

**Summary of decisions and recommendations from
the Twelfth Meeting of the UK Biobank Ethics and Governance Council
(11 June 2007)**

1. The Council approved the circulated minutes of its eleventh meeting.
2. The Council agreed that actions should not be accredited to specific individuals in the summary of decisions and recommendations document.
3. The Council agreed to remove the question relating to follow-up of participants from the 'tracking of requests to UK Biobank' document as this subject is being actively addressed by UK Biobank.
4. 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'.
5. The Council agreed that UK Biobank's recruitment 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 (e.g. SOPs relating to recruitment of 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)).
The Council agreed to request from UK Biobank, in time for its next meeting:
 - 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.
6. The Council agreed to request from UK Biobank, in time for its next meeting, a list of numbers of participants categorised by their stated ethnicity.
7. The Council agreed to request from UK Biobank, in time for its next meeting, a time line and program of work regarding the development of the draft access and intellectual property 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).
8. 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)." 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 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 and the Ethics and Governance Framework 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).

9. The Council held a public meeting in June 2007 at which attendees expressed comments and concerns about data security. The Council agreed to invite UK Biobank to present its IT and data management strategy, with a focus on data security, at the next Council meeting.
10. The Council agreed to hold an evening public meeting in Oxford in December 2007.
11. UK Biobank is developing thank you cards for participants. The Council agreed to request that UK Biobank include the EGC website details on its thank you cards (as a method of raising awareness about the EGC among participants).
12. The Secretary will develop FAQs and/or opinion pieces to post on the Council's website. In addition the Secretary will review and, where appropriate, seek to revise the EGC website content and design.
13. 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 agreed to propose to its Funders that members may be considered for renewal, subject to an appraisal, without open competition. The Secretary will draft an EGC recruitment and re-appointment process and submit this to the Funders for approval.
14. The 24 September 2007 Council meeting has been cancelled. The Secretary will identify a new meeting date.
15. The 2008 meeting dates were confirmed: 17 March, 9 June, 15 September, 8 December.

Recommendations to UK Biobank

16. UK Biobank's draft access and intellectual property policy (May 2007) was considered by the Council to be an improvement on the previous draft. The Council recommended further development of the policy including 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.
 - 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.

17. Recruitment:

- 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. The Council recommended that if the assessment centre process is not entirely in Welsh this should be stated in the invitation letter.
- UK Biobanks 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. UK Biobank should be extremely clear when communicating to participants the separateness of the BHF nurse and the UK Biobank project. (e.g. this should be presented as an option, separate to recruitment to UK Biobank, when people are initially invited. Further, staff at the assessment centre could re-iterate the point that visiting the BHF nurse is an additional opportunity and not part of UK Biobank.)

18. UK Biobank might consider including questions relating to the ethics and governance of the project in its post-visit survey (in order to elicit the degree of a participants' awareness and/or concern about e.g. confidentiality, feedback policy, existence/role of the EGC).

19. UK Biobank might supply further information about data security on its website to allow actual or potential participants or other groups to understand the high levels of security which are deployed by UK Biobank, for example a diagrammatical representation.