

People Science & Policy Ltd

UK Biobank Consultation on the  
Ethical and Governance  
Framework

Report prepared for

The Wellcome Trust  
and  
The Medical Research Council

03/004/sk  
June 2003

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## **Executive Summary**

### ***Introduction and method***

People Science & Policy Ltd (PSP) has established a panel of 64 lay people aged between 45 and 69, the age group that will be invited to contribute to the UK Biobank. All panel members have previously participated in briefing and discussion sessions about the UK Biobank and are familiar with its broad purpose and the early plans proposed for its operation. The panel is not large enough to provide statistically representative data but it provides a cross-section of the population of interest. This panel has been recruited independently and membership is in no way connected to any future invitation to contribute to the UK Biobank.

An Interim Advisory Group (IAG) appointed by the Wellcome Trust and the Medical Research Council (MRC) is working to produce an Ethical and Governance Framework (EGF). Before finalising their report to the UK Biobank team the IAG, supported by the Trust and the MRC, wished to consult with the panel on the draft EGF and the various options still under discussion.

All 64 members of the panel received a letter inviting them to take part in this consultation. They were invited to two, two-hour sessions at a local venue at least two weeks in advance of the meeting. The meetings took place in the evening between 15 May and 12 June 2003. In all, 47 panel members attended the first sessions and 42 attended the second sessions. Panel members have been invited to comment on this report. Any comments will be passed to the Wellcome Trust.

This executive summary is structured around the headings of the IAG report to the funders.

### ***UK Biobank Purpose Statement***

The statement of purpose sums up for the panel members the objectives of the UK Biobank as they have understood them. It was felt that it could be more succinct and that the benefits should be more prominently presented.

## ***I. Relationship between UK Biobank and Participants***

### **A. Understandings and consent.**

#### **1. Recruitment**

##### *a. Selection for participation*

There were some questions about the power of GPs in selecting people for the UK Biobank. Some panel members wanted to be able to opt-in and give permission for access to their records, irrespective of the views of GPs about the project.

##### *b. Procedure for recruitment*

Recruitment was seen as a process with initial letters of invitation coming from the GP. Even if all the administration is undertaken by the UK Biobank, it was thought that this would generate the best response rate. It was not thought to be misleading, as the GP must



endorse the study by granting access to the medical records they hold. Moreover, letters coming from a largely unknown organisation could appear as a breach of confidence before the project has started.

Following the initial letter there might be a fuller information pack and the opportunity to attend local meetings to ask questions before attending the session with the research nurse. After the session with the research nurse, there might be a cooling-off period before the data is processed. It was thought that this process would help to minimise later drop-out, which it was recognised would be expensive as well as having an adverse impact on the scientific quality of the project.

## **2. Consent**

The central issues in obtaining consent from potential volunteers were identified as confidentiality, security of data, the uses to which the data will be put and who will have access to the information. The UK Biobank will need to be able to provide detailed answers to operational questions.

## **3. Collection of data from medical records**

Participants appreciated the necessity of access to past and future medical records and were more concerned about the potential absence of full records and inaccuracies that might be present.

## **4. Feedback of health information to participants**

### *a. At enrolment (including initial blood analyses)*

Participants were happy about the amount of feedback they would receive at the recruitment session.

### *b. After enrolment*

The reasons that feedback will not be provided at an individual level are appreciated. However, many thought that it would motivate some to volunteer, whilst acknowledging that others might not want this feedback. The panel members have already had extensive discussions about individual feedback at earlier sessions, see “*BioBank UK: A Question of Trust*” <http://www.ukbiobank.ac.uk/documents/consultation.pdf>).

## **5. Ongoing dialogue with participants**

The panel members found it difficult to think of how they might “actively participate” after recruitment beyond providing more blood samples and up-dating lifestyle information. A paper newsletter that would provide information on who was using the data and for what purposes was popular. Some were concerned that producing and distributing a newsletter might divert money from research and preferred the option of a website. However, most people recognised that access to, or familiarity with, the Internet would mean that this option would not be appropriate for all the volunteers.

The opportunity to sit on the Oversight Body, the ability to ask questions and to feed in comments were other ideas put forward on how continuing dialogue with the volunteers might be achieved.



## **6. Expectation of recontact**

The panel members understood the need for recontact to collect more information. Indeed in the original sessions questions had been asked about whether the data would be sufficiently reliable if it was only up-dated once in ten years.

There was no expectation that volunteers should receive information from the UK Biobank about the research being conducted or the operation of the project but it was of some interest to most of the panel. Keeping volunteers informed about the progress that the project was making was felt to be a good way of keeping the volunteers engaged and interested.

## **7. Right to withdraw**

While some panel members were adamant that volunteers should not be allowed to withdraw, the majority believed that it was an essential right. There was also the view that being able to withdraw would reassure volunteers about the bone fides of the project.

## **8. Respect for incapacitated and deceased participants' wishes**

There was a strong feeling that volunteers should be asked their views at the time of recruitment about their wishes in the case of death or mental incapacity during the ten years and that these wishes should be paramount.

Respect for relatives after death is essential and the UK Biobank will need to ensure that death records are processed quickly so that contact is not made with relatives after death.

With respect to mental incapacity, relatives might feel that a volunteer is too ill to be recontacted and this will need to be accommodated.

## **9. Expectation of financial gain**

There was no expectation of financial gain for the volunteers. It was accepted that the data would be used by commercial companies, particularly pharmaceutical companies, for profit but it was thought that these types of organisations should pay for access to the UK Biobank.

# **B. Confidentiality**

## **1. Commitment to maintaining confidentiality**

The commitment to confidentiality was seen as paramount.

## **2. Anonymisation**

It was important to the panel members that researchers should not know the identity of the individuals with whose data they are working.

## **3. Re-identification**

The need for re-identification was understood by everyone who took part. Some groups recommended the use of high-level encryption and encoding to remove the need for anyone to be able to access the full dataset for any individual. Others recommended that two or more people should hold part of the “key” and that it should be people within the



UK Biobank structure – perhaps the Chairs of the Oversight Board, the Scientific Committee, the Ethics Committee or the Chief Executive.

#### **4. Security**

While it was acknowledged that the data is not a matter of “national security”, it was assumed that security would be tight. Some panel members were unconcerned about who saw their medical records but others were much more wary.

### ***II. Relationship between UK Biobank and Research Users***

#### **A. Stewardship of data and samples**

It was assumed that the professionals recruited to work at the UK Biobank would have professional codes of conduct that would be enforced.

#### **B. Research access to data and samples**

##### **1. General terms of access**

It was agreed that access should be for medical research, which would include the identification of the causes of illness and cures as well as investigating what is detrimental to health. It was envisaged that most users would be academics and the pharmaceutical industry.

Use by the food industry to develop healthy foods or foods that would protect health, was sanctioned, where it arose. Access by insurance companies was ruled out by everyone. Access by tobacco and alcohol companies, who might claim to be able to make products that were safer, was also raised by some panel members, but seen as a more ambiguous area.

Access by non-UK organisations was accepted but it was suggested that more rigorous checks might be needed for non-UK companies.

##### **2. Specific terms of access**

Panel members recommended that there be a fee for access to the information in the UK Biobank. Furthermore, any organisation likely to make a profit from their research results should be charged more than others, probably through a profit-sharing formula.

##### **3. Requirement of data sharing and broad release of findings**

The philosophy that all results will be published and that information will be fed back to the UK Biobank as a condition of access was widely supported.

### ***III. Relationship between UK Biobank and Society***

#### **A. Internal Governance**

##### **1. UK Biobank Board of Directors**

This body was thought to be responsible for the day-to-day running of the UK Biobank. It was assumed that it will comprise suitably qualified and experienced professionals.



## **2. Oversight Body**

The Oversight Body should perhaps consider another name as “oversight” is commonly associated with an error.

There was consensus that there should be some independent professionals on the Oversight Body.

The main function of the Oversight Body should be to oversee the workings of the UK Biobank, to ensure that the rules are being abided by, to agree changes in policy, particularly with reference to the ethical and governance framework, and to act as an arbiter of last resort on operational and access matters.

It was thought an Oversight Body that meets a few times a year, paying members’ expenses or a small allowance and receiving staff reports, should be able to meet this aspiration, provided that it is given the authority to challenge the reports laid before it. However, it was suggested that thought should be given to an external auditing procedure to ensure that not only are the finances being correctly managed but that operating systems are being adhered to.

The Nolan principles were recognised as having weaknesses but the transparency of the process largely reassured the more sceptical participants. The independent assessor will be an important figure and, it was suggested, could be one of the volunteers or a GP.

## **B. External Governance**

### **1. NHS ethics review**

This was discussed in some groups and the existing processes provided reassurance to the panel members. Some within these groups thought that this process rendered the proposed UK Biobank Ethics Committee redundant.

### **2. Department of Health Research Governance Framework for Health and Social Care**

Participants believed that where there are existing relevant codes of conduct, these should be applied, whether they had originated in the UK or overseas.

## **C. Benefit sharing and intellectual property**

The panel members see the final outputs as benefiting society as a whole through better diagnosis and treatment of disease. They recognised that individual companies exist to make a profit and are therefore unlikely to invest in research if they cannot protect their intellectual property rights. It was suggested that one way to address this might be to recover some proportion of profits in the case of medicines being developed as a result of the UK Biobank data.

## **D. Contingency in event of closure of UK Biobank**

This was not discussed in this consultation.

## ***IV. Adoption, implementation and revision of the EGF***

An EGF should be adopted by the funders initially and subsequently up-dated and revised by the Oversight Body.



## 1. Introduction

### 1.1 The Panel

People Science & Policy Ltd (PSP) has established a panel of 64 people aged between 45 and 69, the age group that will be invited to contribute to the UK Biobank. Annex 1 gives details of the panel profile. The panel does not include anyone who might have a professional interest in the UK Biobank project, such as those involved in medical and biomedical research, general practitioners and nurses. Separate consultation exercises are being undertaken with these groups. While the panel is not large enough to provide statistically representative data, and indeed was never designed for this purpose, it provides a good cross-section of the population of interest. This panel has been recruited independently and membership is in no way connected to any future invitation to contribute to the UK Biobank.

All the panel members have previously participated in briefing and discussion sessions about the UK Biobank and are familiar with its broad purpose and early plans for its operation. Reports on this work are available from the UK Biobank website at <http://www.ukbiobank.ac.uk/ethics.htm>. It takes some time to brief people on the UK Biobank project and to answer the immediate questions that arise. Hence the idea of the panel is to enable the UK Biobank project team, and others, to consult with potential volunteers on various issues during the development of the project, without having to spend time briefing new participants on each occasion.

In addition, the opportunities for reflection and consideration offered by the reconvening of panel members over time, allows them to revisit questions and place new issues into context as they arise. As one of the panel members put it:

*“The more we do, the more interesting it gets.”*

Woman, Plymouth

### 1.2 The Ethical and Governance Framework

The project has now reached a critical stage with an Interim Advisory Group (IAG) of ethicists, lawyers, social scientists, philosophers and lay people working to produce an Ethical and Governance Framework (EGF). This covers issues of confidentiality, consent, withdrawal, recontact, participation, feedback, benefits, uses and users, commercialisation and oversight/monitoring. Before finalising their report to the UK Biobank team the IAG, supported by the Wellcome Trust and the Medical Research Council (MRC) wished to consult with the panel on the draft EGF and the various options still under discussion. We therefore canvassed the panel members' views on the draft EGF as well as other new ideas such as alternative recruitment approaches, data collection and the “statement of purpose”.

### 1.3 Method

All 64 members of the panel received a letter inviting them to take part in this consultation. They were invited to two, two-hour sessions at a local venue at least two weeks in advance of the meeting. The meetings took place in the evening between 15 May and 12 June 2003. In all, 47 panel members attended the first sessions, three were unable to make the second sessions but made this clear when they responded to their invitation. Unfortunately two others also missed the second sessions, due to unforeseen





circumstances. The meetings were tape-recorded and panel members were guaranteed confidentiality in the usual way.

The first session began by reminding people about the UK Biobank project and providing an up-date on developments since they had last been involved with the project, including the establishment and role of the Interim Advisory Group (IAG). In the first session panel members were introduced to the draft EGF and explored the issues widely. In the second session panel members reflected on the issues and made recommendations to the IAG.

**Panel members will receive a copy of our report after 24 June and will be invited to comment in writing or by telephone. They will subsequently receive a copy of the IAG's report and again be invited to respond. Comments will be passed to the Wellcome Trust.**

Annex 2 presents the topic guides for both sessions and annex 3 the stimulus materials that were used to present the draft EGF to the members of the panel.

## **1.4 The report**

This report sets out the findings from this consultation. The next section looks at the role and membership of the proposed Oversight Body and how members might be appointed.

Section 3 explores participants' perspectives on recruitment and data collection as well as issues related to the UK Biobank re-contacting volunteers (whether to request more information, to impart information about the project or to facilitate participation in the decision-making processes). Hence it includes views on feedback both individual and global and participants' feelings about benefits and beneficiaries.

Section 4 discusses participants' views on the statement of purpose, consent and withdrawal and includes comments on dealing with death and mental incapacity. In so far as consent covers how the data will be used and by whom, this section also looks at uses and users. After the first session it was agreed that the participants needed far more information about the selection criteria for the collaborating centres before they could discuss the possibility of "special access" by the collaborating centres. For example, the reason they were selected as collaborating centres may be a reason to give them special access. It was therefore agreed by the Trust and the MRC that it would not be practical to cover this topic in sufficient depth.

The final section highlights the recommendations the panel members made to the IAG.



## 2. Oversight body

### 2.1 Introduction

This section sets out participants' views on the role and membership of the proposed Oversight Body (OB) and how members might be appointed. The IAG asked that participants focused primarily on the broad role of the proposed OB. However, some groups found it easier to deal with the practicalities and so our approach with them was to build upwards from who might sit on such a body and why these categories of people were thought to be appropriate in order to explore the role of the OB.

In combination, approaching the question from two different starting points enabled us to fully explore the role and remit of any OB and the confidence the proposed appointment system will engender in potential volunteers. Hence this section is structured under a number of subheadings: membership, role, remuneration, funding and appointment procedures.

It should be remembered that in some of the original consultation activity, there were reservations about the need for an oversight body (see "*BioBank UK: A Question of Trust*" <http://www.ukbiobank.ac.uk/documents/consultation.pdf>). Those reservations were not present in the current round of discussions. Rather the establishment of an OB was widely perceived as of critical importance.

One participant questioned whether "Oversight Body" was an appropriate title. In his view an "oversight" was something that has been missed. This participant felt that the title "Overseeing Body" would better reflect the aim of the funders. Indeed the rest of the group adopted the title for the remainder of the session.

### 2.2 Membership

#### 2.2.1 Expert members

The spontaneous reaction of participants was to propose an "expert" committee. Indeed some saw no reason, at least at first, why the OB should not be composed of entirely Wellcome Trust and MRC representatives.

*"If anything goes wrong they've got everything to lose."*  
Woman, Manchester

But others felt that:

*"This oversight body would be the first line of defence against something undesirable happening. Not by the present people, who I'm sure are all fine and worthy people, but you don't know who'll be there in twenty years time."*  
Man, Scotland

For the most part participants were adamant that the OB must include "*professional people, who know what's going on*". Typically it was proposed that people with medical



and scientific knowledge as well as some representatives with legal training were essential.

*“People who understand what the hell these researchers are talking about.”*  
Man, Plymouth

In the groups where it was raised, the idea of including representatives of any religions was generally rejected. The main reasons for rejection were:

*“Religion makes it all too heated.”*  
Woman, Manchester

Man 1: *“Clerical people can be a bit backward in their thinking.”*  
Man 2: *“They can be yeah, but I mean an academic, a theologian, not a vicar.  
Just to give a balance really.”*  
Men, Northallerton

The suggestion was also made in Scotland that a general theological or moral philosophy perspective might be more helpful than simply drawing representation from one or more recognised faiths.

### 2.2.2 Lay members

Some participants were adamant that **only** those with qualifications in relevant professions should be members of the OB. Others felt that there should be some representation from the volunteers but usually the groups proposed that this should be a minority. The case for including professionals rested on the argument that:

*“I wouldn’t like to be part of it [the UK Biobank] if I thought it was just run by Joe public.”*  
Woman, Manchester

Some panel members believed that ordinary volunteers would not be in a position to truly oversee the behaviour and running of the UK Biobank because they could *“have the wool pulled over their eyes.”*

*“I wouldn’t have a clue what was going on”*  
Woman, Manchester

*“Its no good having someone like me...I wouldn’t have any idea. They need to have some idea of what’s going on...they need someone who’s got a bit of knowledge.”*  
Man, Wales

However, it was also argued in the same group that:

*“What they’re overseeing is not a medical process, but a business process effectively. The medical processes and all the rest of it comes out of the science committee.”*  
Man, Wales



In all of the groups the majority of panel members believed that there was a role for lay members.

*“I think sometimes medical people and scientists can get lost in a little world of their own without getting their feet on the ground. Maybe someone could hold them down on the ground a bit and show how it affects normal folks.”*  
Man, Plymouth

One participant proposed in the reconvened session, that the OB have at least 50% of its membership drawn from volunteers to ensure that their interests were safeguarded and the group tended to agree with this idea. The same group had, in the first session, discussed whether any of the OB needed to be professionals from relevant fields, although they tended to believe that they should be. The argument for having an entirely lay OB rested on the ability of the OB to seek professional input as and when the need arose.

There was an interesting interaction in the Manchester group of women about the pros and cons of lay members on the OB. One woman saw the OB in the following way:

*“To me it sounds like a board of governors of a school. So, you have like a chair person and in a Catholic school it’s the priest of the parish. Then you have a couple of people from the local authority, a local councillor, a couple of teachers who belong to the school and you have a parent as well. At least one parent governor. It sounds the same sort of thing to me. It’s the way things should be made-up. So you’ve got people who are, you know, in charge, people who know. So in this field you’d have a couple of doctors, err, someone who is quite up in the medical world as the chair person..... you have [also] got someone who’s down to earth and, you know, not as highly qualified as that...a normal person. Someone who’s got an interest in it and wants to make sure it’s being done right. Like in the school the parent governor obviously has a child at the school, so they want to make sure that the board of governors are doing everything right, from the parents’ point of view. So that person would be representing the people who have donated.”*

When challenged by another member of the group about the ability of any lay representative to monitor what was going on, a third member of the group said:

*“It’s like what we’re doing now. We’ve all got our own views through learning and listening. That’s what would happen there. Things would be openly discussed.”*

and the first woman continued:

*“You’re not necessarily going to go down into the real medical bits where you haven’t a clue what they’re talking about... It’s going to be more the ethics of things and making sure the money’s being used right and that everyone is doing their job correctly, there’s a lot more to it than, you know, being in an operating theatre. It’s not that sort of actual hands on medical stuff.”*  
Women, Manchester



There were mixed views on whether lay members of the OB should be “*educated*” or “*professional*” people. In one group, those from occupations such as teachers, librarians and civil servants were suggested. In another, the opposite position was taken.

*“Professional people, they’ve all gone through the same sort of universities and they all tend to have the same viewpoint. Someone from outside though may have a totally different viewpoint and raise things that they haven’t seen before.”*

Man, Plymouth

There was concern however, that lay representatives should not be “*professional consumers*”. This included both the “*great and the good*” who are “*wheeled out*” to sit on bodies and people who are drawn from consumer bodies, but have become professionals and are no longer representative of “*real consumers*”.

*“Not professionals who sit on God knows how many committees”*

Man, Wales

In one group the debate about whether or not lay members had a role led to the recommendation that it should be clear what any lay member brings to the OB. Those against the idea of lay members argued that they could stop important research because of a lack of understanding. As a counter to this it was argued that as part of the application procedure lay applicants should be asked to demonstrate that they would bring new ideas, a different perspective; and be able to articulate why they wanted to be a member of the OB. It was thought that lay members should be interviewed by the appointments board.

*“The people making the decisions will be astute enough to know what they’re looking for.”*

Woman, London

In other groups people believed that the principal skill that lay participants would bring would be the ability to ask questions that reflected the everyday concerns of the volunteers. This would ensure that the OB did not lose sight of these and remained responsive to the volunteers they are safeguarding. Several participants suggested that all volunteers could be asked at recruitment whether or not they would be interested in sitting on the OB.

Some participants felt that finding lay volunteers willing to make the commitment necessary to sit on the OB might be difficult, although in this age group the “*early retired*” were thought to be good candidates for membership. It was suggested that people should have to commit to serve for a minimum term of a year and preferably two but it was felt:

*“You can’t expect people to commit for ten years.”*

Man, Northallerton

Neither was a ten year commitment thought to be desirable. There was a general consensus that there should be some sort of rolling replacement of all OB members, “*like councillors*”, with a definite retirement age. One group recommended a fixed term of three years with the Chairman perhaps serving five years to provide continuity and guidance to new members. Many panel members thought that it was desirable to have



injections of fresh blood to ensure that the OB members remain keen and motivated. There was also a sense that very long terms of appointment might lead to the OB members becoming too close to the UK Biobank and therefore less willing to be critical. One group suggested that the national retirement age should be applied.

It was suggested that a panel or lay sub-committee, could be formed from the volunteers who agreed to take a more active role who would receive additional briefing material. People could then be co-opted from this panel onto the OB, thereby spreading responsibility and workload.

### 2.2.3 The Oversight Body as volunteers

In several groups the same proposal emerged independently. It was suggested that if all those on the OB in the age group 45-69 volunteered to take part, irrespective of whether they had been selected through the normal channels, they would have a real interest in ensuring that the UK Biobank was effectively monitored. This idea was very popular when put to other groups.

### 2.2.4 Independence

There was some concern however, that those on the OB should be independent from the UK Biobank. It should therefore not be comprised of people likely to want access to the data.

Man 1: *“It needs to be composed of people who have absolutely nothing whatsoever to gain...”*

Man 2: *“From the other people...”*

Man1: *“The Trust”*

Man 3: *“Its got to be something like a factory inspector. When they go into a firm, they’ve got nothing at all to do with the firm.”*

Man 1: *“No conflict of interest at all.”*

Men, Wales

It was acknowledged that finding medical and biomedical research experts with appropriate levels of knowledge but with no interest in the resource would be difficult, if desirable.

It was also recommended that all members of the OB should declare any relevant issues on a continuing basis. The MPs register of interest was used as a parallel

## 2.3 Role

It was agreed by participants that the primary role of the OB was to oversee and monitor the UK Biobank to ensure that there was no *“funny business”* going on. The OB must act in the interests of the volunteers and as the final arbiter on policy and practice. So, for example, it would make final decisions on changes in ethical guidelines and matters of policy and would also be responsible for making final decisions on access where existing procedures were unable to resolve an individual case. It was accepted that the OB would not see all applications or be involved in day-to-day issues. However, in some groups it was suggested that the OB should see the reports from researchers who had used the UK Biobank to ensure that the research that had been conducted was in accordance with the aims and objectives of the UK Biobank.



In-line with the briefing we received from the Wellcome Trust and the MRC, participants were briefed that the OB would meet a few times a year and would probably only be paid expenses or a small attendance allowance. Although, the actual frequency of meetings will be determined by the OB itself once it is established. That it would meet only a few times a year seemed appropriate for these functions.

*“There’s nothing to do on a day-to-day basis.”*

Man, Wales

However, participants expected that it would be able to hold “*extra-ordinary*” meetings, if the need arose.

There was however, confusion about how the members would be able to monitor what was really going on. Some were suspicious that reports drafted by staff could be “*economical with the truth*”. This generated long debates in some groups, with discussions about how and when issues would be referred to the OB.

One response to this was a proposal for an external auditing system undertaken by an independent organisation that reported directly to the OB. It was felt that this could be an annual or biennial task. One group perceived the role as similar to that undertaken by external quality assessors in industry.

Man 1: *“Its like quality control...you do an ad hoc spot check...unannounced.”*

Man 2: *“It’s worth having an external check...they do keep you on your toes.”*

Men, Plymouth

Others concluded that the people running the UK Biobank were reputable and if individuals did not trust the system, they should not volunteer. Again the question of independence was raised:

*“This overseeing body has got to be quite a powerful body hasn’t it? It’s got to be very strong, its got to be a strong group. It’s got to have people who can say no and mean no.”*

Man, Wales

An important role for the OB was felt to be a monitoring of the ethical framework for the UK Biobank to take account of changing social attitudes and the development of science.

*“Ethics should be sorted out at the beginning and become part of the remit of the oversight body. Part of the philosophy as it were.”*

Man, Scotland

## **2.4 Remuneration**

With respect to payment to members of the OB it was suggested by some that payment should be in accordance with the level of responsibility and to recognise the importance of the role of the OB.



## 2.5 Funding

There were also some discussions that arose spontaneously about how the OB should be funded. While some felt that the obvious source of funds was the £45 million allocated by the funders to date, others felt that this might compromise members and sought other sources of income. “The Government” was one suggested source, another was the income generated from payments to the UK Biobank for access, with an initial loan until income is generated.

After some debate it was generally agreed that the funds should come from the allocated £45 million. The positive aspect to this was viewed as the independence that the OB would have from other funders who may seek to set a particular agenda, whether political or commercial. The counter argument was that the more money spent on administrating the UK Biobank, the less would remain to ensure that adequate numbers of volunteers were recruited and retained.

## 2.6 Appointment system

The facilitators set out the “Nolan Principles” for participants using Stimulus Board 5 and explained that this was the proposed mechanism by which members of the OB would be appointed. Three main areas of concern were raised.

### 2.6.1 Main concerns

Firstly, one participant questioned whether, in reality, the “jobs” will have already been filled. That is, will the funders (who are ultimately responsible for the appointments under the system) already have earmarked preferred candidates, would it be “*jobs for the boys*”? This was raised by others who said that the proposed system was “*fine as long as it really is open to everyone*”.

Secondly, there was a concern that appointments including the appointment of the independent advisor would be done by the funders.

*“I think it’s worrying that the people organising it can choose who is on this body.”*

Woman, Scotland

Thirdly there was a query about the role of politicians in the appointments as the MRC and Department of Health are government bodies. In many of the groups, there was strong opposition to any form of political input to the selection procedure. The facilitators were able to reassure participants in the reconvened sessions where it arose, that the funders had advised that appointments will not require Ministerial approval.

### 2.6.2 Other concerns

There were other queries at a more detailed level regarding the appointment process. These included where the positions would be advertised and what systems would be put in place to deal with a potentially large number of applications and ensure that all were treated equally.

Some groups also raised the question of how OB members could be dismissed, if they were failing in their duty. They recommended that what was expected of OB members should be clearly set out.





On balance, participants accepted that the “Nolan” approach was sound in principle and were somewhat reassured by the statement of transparency; that is, that anyone could ask for information about the process and that it would be open to public scrutiny. The independent assessor was felt to be an important figure and it was suggested that this could be a UK Biobank volunteer or someone such as a GP.

In the Scottish group, it was suggested that an electoral college could be constituted to make the final selection of members for the OB. Constituencies could include the funders, scientists, politicians and the volunteers. In a minority role, politicians were not dismissed out of hand as one constituency.

## **2.7 Complaints procedures**

In some groups we were able to discuss the procedures that panel members thought should be in place to deal with complaints. Where it was discussed it was agreed that there must be a procedure in place. It was thought that in the first instance a local contact should be approached; someone at the relevant collaborating centre. If satisfaction was not gained at this level, higher recourse to a quality control unit or senior manager in the co-ordinating unit would be needed.

*“That’s what happens in industry.”*  
Man, Northallerton

The OB was seen as the final arbiter, if complaints could not be dealt with through this process.

## **2.8 Conclusions**

The OB should perhaps consider another name as “oversight” is commonly associated with an error.

On balance a consensus formed around the idea of having a largely professional OB with people expert in medicine, medical research, medical law and medical ethics with one or two lay representatives from the volunteers. Some participants proposed religious representatives to cover “*moral issues*”. However, on balance such representatives were rejected in favour of other experts, perhaps academics, who could bring this perspective.

There was consensus that there should be some relevant and independent professionals on the OB. It was however, recognised that it will be difficult to find medical researchers with appropriate knowledge who would be unlikely to want to use the UK Biobank.

The main function of the OB should be to oversee the workings of the UK Biobank, to ensure that the rules are being followed, to agree changes in policy and to act as an arbiter of last resort on operational and access matters.

It was thought an OB that meets a few times a year, paying members expenses or a small allowance and receiving staff reports, should be able to meet this aspiration, provided that it is given the authority to challenge the reports laid before it. However, thought should also be given to an external auditing procedure to ensure that not only are the finances being correctly managed but that operating systems are being adhered to.



The Nolan principles have their weaknesses but the transparency of the process largely reassured the more sceptical participants. The independent assessor will be an important figure and could be one of the volunteers or a GP.



## 3. The UK Biobank and its Contact with Volunteers

### 3.1 Introduction

This section covers recruitment and data collection as well as issues related to the UK Biobank recontacting volunteers. Recontact by the UK Biobank could be either to request more information or to impart information about the project or to facilitate participation in the decision-making processes. Hence the section includes views on feedback, both individual and global, and participants' feelings about benefits and beneficiaries.

### 3.2 Recruitment

To date it has always been explained to those taking part in consultations that recruitment would be through general practices with letters coming from GPs. More recently it has been proposed by the UK Biobank team that Primary Healthcare Trusts (PCTs) could be used as a source of contact names and addresses, with a letter being sent from the UK Biobank direct to potential volunteers.

#### 3.2.1 Letters from GPs

The panel members who took part in this consultation unanimously felt that even if the letters are generated by the UK Biobank, some form of covering letter should be enclosed from the individual's GP. This, they felt, would boost the response rate as it would provide evidence that the project is bone fide and thus reassure and encourage people to take part. It was not felt that this was misleading as in some sense GPs would be endorsing the project by agreeing to take part in the project.

*"Even if it never goes anywhere near the GP, if Biobank does all the work, it should come from him [GP]."*

Woman, London

The GP was felt to be not simply endorsing the project, but providing a known reference point for the recipients.

Man 1: *"I think that people will be more suspicious of something coming through their letterbox unannounced"*

Woman 1: *"From someone they don't know"*

Man 1: *"It would scare them a little or they'd be very sceptical...If it came from a medical centre like a hospital or a GP"*

Man 2: *"You've got the trust with the GP"*

Woman 2: *"If you've got the letter and it's on your own GP's headed paper you'll read it."*

Group conversation, Plymouth

#### 3.2.2 Letters from Biobank

It was thought that getting a letter direct from the UK Biobank gave out the wrong message with regard to confidentiality. Panel members said that this would give the impression that your name and address had been passed to the UK Biobank by a third party.



*“If it comes from the Biobank right away you think ‘well my doctor’s given my name and address to another company, they’ve accessed my information without my permission and they’re asking me for other information and telling me they’re going to treat it with respect and confidentiality’ well its got off to a bad start right away.”*

Man, Scotland

Man 1: *“If you got a letter from Biobank saying we got your name from your medical records, it’s a different situation.”*

Man 2: *“In fact I’d hit the roof... its taking your own personal security away from you.”*

Men, Wales

### **3.2.3 GP Workload**

All the groups expressed the view that it would not be desirable if the process of recruiting to the UK Biobank added unduly to the workload of GPs. However, in almost all of the groups suggestions were made on how information technology could be used to ensure that all the administrative load was taken by the UK Biobank rather than local practices. Scanning signatures, using headed paper and managing mail merges were all suggested.

Some people thought that the greatest extra load on GPs might come after the letters were received, when people might then contact the surgery to ask questions. It was believed that this might be inevitable, but that every effort should be made to minimise this response, by providing clear guidance on whom to contact for further information and how to contact them.

*“Something in that letter to the patient has got say ‘phone this number’.”*

Woman, Plymouth

### **3.2.4 Awareness raising**

Participants across the groups stressed that there should be an advertising campaign to raise the level of awareness of the UK Biobank. When potential volunteers receive their invitation to take part, if they are already aware of the project, they will be more likely to take part.

*“I’d have thought that before this whole process started, of looking for volunteers, that it would be necessary to do a public relations exercise.”*

Woman, Scotland

At one of the reconvened sessions, it was proposed that there should be an information pack, which could include the answers to frequently asked questions with a contact number for those who want more information.

### **3.2.5 Recruitment as a process**

Recruitment was perceived as a process. First there would be a letter of introduction. This would be followed by the information pack for those who were interested in taking part and an opportunity to ask questions at a local meeting, before the donation session with the nurse. It was also suggested that a two week “cooling-off period” after the



session with the nurse, before the sample and information are processed, would help to minimise later withdrawals.

Local meetings were raised in a number of groups as a practical way of answering the questions of potential volunteers. The panel members were aware that they themselves still had many questions, despite the fact that they had benefited from relatively in-depth information and discussion about the UK Biobank.

*“We’re only bringing up the concerns of the person that [the UK Biobank] want to go to next year, and these concerns may stop them [taking part].”*  
Man, Plymouth

### **3.3 Data collection**

#### **3.3.1 Research Nurses**

The facilitators explained that research nurses would be employed by the UK Biobank coordinating centre but based at the collaborating centres. They would conduct the initial session, collecting the lifestyle data and blood samples from volunteers. The nurses would then pass the blood directly to the coordinating centre and the other information to the collaborating centre. The collaborating centres would reversibly anonymise the data. While it is hoped that much of the NHS up-dating information will flow electronically to the UK Biobank, it has been acknowledged that nurses may need to visit GPs to manually extract data on a once or twice a year basis.

#### **3.3.2 Updating data**

In order to add to the information over the coming ten years, the link between the data and some way of identifying the individual cannot be broken. All of the groups readily grasped the need for this and considered how best to safeguard the confidentiality promised to volunteers. The facilitators were asked by the IAG to explore with panel members “Who should hold the key?” That is, who should be able to access named data? The facilitators used a simple example to illustrate this. It was suggested that the name and address and perhaps NHS number plus the UK Biobank unique identifier would be held in one computer file and the information collected from people, with the unique identifier would be held in a separate file. But someone must be able to put the information together in order for new data to be added to the correct individual.

In two groups a key was felt to be unnecessary as technical solutions could be developed that negated the need to be able to access the full data set. In one group a double-coding process was proposed. In this system data would be anonymised on entry and would then be automatically coded again. In another group it was suggested that a series of pass words would mean that no one would need to be able to access *all* the data. Various members of staff would be able to access different parts of the data and new information could be added without anyone seeing the existing dataset.

Most of the groups however considered who might hold a key and generally sought a trusted group or individual. The chair of the OB or of the UK Biobank Ethics Committee appeared to be preferred. It was felt that these people had not only a role in maintaining the ethical standards of the project but would also be individuals who understood how to behave ethically. Some groups recommended that no one person should have the key but



that several people should have one element of it to reduce the opportunities for abuse. One group asked if there were companies who could be hired to supply this as a professional service but on the whole it was thought desirable to keep the “key” within the Biobank structure, particularly as it would need to be used regularly in order to update 500,000 records.

Some form of audit of the occasions on which the “key” was used was proposed. This was seen as a way of safeguarding the privacy of the volunteers and ensuring not just that only appropriate individuals had access but that the access was only for proper reasons.

Some participants did not think that this level of security was an important issue. They proposed that if people were concerned about confidentiality to this extent they should not take part.

*“We’re not talking about matters of national security.”*  
Man, Northallerton

It was also said that the professionals, such as nurses, who will be involved in dealing with confidential data, have codes of conduct that they maintain, although it was acknowledged that there still needs to be a mechanism to ensure that these codes are up-held.

Another participant in the same group pointed out that the media might attack the UK Biobank if suitable safeguards were not in place and that this could ruin the whole project.

### **3.4 Recontact**

Recontact covers several issues; namely the UK Biobank contacting volunteers to:

- request more information and/or blood samples;
- disseminate information about the project - global feedback;
- provide individual feedback on results; and to
- enable active participation in the decision-making processes.

#### **3.4.1 Additional data**

In the original briefings with panel members they were informed that recontact requesting further information was only likely to happen once in the ten years of the life of the UK Biobank. It has now been suggested that recontact for more information might be more frequent. Panel members had no qualms about being re-contacted during the ten years for more information or additional blood samples. Indeed, in some groups in the original consultation exercises some participants had been concerned that one recontact for updating lifestyle information was insufficient and one or two raised the issue within this consultation exercise. Nevertheless, it was felt that some idea of how often and for what purpose recontact was likely should be given. Otherwise, too frequent contact could lead to people ceasing to respond.

*“People might get fed up if they’re asked too many questions or it gets too involved. They’ve done research before, they must know these things [how often recontact would be likely].”*  
Man, Northallerton



Furthermore, several participants thought that recontact might indicate a particular interest in, or problem with, their health. It will be important to avoid raising concerns over recontact. With local focusing of volunteers there is a strong possibility that volunteers may know of one another. If one person is asked for further samples but another is not, this might cause undue worry.

A safer option was felt to be to explain to all volunteers that it was likely that they would be asked to give further samples as the usage of the bank increased and that all volunteers in a locality should be approached at the same time, whether or not further samples were needed from each individual.

Man 1: *“I’d ask ‘Why are they wanting more of my samples not hers [his wife]?’”*

Man 2: *“Someone needs to say we will come back on a regular basis to all and sundry if there’s a reason for it.”*

Man 1: *“It’s less problematical if you just say every three years everybody is going to be asked for further samples. If you don’t need some of them just throw them away.”*

Man 3: *“Some people worry very much and you don’t need extra stress on your normal life. Especially when you’ve given freely as well.”*

Men, Plymouth

Follow-up could come directly from the UK Biobank.

### 3.4.2 General feedback

It was recognised that the benefits would accrue at a societal, rather than an individual, level (as discussed below). Where necessary the facilitators explained that this would be the result of improved knowledge, diagnostics and treatment and that while there is no health advantage to taking part, neither would there be a health disadvantage.

While information on the research being conducted was thought to be “interesting” and perhaps volunteers had a right to know how their information is being used, there were concerns about the costs of providing feedback. Moreover, it was not completely clear why volunteers would want information of this type or how they would use it and it was not expected until the subject was raised by the facilitators.

Some believed that it is important for volunteers to know about the research being conducted so that they could see how they had helped others. It was also suggested that providing information might stop people thinking they were being “used”. Some form of newsletter was supported, although a website was also popular with the panel members.

*“I’d like to know what they’re accessing it for...whether there’s anything they would consider a success story.”*

Woman, Manchester

The most interesting information was thought to be who was accessing the information and what projects were being undertaken. Nevertheless, this type of information was seen by many as icing on the cake rather than a necessary return for taking part.

*“That’s not what you’re giving the information for.”*

Man, Birmingham



However, some thought that this sort of information was a good way of keeping volunteers engaged and enthusiastic.

Man 1:           *“To say thank you for your efforts.”*  
 Woman:         *“Its nice to be informed or kept informed.”*  
 Man 2:           *“Especially if they want more blood.”*  
 Group conversation, Plymouth

One group suggested that feedback on the general progress of the project would help foster pride amongst volunteers, keeping them interested and engaged.

However, the panel members were very conscious that posting newsletters to half a million volunteers would be an expensive undertaking and some people were very much against it on these grounds. Nevertheless, there was considerable support for the idea in so far as:

*“It would be nice to know you’re helping but I wouldn’t want to see a lot of money going on it.”*  
 Man, Northallerton

Those with access to the Internet were keener on information being provided through a website as an alternative, mainly because this was perceived to be cheaper. It was suggested that those without Internet access could use terminals in GP waiting rooms and that paper copies of reports could be placed in GPs surgeries, rather than despatching papers to everyone. One woman was concerned by the idea of a website, as, being unfamiliar with the medium, she thought that this would mean the individual information would be publicly accessible. It will therefore be important to convey the nature of the information to be held on such a site.

It was suggested that at the point of recruitment, volunteers could be asked whether they wanted to receive a newsletter and if so, whether they preferred this by post or by email alert, as a way of minimising the costs.

There was some debate as to whether there would be anything to report as it was widely acknowledged that the UK Biobank will be:

*“A vastly long term thing.”*  
 Woman, Manchester

*“Really for our children and grandchildren.”*  
 Woman, London

This led to a discussion of how often a newsletter might be sent to volunteers. The general view was that annually was sufficient.

*“Research is a long term thing. I can’t see there being much to say.”*  
 Woman, Manchester





Some felt more frequent newsletters initially might serve to reassure volunteers in the early days.

### **3.4.3 Individual feedback**

It has been agreed that there will not be feedback on individual biological results to volunteers beyond that which can be given at the recruitment session. This was covered extensively and discussed in depth at the first exercise with the panel members. Hence we did not discuss the issue of individual feedback at these meetings on the EGF, except where participants raised it. We have collated and summarised the findings from the earlier consultations on the topic in the box overleaf, for ease of reference.

Where panel members in the current consultation raised the issue of individual feedback themselves, the points made reflected those brought up in previous exercises, namely:

- that some volunteers would like personal feedback, which might provide added motivation for some invited to take part;
- it would be costly and difficult to provide individual feedback;
- individual feedback might not mean much unless interpreted by a scientist or doctor;
- individual feedback could aid preventative action; and
- providing the necessary support to people getting information on potential health problems could add to GP loading.



For many, feedback on individual health status would be a motivator to volunteer. On first presentation, participants saw the initial examination as an “MOT” and had high expectations of the feedback.

*“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.”*

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

*“What’s in it for me?”*

For some, not receiving individual feedback would be a potential barrier to participation.

The expectation of individual feedback to some extent stems from the over-estimation of the health information that could be gained from blood alone. There was little understanding that, in order to make a diagnosis, *specific* tests must be undertaken, and the decision on which tests to run is made on the basis of health history and symptoms. Nevertheless, it was felt that not identifying illnesses from samples donated to the UK Biobank could lead to complaints in the future, unless the limitations are made very clear.

Some, however, were just curious about their health status, about causes of illnesses in their family or why some family members had certain diseases and others did not.

Lastly, 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?”*

On the other hand, it was recognised that some people would not want to know that they have a disorder unless it can be treated and participants were clear that this perspective must be respected.

There were participants who were aware that there was not usually feedback at the individual level from research projects. There was also an acceptance that the scale of the project prohibited any individual feedback, in particular, there was some concern that this would be a waste of money. Another view held 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 .... 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, it was felt that the project:

*“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.”*



### **3.5 Active participation**

There are plans that volunteers should participate in the project throughout the ten years of its life. The IAG was keen to identify how potential volunteers felt they might actively participate and what “active participation” meant for potential volunteers. Here we set out participants’ reactions to, and ideas about, “active participation”, however, some of the ideas presented in the section on the OB also represent methods to actively engage volunteers in the management and oversight of the UK Biobank.

The initial reaction to the suggestion that volunteers might be “actively involved” was one of confusion in all the groups. This meant nothing to most of the panel members beyond donating blood and information. When pushed on what it might mean, someone suggested that it would involve fund raising but on the whole participants had few ideas, other than the role to be played in the OB discussed in sections 2.2.2 and 2.6.3 above. At one reconvened session other suggestions were to help with the paperwork and to support recruitment information sessions. Indeed, one participant questioned the role of the OB, if all volunteers were more actively involved.

Even once some suggestions as to what it might mean were put forward by the facilitators, some people could see no active role for themselves once they had contributed their information and blood sample. Others felt that a few people might want to be able to ask questions, or perhaps complain. To address either of these, clearly identified contact points were said to be needed. However, the question of the cost of this was raised and a website was seen to be a cheap option. Participants were aware that a website also enables volunteers to send emails through the website to the UK Biobank, although some again, felt that the need to respond to emails was an unnecessary cost.

#### **3.5.1 Support groups**

Other suggestions from the IAG that the facilitators put to the panel members for consideration included: public meetings; helplines; and support groups. The latter was ruled out quickly by all the groups as being unnecessary. The view was that people with problems need support and that those who had serious concerns about participating in the UK Biobank should not do so.

*“A support group sounds like you need help – Alcoholics Anonymous is a support group!”*

Woman, Manchester

#### **3.5.2 Public meetings**

Public meetings were more popular with panel members. There was a suggestion that a model akin to an annual shareholder meeting could be used to allow the UK Biobank (through its management board) to report to volunteers.

It was also suggested that public meetings could be used during the recruitment phase, as potential volunteers might want to talk to someone other than the nurse before agreeing to take part.

*“With all due respect to the nurses, there might be questions people want to ask that she can’t answer”*

Woman, Manchester



Local meetings or set times when a more senior person would be available to answer questions were proposed. This suggestion was also made by one of the nurses in another consultation earlier this year.

### **3.5.3 Canvassing views**

It was suggested that any newsletter could have a tear-off section for participants to use to send in views and questions. This might be structured as a questionnaire asking for views and comments on particular issues.

## **3.6 Conclusions**

Participants were unanimous that the initial letter inviting people to take part in the UK Biobank should come from GPs, who will need to agree to take part for their patients to be invited to volunteer. Contact from PCTs could imply a breach of confidence.

Recruitment was seen as a *process* allowing people plenty of time to consider whether or not they want to take part before they “*sign-up*”. This would mean providing access to information, perhaps an “*information pack*” and/or “*local meetings*” opportunities to ask questions and possibly a “*cooling-off period*” after the session with the research nurse.

In groups where there was more knowledge about data processing it was thought that coding systems exist such that no overall “key” is needed. In other groups it was agreed that more than one person should be required to complete the “key” and that these individuals should come from within the UK Biobank structure. The Chief Executive of the UK Biobank, the Chair of the Science Committee or of the Ethics Committee were all suggested as well as the OB.

With respect to recontact, participants were clear that it must be done sensitively so that those re-contacted were not unnecessarily worried that there might be something wrong with their health.

There was widespread support for the idea of a newsletter that would tell volunteers about the research being done using the UK Biobank and the results as they emerge. It was thought that this would help to foster pride in the project among volunteers. There was also some concern that the cost of sending newsletters to half a million volunteers might reduce the UK Biobank’s main scientific activities. A website was thought to be a cheaper option with GP surgeries used to disseminate information to those without computers or the necessary skills. One group proposed that volunteers could opt whether and how to receive news up-dates.

The idea of “active participation” was confusing to those who took part in this consultation. When pressed, they suggested a newsletter and a website were ways of providing information and enabling volunteers to ask questions and feed in their views, although there were concerns about the cost of printing and posting out a newsletter. The opportunity to sit on the OB or a volunteer panel or sub-group were seen as possible routes to achieve active participation.



## 4 Consent

### 4.1 Introduction

This section discusses participants' views on the statement of purpose, consent and withdrawal and includes dealing with death and mental incapacity. In so far as consent covers how the data will be used and by whom, this section also looks at uses and users.

### 4.2 Statement of purpose

The statement of purpose that the facilitators were given was:

*“The UK Biobank will monitor the health of a large number of volunteers for many years, collecting high quality information on environmental and lifestyle factors, linked to biological samples. This will result in a resource that will be used for ethically and scientifically approved research, with the aim of improving the prevention, diagnosis and treatment of diseases and medical conditions within society.*

*Safeguards will be put in place to secure that both healthcare information and samples are held for the public benefit and to ensure due respect for the rights and privacy of the participants.”*

There was general agreement among the panel members that the statement of purpose is in line with their understanding of the UK Biobank project, although one group felt that as drafted it does not grab the attention. It was recommended that a description of the benefits should come first. Some participants thought that it could perhaps be clearer and that a set of bullet points might be easier to digest than a paragraph.

In some sessions the facilitators asked the participants to draft their own statement, before they were shown this proposition. In essence participants see the project as aiming to discover what causes different diseases and thereby to develop cures. As one participant said:

*“The aim is to discover cause. The intention is to see if you can resolve it.”*  
Woman, Manchester

Asking participants in this way revealed some other interesting points. One theme that emerged from several individuals was an interest in the interaction between the environment and health. Several individuals thought that by tracking health in different parts of the country the impact of the environment on health would become clearer than it is today. Another theme of interest was the expectation that there would be a description of the “health of the nation” in the age group.

### 4.3 Giving consent

Potential volunteers to the UK Biobank will only be asked for consent if they understand the purpose of the project, as set out above, potential volunteers would then be asked to consent to:



1. providing lifestyle data and a blood sample at recruitment;
2. allowing on-going access to full past and future medical records held by their GP and any hospitals attended;
3. recontact;
4. the process for making decisions with regard to access to the UK Biobank (yet to be finalised);
5. the process for making decisions about use/types of research that the UK Biobank can/will be used for (yet to be finalised);
6. how benefit will be derived, i.e. at a societal rather than individual level;
7. continued use of data after death (if applicable); and
8. continued use of data after mental incapacity (if applicable).

Given that the panel members have all had some time to become familiar with, and discuss, the basic framework of the UK Biobank they understood that volunteers were being asked to “sign-up” to this. Points one to six have been reported earlier in this report or elsewhere. However, points seven and eight were debated more fully and are reported below. This is partly because the IAG had asked for feedback on these two points specifically, but also because they instantly aroused thoughts and caveats with participants.

#### **4.3.1 Use of data after death**

There is a group of participants who thought that their information would no longer be useful after their death and that they would leave the project if they died within the ten years. Others, however, did appreciate that the information on cause of death would be important to the project. For some, what happens after their death is not of interest to them. Once it was made clear that information about the cause or circumstances of death are likely to be interesting to researchers, panel members tended to be content for their information to remain accessible.

There is, however, a view that some families might not wish to have their relative’s information in the UK Biobank after death. This is countered by others who say that they would have discussed their involvement in the project with their family at the time of their recruitment. They therefore believe that their family should be content for their information to remain part of the UK Biobank dataset. Some participants said that relatives should have the option of withdrawing volunteers from the project on death but others were very much against this and believed that it was the volunteers’ decision that should be honoured.

It was suggested that a similar approach could be taken to that used for organ donation but as some pointed out, relatives have the final say, irrespective of the deceased carrying a donor card. This was new information to some participants. There were those who believed that carrying a donor card meant that one’s organs would definitely be donated. They were unaware that relatives could counter this after death and did not countenance such an approach for the UK Biobank.

The general conclusion was that asking people to consent to their information remaining in the UK Biobank after their death was a reasonable condition for participation. Some suggested that there be an option on the consent form as to what the individual wanted to happen on their death. However, it was proposed that:



*“anyone who’s that nitpicky aren’t going to take part.”*  
Man, Northallerton

and that the “*vast majority*” wouldn’t mind as long as they understood the reason.

A key point made in a number of groups was the importance of treating relatives sympathetically, so it was emphasised that the Biobank records should be rapidly updated to ensure that nothing was sent to a deceased volunteer that might distress their family.

#### **4.3.2 Involvement after mental incapacity**

Involvement after becoming mentally incapacitated generated more debate. Some held the view that the family of anyone who became mentally incapacitated would want to help look for a cure. They would therefore support continued participation in the UK Biobank, but there were concerns about possible recontacts. Someone who is suffering from, and especially in the early stages of developing any form of dementia, could be confused and frightened by recontact, especially if they were required to give blood for reasons they did not understand. It was said:

*“My dad got dementia and I don’t think I’d have wanted him troubled by this sort of thing.”*  
Woman, Manchester

Others felt that if the volunteer had consented when “*of sound mind*”, then they should continue. In one group this was felt to provide insufficient safeguards for volunteers, who might want to withdraw in the light of changing practices at the UK Biobank but who would no longer be capable of doing so.

In line with the IAG draft proposals, we put two options to participants on handling involvement after mental incapacity. The first option proposes that the last valid consent would be taken and that while people would not be able to withdraw, they would be excluded from anything that required new or additional consent. The second option proposes that volunteers could be asked to state what they want to happen if they were to become mentally incapacitated.

Essentially, participants came down on the side of choosing a course of action at the recruitment stage. Possible choices that could be offered were identified as:

- existing information remains in the UK Biobank but no new information is added;
- existing information remains in the UK Biobank, NHS records continue to be added but there is no new contact with the individual;
- existing information is withdrawn from the UK Biobank;
- continued participation (blood could be taken although a decision would be required on whether or not lifestyle data could be collected from a carer).

It was pointed out however, that many people do not want to think about such situations and it was likened to making a will.



#### **4.4 GP consent**

The need for the GP to agree to take part was questioned by some, although others assumed this was necessary for the UK Biobank to access and up-date information on individuals. Some supporters of the project felt strongly that they should be able to volunteer and give permission for their records to be accessed independently of their GP's views. A parallel was drawn with giving permission for insurance companies to access medical records when applying for insurance. These people were not comfortable with the GP owning their records.

*"I'm against the GP being so powerful."*  
Man, Plymouth

There were also concerns about the potential power of GPs in selecting who should be invited to take part.

#### **4.5 Withdrawal**

##### **4.5.1 Initial consent**

Everyone agreed that contributing to the UK Biobank is a long-term commitment and that people must be given time to think about it before "*signing-up*". This, it was felt, would minimise drop out. Some participants recognised that it would be expensive and damaging for the UK Biobank project if people withdraw. Hence they were strongly in favour of ensuring people had time to think through the commitment in advance, in order to minimise drop-out.

*"The initial signing has got to be really, really in depth"*  
Woman, Plymouth

##### **4.5.2 Practicalities**

It was not immediately clear what withdrawal would entail and some participants asked for clarification. The facilitators responded by asking participants what they thought "withdrawal" ought to mean for volunteers. After some explanation of possible options by the facilitators and further debate among participants, it was generally thought that volunteers should be able to choose between two options. Firstly, no longer contributing (either NHS data or directly collected information) while leaving existing data in the bank and secondly, having all their information destroyed. In the latter case questions were asked about how any individual could be sure that their data was actually destroyed. This was seen as a potential role for the OB.

##### **4.5.3 Should withdrawal be allowed?**

Views were divided on the issue of withdrawal. Some were quite adamant that volunteers should not be able to withdraw once they had agreed to take part.

*"I really don't think people should be given the choice."*  
Woman, Birmingham

It was suggested that withdrawal was a "*breach of contract*". In another:





*“These are mature people, they ought to be able to decide on something for ten years. They’re not like some 18 year old who thinks one thing today and another tomorrow.”*

Woman, London

The analogy of giving blood was raised by several participants independently.

*“Once I’ve given my pint of blood I don’t know what happens to it, or care. They could chuck it down the drain for all I know.”*

Woman, Birmingham

However, another view held that the option to withdraw must be available because people may have changes in circumstances that mean they want to withdraw.

*“I defend people’s right to withdraw.”*

Woman, London

It was also thought that this was one of the safeguards being offered and that:

*“If you say there’s no way out for 10 years, that might frighten people off.”*

Man, Northallerton

On the other hand:

*“It might make people suspicious that there’s more to it than meets the eye if you keep asking them [whether they want to withdraw].”*

Woman, Manchester

Some participants thought that if volunteers drop out new volunteers would have to be recruited for another ten years to ensure that there were sufficient complete records. This, they said, would be a great waste of resources.

The idea that people should somehow have to “reconsent” every year was dismissed where it was raised, unless the fundamental nature of the UK Biobank project changed. In this case, one group suggested that the OB should take responsibility for recommending that new consents be obtained from all the volunteers.

#### **4.5.4 Dissatisfaction with the UK Biobank**

The main reason participants identified for wanting to withdraw was use of the information for something with which they disagreed. Having the option to withdraw in these circumstances was seen as particularly important.

*“I would feel far less suspicious if you said to me ‘at any time you’re totally against anything, you can withdraw’.”*

Man, Plymouth

*“If you don’t agree with what’s happening, ...you’re just going to ignore it and think ‘ruddy hell I’ve got to do this again and I don’t believe in what they’re doing’. I’m sorry but if I thought that, I’d want to withdraw.”*

Man, Wales



Some participants believed that volunteers should not be reminded that it was possible to withdraw too often, if at all, for fear of people dropping out for no good reason. Others thought that *“people are not going to be dropping out for no good reason”*, so why not remind them that they can do so if they wish.

An annual reminder that volunteers could withdraw provided reassurance, for some, that the UK Biobank was a reputable organisation with nothing to hide. It was suggested that if the annual newsletter reminded people that they could withdraw, there could be a return slip to sign and post back. Others felt that it should not be made too easy and that it should be necessary to write or telephone the UK Biobank in order to withdraw.

There was concern that people might want to withdraw for the wrong reasons; for example, misinformation in the media. It was suggested that perhaps those wanting to withdraw might be asked for a reason but the consensus was that this was inappropriate.

There was also concern that there was too much emphasis on what could go wrong which was likely to cause anxiety.

*“You need to trust that it’s going to be for the general well-being of future generations.”*

Man, Wales

#### **4.6 Benefits and beneficiaries**

Participants were quite clear that this is something for the future, something long term, that would benefit their children and grandchildren, rather than themselves directly.

*“Its not going to help us, it’s going to help future generations.”*

Man, Wales

Many also thought that this was an easy concept to grasp.

*“Everybody knows that research takes a long time.”*

Woman, Plymouth

*“Its common sense that it will take years.”*

Man, Wales

Yet, in some cases, there was still a sense that the lack of individual benefits could affect recruitment rates.

Man 1: *“To me this Biobank is really looking at the future and future drugs that will assist people probably at a much younger age than us and in ten years time.”*

Man 2: *“I accept that, but at the end of the day, you’ve got to get a 45 year old to go down to the bank [the UK Biobank] and give blood.”*

Men, Plymouth



The facilitators pointed out that individual volunteers might benefit individually from medicines or treatments that result from the research, but that this would be only indirectly and not the direct result of taking part in the UK Biobank.

The previous consultation reported in March 2002 found:

*“...the doctors would be aware of what [the UK 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 [the] 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.”*

#### **4.7 “Gift” or “donation”?**

We were asked to explore with participants whether they thought that a “gift” is different from a “donation” in terms of the blood and information that volunteers are being asked to give the UK Biobank. This was not covered in most groups but where it was, it was thought that the two terms are effectively synonymous.

#### **4.8 Uses**

It was not immediately obvious to some participants why the UK Biobank cannot clearly state for what types of research the information will be used or why participants cannot be given a list of purposes to tick. It becomes obvious once it is explained that medical research is advancing very quickly and that new possibilities come along all the time. However, for many of the panel members who took part in this consultation, “*medical research*” is sufficiently specific.

##### **4.8.1 Acceptable uses**

One group felt that any form of medical research was a legitimate use of the information. When probed on what they meant by the term “*medical research*” they defined it as:

*“looking for the causes and cures of illnesses”*  
Woman, London

but they also thought that medical research included:

*“investigating what’s detrimental to health.”*  
Woman, London

In these definitions they included the effect of lifestyle and the environment on health: mobile ‘phones, landfill sites, legal and illicit drugs were mentioned as examples.

Some groups discussed whether or not priority should be given to different types of illness or disease. One group suggested that the UK Biobank should address “important” diseases, and discussed how “importance” might be measured, using NHS data.

*“You’re looking at things that shorten life and that affect quality of life. The NHS could be a good way of measuring how serious an illness is in the sense that the*



*more chronic, life-threatening, the more money you spend on it...we've already made the decision on what's important in the NHS by spending the money."*

Man, Scotland

In another group, concern was raised that mental health should be given as much priority as other illnesses and diseases.

*"The agony that people go through is on a par with some of the most vicious diseases"*

Man, Wales

One suggestion was that the UK Biobank should focus on diseases where there was a known inherited component. This is because "*genetics*" is largely thought to mean "*inherited*".

*"I think a lot of it is hereditary, but I'm hoping that the Biobank can turn that round. I'd assumed that's what it was for."*

Woman, Plymouth

The potential that the UK Biobank has to help construct a picture of the health of the nation and environmental factors was also raised.

Man 1: *"A couple of people at work said 'I'd be very interested to know if I lived in an industrial area whether my health had suffered by living in that area'."*

Man 2: *"Pretty soon you're going to have trends coming up. Pretty soon, people are going to say 'look at this, look at that, what's causing it?'."*

Men, Plymouth

#### **4.8.2 Unacceptable Uses**

The one use that was roundly condemned as unacceptable was reproductive cloning. In some groups the use of the Biobank for military research was also thought to be unacceptable. In the Plymouth group the conversation on defence uses was more extensive than elsewhere reflecting the importance of the defence sector in the area. In this group some people proposed that it might be appropriate to use the UK Biobank to investigate defence against genetic weapons. After some discussion the group agreed that this was an inappropriate use.

Man 1: *"I'm sitting in the middle here, I work in the defence industry, most people here do. If its to our benefit as a nation to use this information, we should."*

Man 2: *"It shouldn't be one of its prime uses."*

Woman: *"It should be medical only. Let other people who are already doing it [defence research] get on with it."*

Man 2: *"Its like you say, they've got their own resources so they should use that not the Biobank."*

Man 1: *"Well that could be a selling point. Say 'it won't be used for military purposes'"*

Group conversation, Plymouth



### 4.8.3 Behavioural trait research

In most groups this was not explored in any depth. There is a feeling that mental illness is a legitimate area for research but it was difficult to discuss where to draw the line, given all the other material to cover. In one group however, where there was a wide-ranging discussion about uses, the group concluded that having a better understanding of what causes behavioural traits could only be helpful. (The examples used by the facilitator were genes for criminality, homosexuality and intelligence. The group also raised the issues of alcohol tolerance and the affect of alcohol on behaviour, compulsive behaviour and paedophilia.)

*If you don't know, you can't do anything to overcome it."*  
Woman, London

There was however, a discussion about whether or not it would be desirable to use this information, but no conclusion was reached.

*"If you find the gene you could perhaps inject something to kill the gene or remove the gene."*  
*"Yeah, but do we want to go there?"*  
*"That smacks of Big Brother doesn't it?"*  
*"It all goes back to how far do you want to go?"*  
Women, London

### 4.9 Users

Bona fide medical researchers in universities, hospitals and pharmaceutical companies were all recognised as potentially legitimate users of the UK Biobank. However, few people wanted to suggest hard and fast rules.

Man 1: *"Its difficult to say these are good, these are bad, it's a grey area. Universities, hospitals, the NHS are probably all OK."*  
Man 2: *"Is probably good enough?"*  
Man 1: *"We'll never have certainty."*  
Men, Scotland

It was suggested that it ought to be the nature of research rather than the type of researcher that governs access.

*"Any researcher would have to, one, comply with the relevant Government guidelines, then they would have to comply with the Biobank's ethical framework. Other than that I'd like to see a situation where the researcher would have to frame the research in such a way that the end use would be for the benefit of mankind."*  
Man, Scotland

It was also suggested that where there were already relevant guidelines these should be adhered to, whether they were UK-based or international. Some people suggested that if the Local Research Ethics Committees were to be involved, there might be no need for an internal UK Biobank Ethics Committee.



#### 4.9.1 Private and public sector users

A recurring theme was how different types of researchers ought to be treated, in particular those in the private sector compared to those in the public sector. Initial suggestions recommended free access for the public sector, with charges for the private sector. However, there was an appreciation that lines are blurred and that often universities are seeking to make a profit and that academics may move taking their knowledge with them into industry. Some suggested that companies might sponsor research in universities to gain access to the UK Biobank's data. At heart many people did not want to see undue profit made from voluntary donations, they wanted to see society reaping the benefits.

*"We ought to be looking for social entrepreneurship."*

Man, Scotland

*"Its drug companies or something making money out of something I've given for free. If pharmaceuticals are making big money then some of that should go back into the bank [the UK Biobank] or the Treasury."*

Man, Plymouth

It was suggested that a grant scheme could support those who could not afford to pay for access although it was realised that this could end up *"with money going round in circles"*.

#### 4.9.2 Payment for access

Many of the panel members thought that it was appropriate to charge researchers for access, so that they appreciated the value of the information. However, they did not want charges to limit access.

*"The weakness is that you might restrict the access of less well off institutions such as universities. Do you charge a university the same as Glaxo?"*

Man, Plymouth

The most common solution was to combine small access charges with a mechanism for profit-related contributions.

*"I think there should be both an access charge and then a refund [to the UK Biobank] if a company does find a cure."*

Woman, Scotland

Assessing the practicalities of clawing back a proportion of profits was recognised as potentially very difficult. Nonetheless this was thought to be probably the fairest way of ensuring that the UK Biobank and the wider public benefited from profitable discoveries.

*"As a drug company, how do you proportion it? That drug was solely found because of Biobank or 50% or 30%...or we'd already done ten years of research."*

Man, Plymouth

One group discussed this in some depth. They agreed that perhaps when applying for access to the UK Biobank, applicants should set out their current state knowledge on a particular research topic. This would provide a measurable benchmark for the



contribution the UK Biobank then makes in stimulating the final development of a treatment, therapy or medicine.

*“My thought is that when they apply to the Bank they should say ‘well we’ve got this far down the road’ and then you’ve got a measurable. When they’ve discovered what they’ve discovered, you’ve got a second measurable and a panel could determine the influence that the bank had on discovering that thing.”*

Man, Plymouth

### 4.9.3 International access

There was general unease over international access, but also recognition that it probably can not be prevented, so it is better to try to ensure that access is controlled under appropriate terms. There was concern over whether overseas researchers would have to abide by UK guidelines and doubts were expressed over whether the UK is powerful enough to insist on this.

Man 1: *“The Chief Executive will have to have control...to make sure that rogue influences don’t come into it.”*

Woman: *“You don’t want it [data] being sold on to other countries.”*

Man 2: *“Co-operation where they exchange ideas is different.”*

Group conversation, Plymouth

One group saw no problem with international researchers having access to the UK Biobank, provided that reciprocal arrangements were offered where similar databases existed or were being developed.

Publication of research results was seen to be one of the best safeguards. There was a strong suspicion of US corporations in particular. This was based on the impression that the US effort on the Human Genome project was entirely privately funded with the objective of being granted patents. There was a strong preference for open publication of research using the UK Biobank, and that publication of research ought to be a condition of access to the UK Biobank.

It was generally recognised that research into diseases that disproportionately affect specific ethnic groups, such as sickle cell anaemia, Tay Sachs disease and higher rates of heart diseases among South Asians, should be supported. One group said that it was particularly important that any research that focuses on ethnic minority groups be made available to relevant researchers and communities.

It was suggested that additional checks might be required on applications from companies abroad to ensure that applicants were bone fide.

### 4.9.4 Other Users

In some groups other potential users were identified who might claim legitimate access to the UK Biobank. The defence industry has already been discussed in section 4.6.2. Other sectors suggested included the tobacco, alcohol and food industries. All of which might make claims to be able to use the UK Biobank to improve health.



*“What if a tobacco company said ‘we want to make a safer cigarette and some people still enjoy smoking...your information can help’?”*

Man, Wales

One group discussed the food industry in some depth and whether the development of foods like Benecol (which it is claimed may lower cholesterol) was a legitimate use of the UK Biobank data. On balance it was concluded that if it was good for health then it was a legitimate use but that as companies would make money from this product development they should be charged for access.

Everyone agreed that the insurance industry should not have access to individual records. Some were even concerned that the publication of results at a global level could provide insurance companies with information that would result in higher premiums for some.

#### **4.10 Conclusions**

The statement of purpose sums up for the panel members the objectives of the UK Biobank as they have understood them. It was felt that it could be more succinct and that the benefits should be more prominently presented.

The continued use of data after death and mental incapacity was generally supported with the caveat that individuals should be able to opt-out. While it was clear that participants felt that relatives must be treated with respect, most panel members felt that it was the individual’s wishes when “*of sound mind*” that should prevail.

Some participants were strongly against volunteers being able to withdraw. It was recognised by the majority though, that volunteers must have the right to withdraw without giving a reason and that having this option might well give volunteers greater initial confidence in the UK Biobank. Drop-out should be minimised by allowing potential volunteers plenty of time to consider their choices as part of the recruitment process.

The panel members said that the main reason for wanting to withdraw would be inappropriate use of the data in the eyes of the volunteers.

The panel members were content with fairly broad definitions of medical research, focusing on the need to have health benefits delivered by the research that uses the UK Biobank. Similarly they were content that access should be granted to a range of users, but that a clear access policy, including a charging structure, should form an important part of the governance of the UK Biobank.





## **5. Recommendations from the Panel to the IAG**

### **5.1 Introduction**

This section contains the recommendations the Panel members made to the IAG. Where a heading is missing, there were no recommendations under that category.

#### ***UK Biobank Purpose Statement***

To achieve greater impact benefits should be stated first and the purpose could be expressed in a more concise form.

### ***I. Relationship between UK Biobank and Participants***

#### **A. Understandings and consent.**

##### **1. Recruitment**

###### *b. Procedure for recruitment*

All panel members agreed that the initial invitation to take part in the UK Biobank should come from GPs. Not only would this add to the credentials of the project but it would provide reassurance to the public.

It was recommended that there must be sufficient time between receiving the initial invitation and attending the session with the nurse to allow serious consideration of the project. This should maximise the response and minimise drop-out later. An information pack and the opportunity to attend local meetings to discuss issues were ideas put forward to support the recruitment process.

Panel members also recommended that there be an information campaign in advance of direct recruitment to boost the response rate.

##### **2. Consent**

Consent is to be dependent on volunteers understanding certain processes. The UK Biobank will need to be able to provide detailed explanations of the systems to potential volunteers.

##### **4. Feedback of health information to participants**

It was accepted that for a variety of reasons individual feedback, however desirable it might be, would not be possible but this must be clearly expressed to volunteers and the reasons explained.

##### **5. Ongoing dialogue with participants**

The idea of a paper newsletter was strongly supported to provide information on the research being sponsored and the results achieved. Some were concerned that this was diverting resources away from the resource and recommended the use of electronic media. It was suggested that volunteers be asked to opt for paper, electronic or, indeed, no newsletter at all.

Methods of participation panel members said that they would like to see were:



- a newsletter;
- a website;
- the opportunity to ask questions and feed in views via either the website or the newsletter;
- a complaints procedure; and the
- ability to apply to sit on the OB.

They also suggested that volunteers recruited early in the project could support recruitment by attending public meetings for potential volunteers.

## **6. Expectation of re-contact**

Panel members recommended that re-contact plans should be clearly explained to volunteers when they joined the project. They were concerned that re-contact, particularly in the event of further samples being required, should be made in a way that does not cause volunteers to worry about their own health.

## **7. Right to withdraw**

Some participants felt strongly that volunteers should not be able to withdraw from the UK Biobank. A more widespread view held that volunteers should be able to withdraw without giving a reason and that they should be reminded in any newsletter of this option. It was also recommended however, that to withdraw should require some effort on the part of the volunteers, who should have to write or telephone to do so.

## **8. Respect for incapacitated and deceased participants' wishes**

It was strongly recommended that at the point of recruitment individuals be given the choice between the UK Biobank retaining their data or having it withdrawn after death. It was equally strongly recommended that the individual's views should not be changed after death by relatives. It was thought that if the value of the data after death was explained, most volunteers would be happy to have their information remain in the UK Biobank.

Some made similar recommendations with respect to mental incapacity, in that the individual's view should be recorded at recruitment and should not be overturned by relatives at a later date. Others recommended that those who become mentally incapable should be withdrawn from the project, as they would be incapable of making a decision to withdraw if practices changed subsequent to their last consent. Another recommendation held that the consent of relatives would, in practice, be needed for access.

## **B. Confidentiality**

### **1. Commitment to maintaining confidentiality**

Panel members were adamant that the UK Biobank must regard the volunteers' confidentiality as a fundamental component of the ethical and governance framework.

### **3. Re-identification**

Where individual panel members had sufficient knowledge of computing it was recommended that a sophisticated system be designed that would not need a central "key". If a "key" is needed it was recommended that it should not be held by one person but by several people within the UK Biobank structure: the Chief Executive, the Chairs of the



Ethics and Scientific Committees and members of the Oversight Body were suggested as trustworthy to undertake this role.

#### **4. Security**

See the comments at B1 above.

### ***II. Relationship between UK Biobank and Research Users***

#### **B. Research access to data and samples**

##### **1. General terms of access**

The UK Biobank is seen by panel members as a resource to support medical research. They strongly recommended that use of the information for human reproductive cloning should not be allowed. Panel members were happy for the data to be used for other reasons providing there was some benefit to human health.

##### **2. Specific terms of access**

Participants were clear that insurance companies should not have access.

It was recommended that users should pay for access to the data, but that a pricing structure should be established that did not constrain access. It was also recommended that some mechanism should be developed for receiving a percentage of profits from commercial products derived from research using the UK Biobank.

##### **3. Requirement of data sharing and broad release of findings**

It was recommended that open publication of research results achieved using the UK Biobank should be a condition of access.

### ***III. Relationship between UK Biobank and Society***

#### **A. Internal Governance**

##### **2. Oversight Body**

Panel members recommended that there should be a mix of professional and lay members appointed for a time period of less than ten years. All members should be independent of the funders and the UK Biobank.

The proposed mechanism of appointment was broadly accepted but transparency and equity were the central tenets for these members of the panel.

The Oversight Body should act as the guardian of the volunteers' interests, providing the final approval of changes to the ethical and governance framework and acting as arbiter on decisions of access. There must be clear procedures in place to enable the Oversight Body to effectively monitor the workings of the UK Biobank. This might include external auditing reporting directly to the Oversight Body.



## Annex 1 Sample

The consultative panel for the UK Biobank has been drawn from seven locations around Great Britain. The locations are:

- Birmingham;
- Glasgow;
- London (North);
- Manchester;
- Newport;
- Northallerton; and
- Plymouth.

These places were chosen to give a mix of urban and rural locations as well broad geographical coverage.

There are 64 panel members and the broad socio-demographic profile is as follows.

<b>Age</b>	<b>% of sample</b>
45-55	53
56-69	47

<b>Gender</b>	<b>% of sample</b>
Male	50
Female	50

<b>Social Grade</b>	<b>% of sample</b>
AB	16
C1	25
C2	25
DE	34

These percentage distributions are roughly in-line with those of the wider population in the age group of interest.



## Annex 2 Topic Guides

### Session 1

<b>Briefing for participants</b>	<b>Questions and techniques</b>
<p><b>Welcome</b> Thank for coming. Standard introduction and round robin.</p>	<p>USE STIMULUS BOARDS A AND B TO REMIND PEOPLE OF THE BASIC OUTLINE OF THE UK BIOBANK PROJECT.</p>
<p><b>Update</b> Dr John Newton has been appointed as the Chief Executive Officer for the UK Biobank project. Dr Newton is a public health specialist and epidemiologist and is a former Director of Research at the John Radcliffe Hospital in Oxford.</p> <p>The structure of the UK Biobank will be as follows: There will be a coordinating centre based at the University of Manchester plus 6 consortia of 21 universities called collaborating centres. These will be responsible for recruitment and collecting the data. The coordinating centre will be responsible for managing the database.</p> <p>The scientific structure and methodology of the project will be finalised after a period of piloting of different methods.</p> <p>Early consultations recommended that there be some form of body to oversee the operation of the UK Biobank.</p> <p>To help with this process a group was set-up called the Interim Advisory Group and they have also been working on the ethical framework and the format and function of the oversight body but they will finish their work in June.</p>	<p>UP-DATE PEOPLE ON DEVELOPMENTS.</p> <p>STIMULUS BOARD C</p> <p>THIS IS THE FIRST TIME THIS STRUCTURE HAS BEEN COVERED.</p> <p>USE PRESS RELEASE AS BACK-UP</p> <p>What are your initial reactions to this structure?</p>



<p><b>Introduction</b></p> <p><b>Interim Advisory Group</b>                  The Interim Advisory Group was set-up early in 2003. Its role is to advise the three funding bodies (the Wellcome Trust, Medical Research Council and Department of Health) on the development of an ethics and governance framework (EGF) for the UK Biobank. This framework will provide “a set of key principles to ensure that Biobank operates in accordance with its purpose statement, and in the public interest.”</p> <p>This group met in February and April and will meet for the last time at the end of June. After that meeting the group will submit a report to the funders outlining options as they see them, for an ethics and governance framework.</p> <p>There are 9 people in the group and they include lawyers, social scientists, a nurse, philosophers and a consumer representative (with expertise in adult education).</p> <p>The purpose of these two meetings that you’re taking part in is to provide some input to this groups final deliberations before they make their recommendations to the UK Biobank.</p>	<p>SEE ATTACHED NOTE FOR FULLER CVs</p> <p>CHECK WHETHER THERE ARE ANY QUESTIONS AT THIS POINT.</p>
<p><b>Recruitment</b></p> <p><b>Initial contact</b>                  Last time we met we told you that recruitment would be through selected GPs. GPs would be selected from around the UK so that the sample of volunteers would be reasonably representative of the UK population. GPs would be asked to cooperate and all those on their lists in the age groups 45-69 would be contacted. Only people the GP thought were too ill to take part would be excluded. GPs would then send out letters asking potential volunteers to contact a Biobank research nurse – not nurse based at their practice, if they want to take part.</p> <p>Another suggestion has now been put forward that they’d like your views on.</p> <p>Groups of GP practices are now formed into Primary Care Trusts and the idea is to use these Trusts as a source of names and addresses of</p>	<p>CHECK EVERYONE REMEMBERS THIS AND IS CLEAR ABOUT IT.</p>



<p>Trusts as a source of names and addresses of people in the age group and potential volunteers would receive information direct from the UK Biobank rather than via their GP.</p> <p>The GP would have to be aware of your involvement because they would have to give access to your GP records that they hold.</p> <p><b>Data Collection</b> Data will be collected by research nurses who are employed by UK Biobank and will be transmitted to collaborating centres in encrypted form and from there sent on to the coordinating centre, where data will be <b>reversibly</b> anonymised.</p> <p>Either the coordinating centre or a trusted 3rd party will hold the key.</p> <p>Bar-coded blood samples will be transported directly to the coordinating centre.</p>	<p>PAUSE FOR INITIAL REACTIONS. PROBE FOR:</p> <ol style="list-style-type: none"> <li>1. What would your reaction be to getting this letter from the UK Biobank?</li> <li>2. How do they think others who haven't heard of UK Biobank might react?</li> <li>3. Which do you think would be the most appropriate?</li> <li>4. Does a letter from your GP instil a false sense of security/trust as the GP is not really involved?</li> <li>5. How do you feel about the GP knowing of your involvement?</li> </ol> <p>What constitutes 'sensitive' data is there any info they wouldn't want Biobank to have access to?</p> <p>GET REACTIONS TO THIS CONCEPT</p> <p>Does it matter to you who holds the key? Who you think should hold the key?</p>
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<p><b>Purpose of the UK Biobank</b></p> <p>The general purpose of the UK Biobank is currently defined as being:</p> <p>“The UK Biobank will monitor the health of a large number of volunteers for many years, collecting high quality information on environmental and lifestyle factors, linked to biological samples. This will result in a resource that will be used for ethically and scientifically approved research, with the aim of improving the prevention, diagnosis and treatment of diseases and medical conditions within society.</p> <p>Safeguards will be put in place to secure that both healthcare information and samples are held for the public benefit and to ensure due respect for the rights and privacy of the participants.”</p>	<p>STIMULUS BOARD 1</p> <p>Do they understand the statement, language used? Would they agree to participate on the basis of this understanding?</p> <p>Get feedback on this. In particular, on the word “monitor”. Does this imply feedback at the individual level?</p> <p>What would you expect this to mean?</p>
<p><b>Consent</b></p> <p>At recruitment people will be asked to consent on the basis of an understanding of the “statement of purpose” (AS ON STIMULUS BOARD 1) and consent to:</p> <ol style="list-style-type: none"> <li>1. Providing lifestyle data and a blood sample at recruitment</li> <li>2. On-going access to full past and future medical records at GP and any hospitals attended</li> <li>3. The process for making decisions on access to the UK Biobank</li> <li>4. The process for making decisions about use/types of research that the UK Biobank can/will be used for – it will be necessary for volunteers to understand that it is not possible to be specific about the research that might be conducted in the future.</li> <li>5. Recontact</li> <li>6. How benefit will be derived, i.e. At a societal rather than individual level</li> </ol> <p>NB Biobank participants become more valuable to the project over time, as more information becomes available.</p> <ol style="list-style-type: none"> <li>7. Continued use of data after death</li> </ol>	<p>STIMULUS BOARD 2</p> <p>GO THROUGH EACH BULLET</p> <p>SEEK FIRST REACTIONS. How should consent be obtained? What else would you want to know? Is this information sufficiently detailed?</p> <p>Should there be any conditions attached to consent for all or any of these points? Eg should recontact only be possible by the UK Biobank itself? What about the collaborating centres?</p>





<p>Next of kin legally have no rights of control over use/continued involvement after death.</p> <p>[NB in law in England and Wales someone cannot consent on another's behalf but law may change to cover post mortems and they can in Scotland.]</p> <p>8. Use after mental incapacity. <i>Last valid consent would be taken. Will no longer be able to withdraw but would be excluded from anything that requires new or additional consent.</i></p> <p>OR <i>Volunteers could be asked to state what they want to happen if become mentally incapacitated.</i></p> <p><b>On-going consent</b> It has been suggested that an annual newsletter would remind volunteers that they can withdraw and how to do so.</p>	<p>Are there any special issues around the use of data after death? What about families and their expectations?</p> <p>Any preferences? General views?</p> <p>Is this necessary? Is it reassuring? What do you understand by on-going consent? Is there a need for on-going consent? How might on-going consent be obtained?</p>
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<p><b>Withdrawal</b></p> <p>Volunteers have the right to withdraw at any time. Essential to preserve voluntary nature of project.</p> <p>Withdrawal could be:</p> <ol style="list-style-type: none"> <li><i>1. Destruction of identifiable samples and data and breaking link to medical record</i></li> </ol> <p>OR</p> <ol style="list-style-type: none"> <li><i>2. Discontinue participation – not collecting further information and break the link between participant and samples and data/medical record. Existing data could be used but there would be no further contact.</i></li> </ol> <p>NB some data and some of the blood sample may have already been used and will not be able to be withdrawn from previous studies.</p>	<p>What does withdrawal mean to you? What would you expect to happen as a result of saying you want to withdraw?</p> <p>THEN PRESENT THE 2 OPTIONS ON BOARD 3</p> <p>GET INITIAL REACTIONS</p> <p>Which preferred? Are there any other options you would prefer?</p> <p>It is thought that some volunteers would be happy for their information to be used but would not want to be recontacted, eg because of advancing age. Does this lead to a third option of tracking and sample and information use but no more data that must be collected from the individual and no newsletters etc sent?</p> <p>Are there any reactions to this point?</p>
<p><b>Recontact</b></p> <p>Recontact is likely for three reasons:</p> <ol style="list-style-type: none"> <li>To provide information on the project</li> <li>To collect additional data by linking to other databases</li> <li>To collect further information or samples</li> </ol> <p>Recontact will be through the UK Biobank but to conduct genetic tests that are highly predictive, your GP might make the contact.</p>	<p><b>STIMULUS BOARD 4</b></p> <p>Is recontact desirable/acceptable? Is it necessary? For all 3 purposes listed? Should this recontact come from the UK Biobank or from the GP?</p> <p>Is recontact necessary for this reason? How acceptable is recontact by a third party? By implication there may be a result that gives useful, personal health data. Should this then be available to the volunteers concerned? How should this information be imparted? By whom?</p>
<p><b>Active participation</b></p> <p>There are plans that participation throughout the lifetime of the UK Biobank should be active in so far as getting feedback from volunteers on the project.</p> <p>This feedback and other input from the volunteers would be used to inform decision-making and would have some influence.</p>	<p>What does active participation mean to you? What sort of participation do you expect/want? Do you need to consent to this?</p> <p>Is this necessary? What might your views impact on?</p>



<p><b>Benefits</b></p> <p>Participants will not be offered any financial inducements to take part.</p> <p>Reasonable expenses, such as travel costs, may be reimbursed.</p> <p>Samples will be treated as gifts or donations.</p> <p>Benefits from the research results will be for society as a whole, not at an individual level, although in time this should translate into better healthcare and medicines.</p>	<p>Should they be? What would you expect?</p> <p>Should they be? Is this important?</p> <p>What does ‘gift’ mean to you? – What does ‘donation’ mean to you? Do they mean different things? If so, what?</p> <p>What does this mean to you?</p> <p>What do you understand by “benefit”? What do you understand by “society”? PROBE FOR: NHS, national, disease group, participants, international, etc.</p>
<p><b>Uses and users</b></p> <p>Proposition: All proposals to use the UK Biobank data will be scrutinised to see whether they comply with the statement of purpose. They will be subject to scientific and ethical review by the UK Biobank coordinating centre – science committee and ethics committee and by external bodies e.g. the NHS research ethics committee.</p> <p>Access for other purposes will not be granted. Exclusive use will not be granted to any party.</p> <p>Access will be under strict terms and conditions and users will need to agree to the terms of the EGF and other policies.</p> <p>Access will be granted to users based outside the UK under the same strict terms and conditions.</p> <p>The UK Biobank remains in control of the samples and data at all times and will own the data although because it is a charitable company it sees itself as custodian, holding the data in trust for public benefit.</p>	<p>STIMULUS BOARD 1 (STATEMENT OF PURPOSE)</p> <p>How would you want this process to work? Who should be involved? How transparent should the process be? Would you want to know what has been refused? Would you want to know why? Would you want to know what has been approved?</p> <p>Should there be an appeals procedure for applications refused? Who might appeal be made too?</p> <p>Should there be special access for the collaborating centres?</p> <p>Does this raise concerns? Should there be special controls put in place? Such as...?</p> <p>JUST COLLECT ANY RESPONSES</p>



<p><b>General feedback</b></p> <p>Proposed methods include: newsletters websites, public meetings, helplines, support groups and on-going consultation.</p> <p>The IAG has recommended that a consultative body be set-up as a way of enabling dialogue and getting people’s input.</p> <p>It will be a condition of access to the data that any results are published. This will include “positive” and “negative” results. Results may be treated as confidential for short periods of time to allow patent applications to be made.</p> <p>A complaints procedure will be established for volunteers.</p>	<p>General response to these ideas? Is there anything else you’d like to see – any other ideas for feedback mechanisms? How often would you want to receive a newsletter? What might it contain? Would you go to public meetings? Would other people?</p> <p>How might this work? What would be the on-going role of such a body, if any? How would it relate to the oversight body?</p> <p>Reactions to publication? It means that everyone (stress all researchers) will be able to access the findings of the research so will benefit all research community.</p>
<p><b>Individual feedback</b></p> <p>As previously informed. There will not be any beyond that which can be instantly derived from the initial session.</p> <p>Feedback would not be given in relation to blood samples taken as tests would not be of a clinical standard.</p>	<p><b>IT SHOULDN’T BE NECESSARY TO SPEND TIME ON THIS AS IT HAS BEEN WELL COVERED BEFORE AND WE DO NOT WANT TO GO ROUND PREVIOUS ARGUMENTS AGAIN. THERE ARE OTHER ISSUES TO COVER THIS TIME</b></p> <p><b>UK Biobank is not a therapeutic endeavour. Its research nurses are not involved in providing medical care to its participants, and therefore have no “duty of care. The initial data collection is not a “health check”.</b></p> <p><b>The protocol for initial data collection should cover feedback of baseline physiological measurements.</b></p> <p>UK Biobank cannot provide individual feedback for a number of reasons: tests could take place years later but the result would apply to the day the sample was taken; testing is not undertaken to clinical standards and would have to be repeated to validate the result; the significance of some results would only become clear over time or can only be interpreted at a population level; some readings (e.g. calcium, cholesterol) would change over time in storage.</p>



<p><b>Confidentiality</b></p> <p>Samples will be anonymised as soon as possible with only authorised personnel being able to identify individual volunteers.</p>	<p>THIS IS AS BEFORE AND SHOULD BE COVERED ONLY IF TIME</p>
<p><b>Oversight Body</b></p> <p>It is likely that it will:</p> <ol style="list-style-type: none"> <li>1. agree the final ethical and governance framework,</li> <li>2. monitor that the EGF is being complied with</li> <li>3. safeguard participants and provide a route to public accountability</li> <li>4. advise on applications that raise particular ethical issues and on the strategic direction from an ethical viewpoint</li> </ol> <p>It will comprise 10-12 individuals with experience in ethics, law, biomedical and social science, public policy, healthcare, consumer and patient representation.</p> <p>Members will be appointed by the funders according to Nolan principles. SEE HAND OUT ON THESE AND STIMULUS BOARD 5</p>	<p>FOCUS ON FUNCTION/REMIT, POWERS AND NATURE</p> <p>Begin by brain storming what such a body should do, what role it should have.</p> <p>WE HAVE ALREADY COVERED THE TYPES OF PEOPLE WHO MIGHT SIT ON THE OB BUT WORTH SEEING IF THIS CHANGES WHEN BEING MORE PRECISE ABOUT ITS ROLE.</p> <p>Do you think it will be independent given that the members will be appointed by the funders. Is the use of Nolan principles reassuring?</p> <p>PROBE FOR WHETHER THIS MEANS ANYTHING TO PARTICIPANTS</p> <p>Do you feel the OB is the right body to deal with any complaints against Biobank?</p>
<p><b>Close</b></p>	<p>Thank everyone for coming, remind about date, time and location of reconvened session.</p> <p>The purpose of the session next week is to get a set of recommendations for the IAG. So please think about the things we have discussed and talk about them to friends and family.</p>



## **Session 2**

### **Briefing**

It is likely that not everything on the topic guide for session 1 was covered. Unless these topics are raised by group members, do not pursue them. Subsequent sessions in other locations will be structured to ensure that all the topics on the session 1 topic guide are covered in more than one group.

### **Introduction**

Thank everyone for returning. Last time we looked at the issues that the Interim Advisory Group has raised in relation to the ethical and governance framework for the UK Biobank.

The purpose of tonight's session is to pick-up what you think are the main points on the ethical framework and the oversight body that you want to feedback to the Advisory Group for them to consider before they make their final report to the UK Biobank team.

So let's begin by collecting together everyone's thoughts since the last session.

USING FLIP CHART COLLECT THOUGHTS SINCE LAST SESSION

### **Outstanding questions**

Provide answers to any outstanding questions collected by the facilitator during the first session. Allow a brief discussion of the answers.

### **Specific topics**

Has anyone got any (further) thoughts on xxxx [TOPICS ASKED SPECIFICALLY TO THINK ABOUT]?

NOTE KEY POINTS ON FLIP CHART  
PROBE REASONS FOR POINTS, ETC

### **Feedback to IAG**

As we said at the last meeting, these two sessions are designed to provide feedback to the interim advisory group on important parts of the governance of the UK Biobank and the ethical framework that it will operate within. You have raised a number of issues and I'd like you to focus on these and think about the key points you want to make on each of these topics

USING BOARD 5 WITH LIST OF TOPICS COVERED IN SESSION 1

### **Closure**

Are there any other points you'd like to feedback to the Advisory group for them to consider in their deliberations on the ethical framework and the Oversight body?  
Are there any other points you'd like to feedback about the UK Biobank more generally to the UK Biobank team?

### **Thank and close**



## **Annex 3 – Stimulus Material**

### ***Board A***

#### **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.

#### ***What***

Blood sample from which DNA will be extracted  
Permission for NHS records to be accessed for ten years  
Lifestyle information collected by questionnaire  
Monitored for at least ten years  
Recontacted for more information

#### ***Funding***

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

£45 million over 10 years.

### ***Board B***

#### ***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

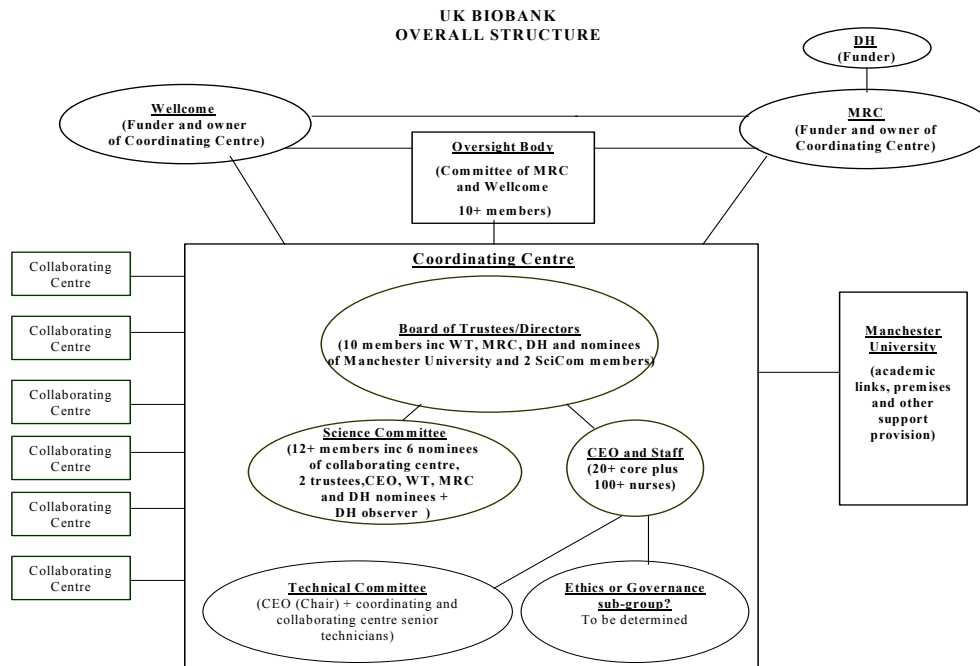
#### ***Examination e.g:***

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



## Board C

C



## Board 1

Purpose:

“The UK Biobank will monitor the health of a large number of volunteers for many years, collecting high quality information on environmental and lifestyle factors, linked to biological samples. This will result in a resource that will be used for ethically and scientifically approved research, with the aim of improving the prevention, diagnosis and treatment of diseases and medical conditions within society.

Safeguard will be put in place to secure that both healthcare information and samples are held for the public benefit and to ensure due respect for the rights and privacy of the participants.”

## Board 2

At recruitment on the basis of understanding the “statement of purpose” volunteers asked to consent to:

1. Providing lifestyle data and a blood sample at recruitment
2. On-going access to full past and future medical records at GP and any hospitals attended
3. The process for making decisions on access to the UK Biobank
4. The process for making decisions about use/types of research that the UK Biobank can/will be used for – it will be necessary for volunteers to understand that it is not possible to be specific about the research that might be conducted in the future.
5. Recontact
6. How benefit will be derived, i.e. At a societal rather than individual level





7. Continued use of data after death

8. Use after mental incapacity

### ***Board 3***

Withdrawal:

Destruction of identifiable samples and data and breaking link to medical record

OR

Discontinue participation – not collecting further information and break the link between participant and samples and data/medical record. Existing data could be used but there would be no further contact.

### ***Board 4***

Recontact likely:

To provide information on the project

To collect additional data by linking to other databases

To collect further information or samples

Recontact will be through the UK Biobank but to conduct genetic tests that are highly predictive, other organisations/researchers might make the contact.

### ***Board 5 – Nolan Principles***

Responsibility for appointments lies with Wellcome Trust and MRC

Selection on merit

Independent scrutiny

Equal opportunities

Probity

Openness and transparency

Proportionality