

UK Biobank Ethics and Governance Council Twentieth Meeting

Meeting at Wellcome Trust
215 Euston Road, London, NW1 2BE

Monday 7 Sept 2009 at 10.30am

Agenda

1. **Apologies**
2. **Minutes** of nineteenth meeting held on 8 June 2009
3. **Matters arising**
 - (i) Summary of decisions and recommendations from nineteenth meeting held on 8 June 2009
 - (ii) Tracking of requests to UK Biobank
 - (iii) Subgroup reporting as necessary
 - (iv) EGC workshop
 - (v) Equality and diversity impact assessments
 - (vi) Workplan 2009-2010
4. **Update from UK Biobank: Proposal for enhanced phenotyping of participants**
(Professor Rory Collins, Chief Executive Officer, UK Biobank)
5. **Update from UK Biobank** (Professor Rory Collins, Chief Executive Officer, UK Biobank)
 - (i) General update from UK Biobank
 - (ii) Update regarding recommendations from EGC19 (including arrangements for UK Biobank information systems and equality and diversity progress)
 - (iii) Development of UK Biobank's access and intellectual property procedures
 - (iv) Biannual report on longitudinal follow-up of participants
 - (v) Post-visit survey
6. **UK Biobank Communications** (Mr Andrew Trehearne, Head of Communications, UK Biobank)
7. **Closed discussion of matters arising under items 4 - 6**
8. **Communications activities**
 - (i) External speaking opportunities
 - (ii) External enquiries to the EGC
9. **Report on meetings attended**
 - (i) Tiss.EU project's international workshop 25-26/6/09
 - (ii) UK Biobank archive facility opening 28/07/09
 - (iii) Visit to Taiwan Biobank 01/09/09 – 04/09/09
10. **Any other business**
11. **Date of next meetings**

**UK Biobank Ethics and Governance Council
Twentieth Meeting**

**7 September 2009
Wellcome Trust, London**

Present: Professor Martin Richards (Vice Chair), Professor Ian Hughes, Professor Paolo Vineis, Professor Erica Haines, Dr Roger Moore, Professor Roger Higgs, Mrs Margaret Shotter, Ms Tracey Phillips, Dr Jonathan Hewitt, Mr Andrew Russell and Professor Heather Widdows.

In attendance from EGC Secretariat: Ms Adrienne Hunt.

Observers: Ms Katherine Littler (Wellcome Trust) for the whole day. Dr Catherine Moody for the morning only and Dr Catherine Elliott for the afternoon only (Medical Research Council).

Speakers: Professor Rory Collins (Principal Investigator and Chief Executive, UK Biobank), Mr Jonathan Sellors (Company Secretary, UK Biobank) and Mr Andrew Trehearne (Head of Communications, UK Biobank) for items 4 - 6 inclusive.

1. Apologies

Apologies were received from Professor Graeme Laurie. Professor Martin Richards, as Vice Chair, took responsibility for chairing the meeting in Professor Laurie's absence.

2. Minutes of nineteenth meeting held on 8 June 2009

The Council approved the circulated minutes.

3. Matters arising

Summary of decisions and recommendations from nineteenth meeting held on 8 June 2009

The Council approved the circulated summary of decisions and recommendations.

Tracking of requests to UK Biobank

The Council noted that the requests for further information will be addressed during the afternoon discussion with UK Biobank.

Subgroup reporting as necessary

Access and Intellectual Property (AIP)

The recent National Cancer Research Institute report 'Samples and data for research: Template for access policy development' (June 2009) was distributed to the Council for information. Members considered it to be a very useful document while noting that it does not address some of the questions that arise in UK Biobank's trust model of broad consent (e.g. what methods will be used to assess and prioritise research projects in accordance with 'public good' criteria and which criteria will be used for this purpose?).

At the Council's last meeting UK Biobank offered to give the EGC sight of the draft AIP procedures if they were approved for distribution by the Board of Directors at its meeting on the 25th September 2009. As an interim step the Council had requested an update paper from UK Biobank describing its approach to a number of priority areas (as previously identified by the EGC's AIP subgroup). The Council had been informed, however, that a verbal and not a written report would be provided later in the meeting. This was because UK Biobank was still in the process of researching and developing its procedures. Members also noted that the Board's September meeting has been cancelled and queried what implications this may have for the timing of the distribution of the procedures to the EGC. Members emphasised the importance of the procedures and the need for UK Biobank to allow sufficient time for consultation (with the EGC and with other stakeholders). Members agreed on points to raise with UK Biobank under item 5.

Communications

The Communications subgroup will meet in November to discuss the March 2010 public meeting format and content. Issues regarding access and IP are the intended focus of the meeting, dependent on the Council receiving UK Biobank's draft procedures in sufficient time.

Information Security

At its last meeting the Council addressed a number of questions to UK Biobank regarding its relationship with the Clinical Trial Service Unit and the potential outsourcing of the database development. Members discussed UK Biobank's response and agreed on points to raise with Professor Collins under item 5.

EGC workshop

The majority of invited speakers have confirmed their availability for the EGC's 8th December 2009 workshop on public involvement. Members endorsed Professor Heather Widdows' offer to sit on the discussion panel at the conclusion of the workshop.

Equality and diversity impact assessments

The Secretary has undertaken three initial assessments which will be discussed with Ms Tracey Phillips and Professor Laurie: the Council's published material, its public meetings and the process by which members are recruited.

Workplan 2009-2010

A decision regarding the Council's funding beyond September 2010 will be informed by a review of the EGC's activities by its funders, the Wellcome Trust and the Medical Research Council. As part of this review the Council will be required to submit a workplan for 2010 and beyond. Members reviewed the Council's progress against its current workplan and were invited to proposed future initiatives. The following points were raised during the discussion:

- In its review submission the Council should reflect on its own work, including the nature, scope and balance of EGC activities; its relationship and communications with UK Biobank and the potential for, and desirability of, an expanded role to include other cohort studies.
- The Council should request sufficient funds so it might continue to commission research as and when required.
- The EGC should keep on its agenda the implications of possible commercialisation of results of research using UK Biobank data and/or samples. The Council might commission further research in this area and/or invite an external speaker to attend a future meeting to address relevant issues.
- The Council agreed to write a series of papers on key ethical and governance issues as one element of its future workplan. The papers could draw together the Council's analysis and discussion on specific topics in a single place and in an accessible format. The Council agreed that, in the shorter term, it would be useful to write a paper on the use of MR imaging, potentially for publication in an academic journal (e.g. The Journal of Medical Ethics). The paper could describe the ethical issues involved and how these might be addressed (e.g. elements of consent, feedback protocol etc) rather than offer a position statement. The Council hopes that such a paper would be of value to other organisations that are addressing this issue (for example, two of the birth cohort studies are planning to pilot MR imaging studies). The funders confirmed that they did not consider this initiative to represent any conflict of interest.

ACTION: Dr Jonathan Hewitt, Professor Richards and Professor Widdows expressed an interest in authoring the paper. Members should confirm with the Secretary if they are also interested in writing the paper. [All]

4. Update from UK Biobank: Proposal for enhanced phenotyping of participants (Professor Rory Collins, Chief Executive Officer, UK Biobank)

No-cost enhancements

The no-cost enhancements to the baseline assessment visit have been piloted in Middlesbrough (including a hearing test, a finger clip to test arterial stiffness, additional cognitive function tests and a diet questionnaire at the end of the assessment visit). Implementation of the new measures presented a number of challenges including both technical and timing issues. These have now been resolved and the enhancements have been successfully introduced into the operations of a second assessment centre. The schedule for opening new assessment centres has been staggered in order to allow time for the no-cost enhancements to be rolled-out to all further existing assessment centres.

Extra-cost enhancements

UK Biobank has received a further £6 million of funding to support the introduction of additional enhancements to the baseline assessment centre visit (including cardiovascular fitness assessment, activity monitoring, the collection of blood for RNA extraction, the collection of saliva samples and ocular measures).

During the peer review process UK Biobank was asked to provide further justification of the value of the ocular measures in terms of the development of disease during long-term follow-up and further justification regarding the choice of equipment. In its response UK Biobank drew on the practice of other organisations, notably the EPIC-Norfolk study which uses similar techniques. The iterative dialogue between UK Biobank and the peer reviewers resulted in a positive funding decision.

The enhancements will be introduced in three phases:

1. The following measures were introduced at the Liverpool assessment centre in August 2009 and will be rolled-out to all centres during September:
 - i. Collection of an extra 4ml of blood for RNA extraction (just under 50ml is now collected at baseline in total).
 - ii. Collection of a saliva sample.
 - iii. Eye measures including intraocular pressure and refraction and sight tests.
2. The following measures will start to be introduced at all assessment centres in December 2009: Photographs of the eye and fitness assessment (the latter involving arm lead ECG which will provide information at rest, during and after exercise).
3. UK Biobank intends to ask all participants if they would be willing to wear a watch-style activity monitor for a week before mailing it back to the project. In order to focus on implementation of the enhancements above, and complete validation of the accelerometer, UK Biobank has decided to wait until after recruitment has ended before contacting participants about this enhancement. UK Biobank has based its estimates on approximately half to two thirds of participants being willing to participate in this additional activity (but this will be informed by piloting).

The standard feedback form that participants receive at the conclusion of their assessment centre visit has been revised to include the results of the intraocular pressure measurement. The form indicates whether or not the result is high and recommends that those with a high result visit their GP or optician.

The Council and Professor Collins discussed the following:

- The fitness assessment and the possibility of providing feedback of the results. Professor Collins offered to look into the possibility of providing feedback although questions were raised about how informative such feedback might be (as the results may be only indicative of a potential future health issue rather than strongly correlated).
- The development and validation of UK Biobank's diet questionnaire. An academic group was supported by the project to develop the one-day web-based diet diary. The diary was initially validated by inputting data from random days of diet diaries from the EPIC study and allowing these to be automatically coded by UK Biobank's web-based system. Data from this automatic coding was compared with the original EPIC study manual coding and the results found to be very similar for a range of nutrients. In a second validation exercise, volunteers were asked to complete UK Biobank's web-based diet questionnaire and were then interviewed using the standard EPIC diet diary systems. UK Biobank again found good agreement between the two methods and, indeed, found that some people forgot to include items during the interview (possibly because of a perceived time pressure during a one-to-one interview as compared to the web-based questionnaire which is completed at the volunteer's own pace). The next stage of validation will involve doubly-labelled water to determine the accuracy of energy estimation.

UK Biobank will address diet variation over time by asking participants to complete the web-based questionnaire several times over a period of time. Professor Collins concluded that while no diet questionnaire is perfect it is hoped that UK Biobank's questionnaire will provide a good classification of participant's long-term dietary habits.

- The majority of participants will receive a request to undertake the web-based diet questionnaire after, rather than during, their baseline assessment visit. The Council queried the accessibility of participation in UK Biobank's diet questionnaire given that 70% of participants have provided the project with text or email contact details. A concern was expressed that the socio-economic response to the questionnaire may not be representative of the cohort as a whole as it is likely that the less wealthy cohort members may not have ready internet access. This may limit the amount of information UK Biobank receives regarding poorer diets and related health outcomes. Professor Collins commented that the questionnaire will be conducted during the initial assessment centre visit of the last 110,000 participants, therefore capturing the full range of socio-economic groups within that proportion of the cohort. The questionnaire would then be rolled-out to the remaining approximately 390,000 participants by text and email and, if no such contact details were provided, by letter. Participants without internet access might use their local library facilities to complete the questionnaire. Professor Collins

proposed that UK Biobank could assess access issues by investigating the determinants of who does and does not complete the questionnaire.

Subject to the following, UK Biobank hopes that the baseline data will be 'clean' and available for access by the end of 2010 (there will be little follow-up data at this early stage):

- Access requests will only be considered once recruitment has ended (currently scheduled for June 2010).
- The database containing participants' assessment centre and follow-up data will take some time to scope, design and populate (see item 5 below).
- UK Biobank's follow-up pilots are due to be completed by mid 2010. The pilots should give the project a clearer idea as to what type and format of data is available. UK Biobank is currently in discussion with the Research Capability Research programme as a potential supplier of follow-up data.

In addition to the extra-cost enhancements to the baseline visit, UK Biobank had also proposed a future re-assessment visit involving MR imaging. This aspect of the enhancement proposal has not been funded at this stage. The funders recommended that UK Biobank conduct a more wide-ranging consultation with the scientific community and respond to a number of issues regarding the value of such a major investment.

UK Biobank plans to ask a number of imaging experts to review its detailed protocol with a view to submitting a revised protocol to UK Biobank's International Scientific Advisory Board (ISAB) in late February 2010 and a re-submission to the funders in the first¹ quarter of 2010. UK Biobank hopes to receive funding to conduct a pilot phase starting in the first half of 2011. The budget for a pilot would be in the region of £6 million, half the costs of which could be retrieved by re-allocating the imaging machines to other research facilities if the main phase is not subsequently funded.

UK Biobank's outline imaging incidental findings protocol will be revised in the light of comments received from the EGC and other stakeholders and will be provided to the Board, EGC and ISAB for review prior to the funding re-submission. From June to December 2010, UK Biobank plans to develop a detailed protocol for the management of incidental findings based on discussions with participants, radiologists and other experts. Only then would the project be in a position to pilot any imaging (providing that it was funded) in 2011.

5. Update from UK Biobank (Professor Rory Collins, Chief Executive Officer, UK Biobank)

General update from UK Biobank

With a current total of 360,089 participants, recruitment is on track to complete in June 2010. A cumulative average of 99.8 participants is being recruited per day per assessment centre (compared to the budget prediction of 100 participants per day per assessment centre). Due to the success of recruitment the project expects to

¹ Post meeting note: The re-submission is now expected to be made in the second quarter of 2010.

reach its target of 500,000 participants through the operation of only 24, rather than the predicted 35, centres. This represents a major saving for the project as the predicted costs of relocating and opening new centres have been reduced.

Professor Collins updated the Council on the status of the assessment centres:

Assessment centre	Closing month	Opening month
Leeds	July 2009	
St Bartholomew's Hospital	August 2009	
Nottingham	September 2009	
Bristol	October 2009	
Middlesbrough	December 2009	
Liverpool	March 2010	
Hounslow	May 2010	
Sheffield		August 2009
Croydon		September 2009
Birmingham		October 2009
Barking		February 2010
Swansea		January 2010

The mobile assessment unit should be operational in December 2009. Given that the unit is funded by the Welsh Government it is likely that it will be used exclusively in Wales for the baseline assessments, starting in Swansea. The unit may be used beyond Wales for the future repeat of the baseline visit in a sample of the whole cohort, which will occur every few years and will involve 20-25,000 people.

Update regarding recommendations from EGC19 (including arrangements for UK Biobank information systems and equality and diversity progress)

Equality and diversity

UK Biobank is working with a consultant, as recommended by the EGC, to identify and address equality and diversity issues as they relate to the project. The aim is for the project to adopt an ongoing process for identifying and addressing such issues rather than simply conducting a one-off audit of activities.

At its last meeting the Council sought confirmation that the UK Biobank assessment centres, including the mobile unit, are compliant with the Disability Discrimination Act (DDA). Professor Collins confirmed that he has passed this query to the developers of the mobile unit and he offered to provide further information after the meeting regarding the unit's DDA compliance.

Biannual report on enquiries and complaints

At its last meeting the Council noted that UK Biobank's biannual report did not contain reference to the Miscellaneous category of enquiries and complaints (which had been a substantial category in previous reports). Professor Collins confirmed that he has asked Dr Tim Sprosen to check whether or not this was an omission and to ensure that any miscellaneous enquiries and complaints are included in future reports.

UK Biobank information systems

UK Biobank's overarching database system will contain participant data derived at the assessment centre, sample analyses and clinical follow-up data along with a user portal and tools for access. The database will also need to be capable of holding any data resulting from the proposed imaging enhancement measures if this initiative is funded in the future.

Professor Collins explained that it had been decided not to build the database in-house at the UK Biobank coordinating centre in Cheadle because the centre does not have the requisite expertise. There is no single person who would be able to design and build all aspects of this database; instead the expertise of many individuals would be needed but only on an occasional and part time basis. Given the above, the Board of Directors has agreed that the project should explore the potential for developing the database through an academic collaboration.

In the first instance UK Biobank will determine the scope of the IT system and the composition of the academic collaboration. To this end, UK Biobank is hosting a scoping meeting with scientists who have expertise in creating genetic and proteomic databases. The feasibility of the system design will be assessed during January – June 2010 after which the database system will be built, tested and implemented during June – December 2010. The first access to the baseline data may then be possible by January 2011.

The Council noted that the proposed process for the development of the database is a significant departure from that described to the EGC's Information Security subgroup during a visit to the UK Biobank coordinating centre earlier this year. Professor Collins confirmed that an alternative route was being taken at that point in time, but the approach had proved unworkable for the project's purposes. The current strategy had therefore been put to the Board and was approved.

After its last meeting the Council asked UK Biobank to clarify the scope of the ISO 27001 accreditation that it hopes to receive (given the role of the Clinical Trial Service Unit (CTSU) in handling the participant invitation process and the proposed outsourcing of the database). Professor Collins confirmed that UK Biobank is continuing to pursue accreditation for UK Biobank's systems and agreed that data security issues will need to be addressed as part of the database future development process.

At its last meeting the Council endorsed UK Biobank's proposal to commission an independent external audit of CTSU's security provisions. The audit will be paid for by UK Biobank and will report to Dr Tim Peakman (UK Biobank's Executive Director with responsibility for the project's data security). On the advice of the external testers, the penetration testing and audit of CTSU will take place in the next few months after the planned installation of a new firewall.

Regarding the relationship between UK Biobank and CTSU, Professor Collins confirmed that CTSU is a contractor on behalf of UK Biobank under a formal agreement. This relationship was approved by the Board of Directors during the planning stages of the project, with necessary consideration given to the potential

conflict of interest (in light of Professor Collins' role as co-Director of CTSU). Professor Collins was not involved in the discussion or decision at that stage and, at present, he does not involve himself in negotiations with CTSU; this responsibility falls to other colleagues at UK Biobank e.g. Dr Peakman and Mr Jonathan Sellors. Professor Collins confirmed that CTSU is not expected to be involved in the development of the overarching database but that it is likely to be involved in disseminating invites for re-assessments in the future (since that is an extension of their existing systems).

The Council returned to this item in closed session in the afternoon and agreed to request a site visit to CTSU involving the Council's Information Security subgroup, Dr Peakman and those individuals from CTSU who are responsible for the security of UK Biobank's data. The purpose of the visit is for the subgroup to refine its queries with Dr Peakman to arrive at the level of reassurance about data security that it and participants might expect. The Council agreed that the meeting could usefully include discussion of the following:

- The governance arrangements between UK Biobank and CTSU and in particular the lines of responsibility and accountability. Specifically, the Council will request a diagram that describes the governance relationship between CTSU and UK Biobank and elaborates on the lines of accountability and responsibility (including at the level of the individual).
- The nature of the relationship (e.g. contractual) between UK Biobank and CTSU and how this relationship might change over time.
- CTSU's data processing and storage mechanisms and the related security provisions.
- The proposed audit of CTSU (including timetable, who is conducting the audit etc) and of the planned penetration testing of CTSU.

Development of UK Biobank's access and intellectual property (AIP) procedures

UK Biobank will meet with its funders on 24th September to discuss the project's draft AIP procedures (i.e. outline of planned content which will be expanded during future development) and will request that the procedures be released to the EGC as soon as possible (subject to any amendments required by the funders prior to distribution). The Board of Directors will also be asked by email (rather than wait until the next Board meeting, currently timetabled for December) to approve the distribution of the procedures to the EGC for initial comment in the short term.

The Council welcomed UK Biobank's offer to expedite the process by which the procedures are brought to its attention. The Council considers the AIP procedures to be fundamental to the principle of UK Biobank and its model of broad consent and that it is essential for UK Biobank to give the necessary time to the process of consultation (with the EGC and UK Biobank's other stakeholders). Members reaffirm the Council's hope for a robust consultation period and for no further slippage in the development timetable.

Professor Collins commented that the project is working towards a deadline of January 2011 for the first access to the resource. In light of this timing, and given recent pressures associated with the proposal and implementation of the enhancement measures, it became an operational necessity for the AIP procedures to take a slower track than had been sought. This decision has been advantageous in that, since access is not expected until January 2011, UK Biobank can learn from other initiatives rather than trying to develop its own procedures in parallel with them (e.g. the National Cancer Research Institute report on a template access policy was only recently published in June 2009). Similarly, Professor Collins reported that the Avon Longitudinal Study of Parents and Children (ALSPAC) has recently made data available for research by external investigators and UK Biobank has been able to talk to ALSPAC colleagues about their experience. Professor Collins' reassurance was welcomed by members while some frustration remained at the Council having not yet received any written indication of UK Biobank's development in thinking regarding the procedures.

The Council highlighted the importance of having the procedure in place sufficiently in advance of the resource being open for access so that researchers know what is expected of them in terms of the access application process. Mr Sellors confirmed that he has already been in discussion with researchers and that this process will continue as the procedures and Material Transfer Agreement become available. Professor Collins assured the Council that he wants the procedures to be thorough and in place by January 2011. He also confirmed that the Council will receive not only the procedures, but also the reasoning behind the proposed access and IP policies.

ACTION: Later, in closed session, the Council agreed to write to the funders to ask that they look favourably on UK Biobank's request that the procedures are released to the EGC in the earliest possible timeframe. Professor Collins and Mr Sellors will be informed about the communication. [AH]

ACTION: A meeting of the AIP subgroup will be arranged to coincide with the release of the procedures paper to the EGC. [AH, MS, HW and GL]

Biannual report on longitudinal follow-up of participants

A Longitudinal Follow-Up Group has been active for some time to advise UK Biobank on the process for longitudinal follow-up of participants using routine health records in England, Scotland and Wales. The Council reviewed a number of linkage pilots which are being planned and which will be reviewed at the next meeting of the Longitudinal Follow-Up Group in October.

The pilots will involve data from death/cancer, hospitalisation and primary care records for up to 10,000 participants in each of Scotland (Glasgow), Wales (Cardiff) and England (Nottingham). In addition linkages to the dental records will be piloted for 10,000 participants in England (Manchester).

When a participant provides consent they authorise UK Biobank to access their 'medical and other health-related records' for the purpose of the project. The Council

queried how UK Biobank intends to interpret 'health-related' as this could be an important question for participants. Professor Collins confirmed that only health records are being pursued by UK Biobank at this point in time. Employment and residential records are mentioned in the participant information leaflet but these options will not be explored until after the health record pilots (linkage to these systems is expected to take place mid 2010).

UK Biobank's IT systems need to be sufficiently flexible to allow linkage with various health databases. Once the various data are stored in UK Biobank, related data will be linked through a process of validation. UK Biobank is currently consulting with an expert group to address the required design systems for validation and to consider the level to which UK Biobank can add value by validating the data. For example, UK Biobank could cross-reference various sources of data to determine subtypes of stroke.

The Council queried how and when UK Biobank intends to keep participants informed about which health-related records are being accessed by the project. Information regarding the linkages is available on UK Biobank's website under 'Frequently asked questions' and in the project's protocol. The website will be revised to change the focus from the recruitment phase to updating participants and the public about developments in the project (including how data and samples are being used by researchers and which 'health-related' records are being accessed by UK Biobank).

Post-visit survey

UK Biobank has previously utilised a post-visit survey to investigate participants' experience of the recruitment process. Subsequent to this survey the Council had recommended that UK Biobank move to undertake a more detailed investigation of participants' understandings and expectations of their future involvement with the project. The Council reviewed a revised post-visit survey which UK Biobank intends to conduct at the last six assessment centres.

Members considered that the revised survey stands on its own terms and that it has the potential to provide useful insights regarding the participant experience. However, as drafted and presented, the Council did not think that the proposed survey responds fully to its previous recommendation. The Council had suggested that what is required is not the addition of further questions to the previous post-visit questionnaire because, although this may tell us more about the frequency of misunderstandings, it cannot tell us how or why participants come to make whatever assumptions they may have about participation in UK Biobank. Instead the Council recommended a more in-depth qualitative methodology (e.g. focus groups or interviews).

The Council noted that UK Biobank intends to conduct a number of telephone interviews as a follow-up to the revised survey and that this might provide the more nuanced approach as described above. However, no information was provided regarding the telephone interviews and so members were unable to comment further on the approach.

Members felt that the revised survey could be seen as a preliminary study which builds up to a more detailed survey in the future. Conducting such a detailed survey may be more relevant in terms of longer term participation as it may provide information on people's understanding and expectations after a duration of participation.

Professor Collins offered to provide the Council with a cover letter which sets out the context of the survey and the follow-up interviews (something that will likely be required for the project's MREC submission). The letter may address the questions raised by members during the discussion, including:

- When will the revised survey take place? (The Council has previously recommended that the survey would ideally take place some time after the assessment visit so that participants have had some time for reflection.)
- How many people will be surveyed and how many follow-up interviews will be conducted?
- How will UK Biobank choose who to contact with regards to the follow-up interview?
- How will the follow-up interviews be structured and what questions will be asked?
- How will the data from the survey and follow-up interviews be stored and used?

The Council is keen to offer advice on the structure and content of the proposed follow-up interviews as and when they might be made available.

ACTION: Members should send proposed amendments to UK Biobank's revised post-visit survey to the Secretary for compilation, after which they will be sent to Dr Sprosen. [All]

6. UK Biobank Communications (Mr Andrew Trehearne, Head of Communications, UK Biobank)

Mr Andrew Trehearne updated the Council on the two main strands of the project's communications strategy; awareness raising and long-term communication.

Newspaper, television and radio are UK Biobank's main media for awareness raising. Local media contacts are informed six weeks before an assessment centre opens and are invited to the centre to meet participants on its first day of operation. In general the project receives coverage on BBC local radio, press and some television coverage. This initial contact is followed-up with letters to local paper editors when the 10,000th participant is being recruited or at similar milestones. UK Biobank will often look for a local notable person to support the project (e.g. an MP).

Bus campaigns have been successfully used as a means of raising the profile of the project. The project has also undertaken radio advertising and editorials along with placing notices in local cafes, launderettes, hospitals, health, welfare and religious centres. The project sends letters to local organisations offering to visit and present information about the project, and local GPs, practice managers, local MPs and PCT

leads are all notified prior to the project launching recruitment in a particular town or city.

Publicity was recently generated due to the opening of the archive facility by Princess Anne, The Princess Royal. Co-ordinating with the opening, BBC news online published a video report showing the assessment centre process, including how participants' samples are processed. Mr Trehearne uses significant events as a reason to re-contacts journalists, firstly as a reminder about the project and secondly as a reminder that Mr Trehearne is the contact point for any queries about the project.

UK Biobank considers it important to keep participants informed about the project's progress now and in the longer term. The project envisages a strategy that utilises email and text whereby messages will be sent on a regular basis – for example once or twice a year – encouraging participants to visit the UK Biobank website, where news and developments (including a downloadable/ printable Newsletter) will be posted. About 70% of participants have provided either email or text contact details. Participants who have not provided such details will receive postcards, as will participants for whom the email or text fails to send or is bounced. Participants will be able to chose their level of engagement with the project; for example, some participants may prefer not to receive updates in the future, whereas others may prefer to keep abreast of the project's progress on a regular basis.

UK Biobank's re-designed website will contain lay summaries of research that has been granted access. The summaries may be searchable by disease type or by region of the country so that participants can look for the information most of interest to them. The project may make pod-casts available through the site and could post questions to participants and engage through the web. It is important to remember, however that some people do not, and will not, have ready access to the internet and so hard copies will be made available on request.

During the discussion, the Council recommended that UK Biobank consider its proposed long-term communication strategy in terms of equality and diversity issues (for example streamlining the availability of hard copy newsletters and making materials available in large print version). Mr Trehearne confirmed that he hopes to make the information accessible in terms of using non-technical language and that the aim of the strategy is to make participants want to engage and respond. Because re-contact is likely to generate enquiries, the Participant Resource Centre will continue to operate but at a lower staffing level. A system for escalating enquiries to senior management will also continue to operate in the future.

UK Biobank plans to stagger re-contact by writing to individuals on the anniversary of their participation. This should result in a more manageable process and allow UK Biobank to learn from the outcomes of the early re-contacts and apply these to later re-contacts. The staggered re-contact will also allow the project to learn about, and manage, the bounce-back rate. The Council recommended that UK Biobank make the method of updating contact details as user friendly as possible. Mr Trehearne confirmed that he has been in discussion with ALSPAC about their method of letting people update their contact details. The method by which participants update their

contact details is being devised as part of the web-based diet questionnaire in which participants are asked to re-affirm their contact details.

Mr Trehearne was asked how often UK Biobank has had to respond to negative publicity. There have been at least three negative newspaper reports and at least one case where the project was contacted by an investigative journalist but no news item resulted. A recent editorial in the Lancet had no apparent negative effect on the project (in terms of participant recruitment and withdrawal). Mr Trehearne concluded that one might have expected more negative news items for such a large scale, national project but on the whole people tend to view the project as a positive news story.

7. Closed discussion of matters arising under items 4 - 6

The Council wished the degree of frustration amongst some members regarding the timetable for the provision of information from UK Biobank to be noted. Members are aware, and understand, that UK Biobank has competing priorities (for example the slippage in the AIP timetable for development resulting from other aspects of UK Biobank's operations having taken priority, notably the enhancements). Notwithstanding, the Council is keen to mitigate any sense of frustration, now and in the future, and to work hard at maintaining its excellent relationship with UK Biobank. To this end, the Council proposed a meeting between Professor Laurie and Professor Collins to discuss the relationship between UK Biobank and the EGC, including how this has been managed in the past and how relations and communications might be best managed in the future.

ACTION: The Secretary will update Professor Laurie on the day's discussion and request a meeting with Professor Collins. [AH]

8. Communications activities

External speaking opportunities

Professor Laurie will present a paper on the EGC at the World Biobanking Summit on 25th September 2009 in Edinburgh.

External enquiries to the EGC

The Council noted two external enquiries, the details of which had previously been circulated.

9. Report on meetings attended

Tiss.EU project's international workshop 25-26/6/09

Professor Widdows spoke at a recent meeting of the Tiss.EU project on the subject of broad consent and trust. Tiss.EU is a European Union funded project whose aim

is to evaluate legislative and regulatory documents in relation to the procurement, storage and transfer of human tissue and cells for research in the European Union.

UK Biobank archive facility opening 28/07/09

The Chair and Secretary attended the opening of the UK Biobank archive facility by Princess Anne, The Princess Royal. The £4.5 million blood and urine store will keep 10 million samples at -80°C for the next 30 years and more. The freezer is 7 metres wide and 6 metres high. A press release about the event is available on UK Biobank's website.

Visit to Taiwan Biobank 01/09/09 – 04/09/09

The Chair's planned trip to Taiwan was cancelled due to his ill health.

Dr Catherine Elliott informed the Council that the Bionet project has recently published its final report examining the emerging patterns of scientific cooperation between Europe and China (including in relation to biobanking). The report, which contains recommendations from an expert group, is available on the Bionet website.

10. Any other business

The Council agreed to request a site visit to the Sheffield assessment centre prior to its public meeting on 15th March 2010.

ACTION: Members should contact the Secretary if they would like to visit the centre.
[All]

Members sent their very best wishes to Professor Laurie for a speedy recovery.

11. Date of next meetings

- | | | |
|-----------------|---|------------------------------------|
| 7 December 2009 | - | Council meeting (London) |
| 8 December 2009 | - | Workshop (London) |
| 15 March 2010 | - | Evening public meeting (Sheffield) |
| 16 March 2010 | - | Council meeting (Sheffield) |