

UK Biobank Ethics and Governance Council Twelfth Meeting

Meeting at the Novotel (Manchester)
21 Dickinson St, Manchester, M1 4LX

Tuesday 12 June 2007 at 10.30am

Agenda

1. **Apologies**
2. **Minutes** of eleventh meeting held on 12 March 2007
3. **Matters arising**
 - (i) Summary of decisions and recommendations from eleventh meeting held on 12 March 2007
 - (ii) Tracking of requests to UK Biobank
 - (iii) EGC policy on the publication of Council meeting minutes
 - (iv) Update: Access to the UK Biobank resource: Concepts of the public interest and the public good
 - (v) Update: An exploratory project to study opinions regarding the terms of 'third party' access to UK Biobank
4. **Update from UK Biobank** (Professor Rory Collins, Chief Executive Officer, UK Biobank)
 - (i) General update from UK Biobank
 - (ii) Update regarding recommendations from EGC11
 - (iii) Update regarding the development of UK Biobank's access and intellectual property policy
5. **UK Biobank's communications strategy** (Mr Andrew Trehearne, Head of Communications, UK Biobank)
6. **EGC communications activities**
 - (i) Debrief: Public event (11 June 2007)
 - (ii) Subgroup work
7. **Report on meetings attended**
 - (i) Royal Statistical Society (14/03/07)
 - (ii) EGC Chair and Vice Chair meeting (23/04/07)
 - (iii) P3G Annual General meeting (19 and 20/05/07)
8. **Recruitment process: proposal for 1 year extension**
9. **Any other business**
10. **Date of next meeting and proposed 2008 dates**

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

**12 June 2007
Novotel (Manchester)**

Present: Professor Graeme Laurie (Chair), Professor Chris Wild, Professor Ian Hughes, Professor Erica Haines, Ms Hilary Newiss, Dr Roger Moore and Professor Martin Richards, Dr Anneke Lucassen and Dr Heather Widdows.

In attendance from EGC Secretariat: Ms Adrienne Hunt.

Observers: Miss Ellie Pond for the whole meeting, Wellcome Trust.

Speakers: Professor Rory Collins (Principal Investigator and Chief Executive, UK Biobank) and Mr Andrew Trehearne (Head of Communications, UK Biobank) for agenda items 4 and 5.

1. Apologies

Apologies were received from Ms Sally Smith QC, Professor Roger Higgs and Ms Andrea Cook for the whole meeting.

2. Minutes of the last meeting held on 12 March 2007

The Council approved the circulated minutes.

3. Matters arising

Summary of decisions and recommendations from eleventh meeting held on 12 March 2007

The Council agreed that actions should not be accredited to specific individuals. Subject to this revision the paper was approved.

ACTION: The Secretary will revise the paper accordingly. [AH]

Tracking of requests to UK Biobank

The Council agreed to remove the question relating to follow-up of participants as this subject is being actively addressed by UK Biobank.

ACTION: The Secretary will revise the paper accordingly. [AH]

EGC policy on the publication of Council meeting minutes

The EGC policy on the publication of Council minutes was approved subject to the phrase 'where just cause can be shown' being replaced by the phrase 'in appropriate circumstances'.

ACTION: The Secretary will revise the policy accordingly. [AH]

Access to the UK Biobank resource: Concepts of the public interest and the public good

A draft report was reviewed at the last Council meeting and feedback subsequently provided to the researcher. The final report will be submitted to the Secretary by 30 June 2007.

Proposal: An exploratory project to study opinions regarding the terms of 'third party' access to UK Biobank

Three research groups have indicated their intention to submit a proposal in response to the Council's Invitation to Tender for 'Access, commercialisation, intellectual property and benefit sharing: An exploratory project to study opinions regarding the terms of 'third party' access to UK Biobank'. Proposals will be submitted to the Secretary by 15 June 2007.

A Review Panel has been convened to judge the proposals, comprising two EGC members and two external individuals with expertise in the research subject.

4. Update from UK Biobank (Professor Rory Collins, Principal Investigator and Chief Executive, UK Biobank)

General update from UK Biobank

UK Biobank is currently recruiting in Manchester and Oxford. Contact details are currently being supplied locally by Primary Care Trusts (PCTs) while UK Biobank awaits approval to access central contact details for potential participants in England and Wales. In Oxford, contact details covering several recently merged PCT's have been provided centrally by the new single large PCT. In Manchester contact details are being provided by several different PCT, resulting in a more fragmented process.

The next two centres to be opened will probably be in Glasgow and Edinburgh (reflecting the fact that UK Biobank has been provided with central contact details for Scotland). The Glasgow centre will be the first to open. Invites were distributed in the first week of June with a view to the assessment centre opening in mid July. A joint press release was issued with Generation Scotland on the 4 June. The press release aimed to launch UK Biobank's campaign in Scotland and to highlight the complementary design of the two projects. Generation Scotland is recruiting from 14 General Practices (GPs) in Glasgow and, in order to avoid overburdening individuals and to prevent confusion between the two projects, UK Biobank will not recruit participants registered with these GPs.

UK Biobank had planned to open an assessment centre in Wales but is awaiting approval to access central contact details. In addition, UK Biobank is seeking advice from the Chief Medical Officer (CMO) of Wales regarding the extent to which participants materials should be translated into Welsh if signed by the CMO. At a minimum there is a requirement that the initial invite is in Welsh. The consent and screen notes could also be translated, if necessary. The Council recommended that if the assessment centre process is not entirely in Welsh this should be stated in the invitation letter (so that there is no expectation that the whole process will be in Welsh).

By the end of 2007 UK Biobank aims to have up to 6 assessment centres running throughout the UK.

To date 5, 000 participants have been recruited through the assessment centres in Manchester and Oxford. Attendance rates of 5% and 10% have been achieved, respectively. The low response rate in Manchester was partly attributed to delays in the second "appointment confirmation" mailing to potential participants (which lead to a high 'Did not attend' rate). This has now been rectified. The Manchester and Oxford centres are currently receiving just under and just over 100 attendees per day respectively.

The average duration of an assessment centre visit is 90 minutes. Several improvements to the assessment visit have been addressed during the early months of recruitment, resulting in the introduction of a number of new aspects, including:

- Arrows will be placed around the assessment centre to indicate the flow of participants from station to station (e.g. touch screen questionnaire station, interview station, physical measurements station and blood donation station).
- Participants will be given a card showing them the sequence of the stations that they will be visiting as part of their assessment.
- Signs will be posted outside the stations, which are to be numbered in sequence, pictorially describing the procedure which will occur inside.
- A deli-style counter system is being piloted for people queuing at the same station.
- A coffee machine will be available at the end of the visit.
- A comments box will be available for participants to submit anonymous comments.

UK Biobank plans to pilot an additional station at the Manchester centre where participants will be able to seek advice about cardiovascular risk from a British Heart Foundation (BHF) nurse. Participants will be informed of this extra, optional service through a slip to be included in the initial invite. No information will be exchanged between UK Biobank and the BHF nurse directly; however, a participant may choose to share their UK Biobank feedback form with the BHF nurse. The Council recommended that UK Biobank should be extremely clear about the separateness of the BHF nurse and the UK Biobank project in order to maintain clarity over UK Biobank's policy on providing limited feedback with no interpretation.

Mr Andrew Trehearne is currently devising 'thank you' cards which will be sent to participants after their visit. Also, Dr Tim Sprosen is revising the post-visit

questionnaire which was used during the integrated pilot to elicit participants' views on the assessment centre visit and to test their understanding of the various elements of consent. The Council recommended that UK Biobank might consider including questions relating to the project's ethics and governance in its post-visit survey (in order to elicit the degree of a participant's awareness and/or concern about: e.g. how matters of confidentiality are addressed, the policy on feedback of health information and the existence and/or role of the EGC). The Thank You card and post visit questionnaire will be submitted to MREC for approval and will be brought to the Council's attention in due course.

The first meeting of the International Scientific Advisory Board will take place on 28/29 June at which the Board will be presented with the project's protocol and procedures. In addition, the Board's advice will be sought regarding UK Biobank's proposals for enhancement of the core assessment.

Update regarding recommendations from EGC11

At its last meeting the Council reviewed UK Biobank's Standard Operating Procedures for how an individual's capacity to consent is judged and how incidental findings are managed. It was reported that these have now become part of UK Biobank's Standard Operating Procedures (SOP) and as such are introduced to new members of staff as part of their training. (Staff undertake a 5-day training course, role-playing and intensive monitoring.)

EGC visit to the co-ordinating centre and Manchester assessment centre

Four Council members and the Secretary visited the co-ordinating centre and the Manchester assessment centre on the 11 June 2007. The visits were a valuable opportunity to see the facilities and operations first hand. The Council appreciates the time that UK Biobank staff dedicated to the visits.

UK Biobank aims to recruit as many assessment centre attendees as possible, including those who do not speak a sufficient level of English (e.g. to read the questionnaire) or those with a physical impairment (e.g. visual). Professor Collins confirmed that staff are trained to allow participants to be assisted through the recruitment process in these circumstances or, if the staff member is in doubt about the correct procedure, that they should seek advice from a senior member of staff. Professor Collins also confirmed that assistance is, and has been, provided to such individuals. During the EGC members' visit to the assessment centre, however, UK Biobank staff had given examples of individual being excluded from participation in these circumstances because they considered it inappropriate to permit a third party to assist in the process given the sensitive nature of some parts of the questionnaire.

The Council agreed that UK Biobank's policies need to be in accordance across all assessment centres and that audit procedures should be in place to ensure that SOPs are being consistently followed. Professor Collins confirmed that staff are trained to record the reason why an attendee is excluded from participation. This information can be used by the centre manager to assess if an employee is an outlier with respect to whether or not a participant completes his/her visit (in comparison to other employees). Professor Collins also commented that a record

could be kept of cases where special assistance is provided in order for an attendee to complete recruitment.

The Council agreed to request from UK Biobank, in time for its next meeting¹:

- information on the monitoring system for potential participants who are unable to participate due to a lack of capacity (mental or physical) or an inability to speak a sufficient level of English (i.e. what is monitored, and how?).
- a report on the number of potential participants, for each assessment centre, who were excluded from participation due to incapacity (mental or physical) or an inability to speak a sufficient level of English. The report should also indicate the reason(s) for which the potential participants were excluded.
- a report on the number of participants, for each assessment centre, who were assisted through the assessment centre process because they lacked either the physical capacity or were unable to speak a sufficient level of English. The report should also indicate the reason(s) why this assistance was necessary.

UK Biobank's access and intellectual property policy (13 May 2007)

UK Biobank's access and intellectual property ('A&IP') policy has been revised by Professor Collins in light of comments received by the EGC A&IP subgroup and UK Biobank's Funders.

The May 2007 draft policy incorporates all the principles raised by the EGC A&IP subgroup and was considered by the Council to be an improvement on the previous draft. Some areas remain quite broad, however, and may be open to interpretation. The Council therefore recommended further development of the policy to incorporate a greater level of detail. UK Biobank was requested to provide the Council with a time line and program of work regarding the development of the A&IP policy (including information on the content of the access agreement and the constitution and remit of both the access committee and ad hoc review groups) in time for the next Council meeting.

ACTION: The Secretary will request from UK Biobank a time line and paper describing the program of work regarding the development of the A&IP policy. [AH]

During the course of the discussion the Council recommended that:

- UK Biobank should seek advice from a lawyer regarding the re-drafted policy, in particular the section on patenting.
- The policy could be less jargonistic and may benefit from the inclusion of a glossary.

¹ Post meeting note: The next Council meeting will take place on 1 November 2007.

- The next draft policy would benefit from being explicit about the need for flexibility in and possible exceptions to the standard access agreement. The Council agreed to provide Professor Collins with proposed text in this regard.
- The decisions of the Access Committee could be reported publicly to promote openness and transparency.
- The January 2005 draft A&IP policy suggests a strategy for access to the resource based on privacy considerations. The policy defines three levels of sensitivity of data and samples, applications for access to which are managed through increasingly stringent processes (reflecting the increasing sensitivity of data). The May draft 2007 policy suggests a strategy for access based on the scientific concern of the depleteability of the resource. The merits of each strategy were discussed and the Council recommended that the strategy for access could depend on whether the concerns are scientific in nature (e.g. depletion of the resource), or ethical in nature (e.g. increased risk to participants' privacy). The process of access will differ according to which concern is raised. For example, where the concern is purely scientific in nature it could be considered by the Access Committee only, and simply reported to the Council. Where the concern is also ethical in nature the Council's advice could be sought prior to an access decision being made. The Council agreed to provide Professor Collins with proposed text to be considered for inclusion in the next draft of the policy.

ACTION: The Council will provide UK Biobank with a proposed wording for the two points above. [AH]

EGC public meeting (11 June 2007)

Professor Collins attended and presented at the Council's public meeting on 11 June 2007. The Council acknowledged and appreciated his attendance. Data security was raised by attendees as an area of concern. Professor Collins commented that information relating to the security of data is currently available in the participant information leaflet. The Council recommended that UK Biobank might supply further information about data security on its website (e.g. on its FAQs page) to allow actual or potential participants or other groups to understand the high levels of security which are deployed, for example in a diagrammatical representation.

A question had also been raised about the perceived one-sided nature of the contract between UK Biobank and a participant. Professor Collins commented that the participant information leaflet, and the commitments therein, also form part of the contract and that this fact could be made more explicit to participants.

The 'No further use' option of withdrawal from UK Biobank

The ability to withdraw from participation is an important aspect of consent and is intimately linked with the broad nature of consent employed by UK Biobank. Three options for withdrawal are offered by UK Biobank. The 'No further use' option states that UK Biobank will "destroy all of your information and samples collected previously (although it may not be possible to trace all distributed sample remnants). Only your

signed consent and withdrawal would be kept as a record of your wishes. Such a withdrawal would prevent information about you from contributing to further analyses, but it would not be possible to remove your data from analyses that had already been done.”

It has come to light that it is not possible for UK Biobank to destroy all of a participant’s data due to the project’s back-up and audit system. Professor Collins described the problem to the Council and sought its advice regarding how to address this situation. Professor Collins confirmed that UK Biobank can still guarantee the main principle behind this option i.e. that there will be no further use of the data by researchers.

The Council agreed that the participant information leaflet (PIL) and the Ethics and Governance Framework (EGF) are both now incorrect as currently phrased and that this situation cannot stand. The Council agreed to ask UK Biobank to provide the Council with a briefing note describing in more detail the technical problem surrounding the withdrawal of data from the resource (i.e. why this is not possible).

ACTION: The Chair and Secretary will articulate the Council’s recommendations to Professor Collins after the meeting (including the need to make this amendment to the EGF and PIL public). [GTL and AH]

5. UK Biobank’s communications strategy

Mr Andrew Trehearne, UK Biobank’s new Head of Communications, presented the project’s communication strategy. The strategy aims to develop and protect UK Biobank’s good name and public image (and, by extension, that of its Funders and other organisations with which it works). It does this in order to:

- Assist in the recruitment and retention of participants.
- Help ensure staff and participant loyalty to the project.
- Support the various other activities and goals of the funding bodies and host and participating universities.
- Ensure that post recruitment the project is able to deliver its aims of providing information that will improve the lives of future generations.

The four main strands of the strategy are:

- *Raising awareness of UK Biobank through:*
 - Local and regional media activities (including print, radio and television). In dealing with the press UK Biobank aims to be transparent, consistent and available.
 - Advertising, for example, on local buses, trains or in magazines.
 - Community activities, including through business, libraries and community leaders or groups.
 - UK Biobank’s website.
 - Collaboration with funding bodies, research partners and supporters.

- *Preparing for/ countering negative publicity.*
- *Interacting with stakeholders.* Key stakeholders have been identified as UK Biobank's Funders; other would-be funders and supporters e.g. charities; other research projects e.g. Generation Scotland; researchers and other health professionals and participants.
- *A web presence.* UK Biobank's website has been redesigned with the aim of making it more simple and more accessible to participants. Participants are able to use the site to confirm their appointment, find answers to questions and submit feedback to UK Biobank. The website also lists individuals from the scientific and medical research community that back the project.

It was agreed that it may be advantageous for the Council and UK Biobank to dovetail some communications activities. For example, if UK Biobank sends a news bulletin to participants this may include a section about the EGC's activities. Conversely, UK Biobank has been involved in the EGC's public meetings and has offered to distribute invites to future events to participants on the EGC's behalf. The Council should remain mindful however, not to create a perception that it lacks independence from UK Biobank.

UK Biobank is investigating the possibility of acquiring celebrity endorsement, to appear on the project's website and to be included in advertising materials. Mr Trehearne requested the Council to send him names of individuals who might be interested in endorsing the project and who present the right image (e.g. drawing on the 'health' aspect of UK Biobank).

ACTION: Mr Trehearne will provide Professor Laurie with UK Biobank's letter requesting an individual to endorse the project, to be distributed as Professor Laurie sees fit.

6. EGC communications activities

EGC public meeting (11 June 2007)

The Council considered the meeting to have been a success although some members considered the attendance rate low. Attendees questions were incisive and one member commented, well handled. The meeting highlighted the difficulty of articulating the separation of roles between the EGC and UK Biobank. For example, reflecting the fact that it would not be appropriate for the EGC to speak on behalf of UK Biobank Professor Graeme Laurie, as Chair of the meeting, had allocated questions to either himself or to Professor Collins, as appropriate. One attendee commented that this action created the appearance that the Chair was 'passing the buck' to UK Biobank. It was suggested that the Council could use an independent Chair for future public meetings to add balance to this situation. It was also suggested that different formats could be investigated.

The Council agreed to hold an evening public meeting in Oxford in December 2007².

² Post meeting note: This meeting will be held in the evening of 3 December 2007.

ACTION: The Secretary will organise the public meeting. [AH]

Subgroup work: Development of the EGC's communications strategy

The EGC communications subgroup met for the first time on 13 March 2007. The subgroup discussed the values of the Council and the development of a communication strategy (including the aims, key audiences and methods which the Council might employ as part of the strategy). The Council discussed the notes from the meeting and made a few recommendations for additions to the list of values and key audiences.

ACTION: The Council agreed to request that UK Biobank include the EGC website details on its thank you cards to participants (as a method of raising awareness about the EGC among participants). [AH]

7. Report on meetings attended

Royal Statistical Society (14/03/07)

Ms Hilary Newiss attended and presented at a meeting organised by the Royal Statistical Society as part of the National Science & Engineering Week activities. The meeting focused on UK Biobank and Ms Newiss presented a talk entitled 'Ethics and Governance of UK Biobank'. Subsequent questions related to data security and the possibility of police access to the resource.

EGC Chair and Vice Chairs' meeting (23/04/07)

Professor Laurie reported on a number of matters discussed at the Chair and Vice Chairs' meeting, including:

- Research commissions. Throughout the year members have suggested a variety of research topics which the EGC might commission. The Chair and Vice Chairs considered and categorised the proposals according to the current and future needs of the Council. Mindful that two commissioned projects are currently ongoing, the Chair and Vice Chairs decided not to pursue any further commissions at this point in time. The following was, however, noted:
 - A comparative study of safeguards in other biobanks with respect to data management and security was previously proposed by a Council member. The Chair and Vice Chairs suggested that this topic could be pursued through participation in the Public Population Project on Genomics initiative. It was also suggested that the EGC should seek an update from UK Biobank regarding its IT and data management strategy.

ACTION: The Secretary will invite UK Biobank to present its IT and data management strategy, with a focus on data security, at the next Council meeting. [AH]

- A project has been previously proposed to investigate how different benefit sharing models do and/or could work in practice (i.e. considering the specifics of different models rather than a theoretical discussion paper). It was agreed that this piece of work could be of value to the EGC in the future but should not be undertaken immediately.
- A projects has been previously suggested to address the questions: What ethical issues are the public concerned about? Do these concerns differ across different ethnic groups? What are the opinions of different faith groups on the use of data and samples held by UK Biobank? While it was agreed that this piece of work could be of value to the EGC, it was recognised that further information regarding UK Biobank's strategy for recruiting ethnic groups is required before the EGC decides to pursue this subject.

ACTION: The Secretary will ask UK Biobank to supply a list of numbers of participants categorized by their stated ethnicity (to be presented at the next Council meeting). [AH]

- The EGC's recruitment and re-appointment process (see agenda item 8).
- The EGC's website.

ACTION: The Secretary will develop EGC FAQs and/or opinion pieces to post on the website. In addition the Secretary will review and, where appropriate, seek to revise the website content and design. [AH]

Public Population Project on Genomics (P3G) meeting (19 and 20/05/07)

The Secretary recently attended a P3G meeting as a member of the Ethics, Governance and Public Participation Working Group. The Group discussed the core elements of a generic participant information leaflet with the aim of producing a template leaflet for future studies.

8. Recruitment process: proposal for 1 year extension

EGC members wishing to serve a second term are currently required to make a full application in open competition and, if short-listed, attend for interview. The Council considered a proposal from the Chair and Vice Chairs to allow a one year extension for members wishing to serve a further term. Any change to the current process would require approval from the Council's Funders.

Recruitment to the Council is conducted through a process in keeping with the Nolan Principle of Public Life. The Council referred to the Commission for Public

Appointments rules for re-appointment and agreed to propose to the Funders that members may apply for a second term of 3 years (i.e. re-appointment not extension), subject to an appraisal process, without open competition. Re-appointment would be subject to the strategic needs of the Council (i.e. a member with a successful appraisal might not be re-appointed if a particular skill or knowledge set is required for the Council but not represented by the member seeking re-appointment).

ACTION: The Secretary will draft a recruitment and re-appointment process and submit this to the Funders for approval. [AH]

9. Any other business

No other business was raised.

10. Date of next meeting

The 24 September 2007 meeting has been cancelled. Members have been advised of alternative meeting dates and were asked to provide the Secretary with their availability.

The 2008 meeting dates were confirmed: 17 March, 9 June, 15 September, 8 December.