these can be addressed. AD/FR to then respond by describing implications of different actions and how responses have been developed so far.

AT THE CLOSE OF THIS SESSION ASK PARTICIPANTS TO COMPLETE THE ANONYMOUS VOTING FORM PROVIDED. THIS ASKS WHETHER THEY PERSONALLY WOULD SIGN UP FOR BIOBANK AND ASKS FOR TWO REASONS WHY (OR WHY NOT). EMPHASISE THAT IT IS OK TO CHANGE THEIR MINDS FROM EARLIER POLL.

5:15 – 5:45 Session 9 – An oversight body (TAPE)
SK to introduce this session. The purpose of the session is to put together a list of requirements for an oversight body that can be presented to the governors of the WT and the Council of the MRC. The requirements should be those that the participants feel are necessary regardless of any information that they have been given about existing plans or opposition views. EMPHASISE TO GROUP THAT A CRITICAL OUTPUT OF THIS PROJECT IS A REPORT TO THE DECISION-MAKERS AT EACH BODY AND THAT THIS GROUP ALONG WITH TWO TO BE RUN LATER HAVE A VITAL ROLE TO PLAY IN PROVIDING THE INFORMATION THAT WILL GO INTO THIS REPORT.

[AM/MD TO PREPARE FLIPCHART SHOWING VOTE AND SUMMARY OF REASONS DURING SESSION, WITH COMPARISONS TO INITIAL VOTE WHERE APPROPRIATE]

5:45 – 6:00 Session 10 – Feedback and Close (TAPE)
SK to lead the session opening by presenting the results of the second vote and facilitate discussion of the two votes any changes during the day and the reasons for the changes.

CONCLUDE BY THANKING PARTICIPANTS AND EXPLAINING NEXT STEPS FOR THE PROJECT.

Topic Guide –Day 2, Saturday 26 January 2001

ON ARRIVAL PARTICIPANTS TO BE GIVEN NAME BADGES, BADGES WILL ALSO HAVE A LETTER AND A COLOUR CODE FOR LATER DIVISION INTO PAIRS AND SUB-GROUPS. [PSP TO PREPARE BADGES IN ADVANCE]

Session 1 – Original groups of 10 split by Gender (TAPE)
The purpose of this session is to reintroduce the groups to one another and to explore any thoughts, conversations or observations that participants have had since the introductory session.

USE ROUND TABLE FEEDBACK SUGGESTING THAT EACH PARTICIPANT TAKES A COUPLE OF MINUTES TO SAY WHETHER THEY HAVE NOTICED ANYTHING RELEVANT TO BIOBANK SINCE TUESDAY OR HAD ANY THOUGHTS OR CONVERSATIONS ABOUT THE TOPIC. MODERATORS SHOULD LOOK PARTICULARLY FOR ANYTHING THAT PARTICIPANTS SAY HAS INFLUENVCED THEIR OPINIONS.

AT THE CLOSE OF THIS SESSION ASK PARTICIPANTS TO COMPLETE THE ANONYMOUS VOTING FORM PROVIDED. THIS ASKS WHETHER THEY PERSONALLY WOULD SIGN UP FOR BIOBANK AND ASKS FOR TWO REASONS WHY (OR WHY NOT).

Session 2 – Tuesday's Questions (TAPE)
Questions collected on Tuesday will be displayed on flipcharts for participants. [PSP TO PREPARE FLIPCHARTS IN ADVANCE]

Remind participants of general concept of BioBank USING THE CONCEPT BOARDS and that Tuesday's session was principally about gathering questions. Then introduce WT and MRC staff who will be addressing the questions. Table 1 shows the suggested grouping of questions.

After Tuesday's questions have been addressed seek any new questions.

At the close of this session, the results of the participation vote will be revealed. [PREPARE FLIPCHART SHOWING VOTE AND SUMMARY OF REASONS DURING SESSION]

Session 3 – Pairs work
Whole group to split into pairs, pairs are indicated by numbers on badge (6 is a trio).

They will be asked to role play as two people who have just received letters inviting them to participate, they can assume any relationship they like (could be husband/wife, brother/sister, neighbours, friends, partners or simply met on a train while both reading the letter). One of the pair will have to argue that they should participate (the one wearing a badge with Y on it) the other will have to argue that they should not participate. Each pair will be asked to feedback the 2 or 3 main arguments that they have made both for and against participation.

Session 4 – Feedback from pairs (TAPE)
Each pair to feedback key pros and cons of participation while a master list of each is constructed. Whole group discussion to discuss key themes emerging

Tea Break
DURING TEA BREAK BRIGADE CONS INTO FIVE KEY THEMES[4] AND PRODUCE FLIP CHART SHOWING THESE.

Session 5 – Solutions
This session focuses on the five key areas identified and introduce viewpoints that have been presented to WT/MRC from groups opposed to BioBank and briefly explain the responses [THIS WILL LEAD INTO A BRIEF DESCRIPTION OF THE PROPOSED OVERSIGHT BODY].

Session 6 – Mini-group discussions
Whole group to divide into five mini groups (using colour coding on badges). Each group to develop solutions to issues identified. Each group to prepare a short feedback.

CIRCULATE ROUND THE GROUPS LISTENING TO CONVERSATIONS AND ANSWERING QUESTIONS IF REQUIRED.

Session 7 – Feedback from Mini-Groups (TAPE)
The purpose of this session is to allow participants to present their initial views on how they feel about criticisms of BioBank and how it might be run in order to satisfy any concerns that they have. Each group will need to prepare a short feedback note.

Each of the two groups to feedback their aggregated views on concerns raised about BioBank and how these can be addressed. WT/MRC to respond by describing implications of different actions and how responses have been developed so far.

AT THE CLOSE OF THIS SESSION ASK PARTICIPANTS TO COMPLETE THE ANONYMOUS VOTING FORM PROVIDED. THIS ASKS WHETHER THEY PERSONALLY WOULD SIGN UP FOR BIOBANK AND ASKS FOR TWO REASONS WHY (OR WHY NOT). EMPHASISE THAT IT IS OK TO CHANGE THEIR MINDS FROM EARLIER POLL.

Session 8 – An oversight body (TAPE)
The purpose of the session is to put together a list of requirements for an oversight body that can be presented to the governors of the WT and the Council of the MRC. The requirements should be those that the participants feel are necessary regardless of any information that they have been given about existing plans or opposition views. EMPHASISE TO GROUP THAT A CRITICAL OUTPUT OF THIS PROJECT IS A REPORT TO THE DECISION-MAKERS AT EACH BODY AND THAT THIS GROUP ALONG WITH TWO OTHERS BEING RUN HAVE A VITAL ROLE TO PLAY IN PROVIDING THE INFORMATION THAT WILL GO INTO THIS REPORT.

[PREPARE FLIPCHART SHOWING VOTE AND SUMMARY OF REASONS DURING SESSION, WITH COMPARISONS TO INITIAL VOTE WHERE APPROPRIATE]

Session 9 – Feedback and Close (TAPE)
Present results of the second vote and facilitate discussion of the two votes any changes during the day and the reasons for the changes.

CONCLUDE BY THANKING PARTICIPANTS AND EXPLAINING NEXT STEPS FOR THE PROJECT.

Appendix 3 Concept boards

Concept board 1

Biobank UK

Proposed medical research to improve the ways we can treat and prevent ill health.

Why?

To establish how genes, lifestyle and environmental factors interact to affect health.

Who?

Half a million adults aged 45-69 reasonably representative sample of the UK population.

How

Recruitment through family doctors in selected areas.

What

Blood sample from which DNA will be extracted

Permission for NHS records to be accessed

Lifestyle information collected by questionnaire

Monitored for at least ten years

Recontacted at least once for more information

Funding

Medical Research Council and The Wellcome Trust working with the Department of Health.

£60 million over 10 years.

Concept board 2

Questionnaire and interview

age, sex, postcode, education level, marital status, ethnicity
occupational exposures
habits/lifestyle - tobacco exposure, alcohol consumption, physical activity
diet - general dietary questions/7 day diary
reproductive history
family history and past medical history of specific conditions
medication use
assessment of disability and impairment,
assessment of mental well-being profile

Examination e.g:

height, weight, waist, hip measurements
blood pressure
pulse
blood sample

Appendix 4 Respondent profile

Category	Number
Social class	
AB	**17**
C1	**28**
C2	**9**
DE	**3**
Not available	**2**
Gender	
Male	**29**
Female	**30**
Age	
45-55	**29**
56-69	**30**
Ethnic origin	
White	**48**
Black (including British, Caribbean and African)	**3**
Indian sub-continent (India, Pakistan, Bangladesh)	**4**
Other	**0**
Mixed	**2**
Not stated	**2**