

**Summary of decisions and recommendations from  
the Nineteenth Meeting of the UK Biobank Ethics and Governance Council  
(8 June 2009)**

1. The Council approved the circulated minutes and the summary of decisions and recommendations of its eighteenth meeting.
2. At a recent meeting the EGC Communications subgroup re-affirmed the Council's communications strategy with minor changes. The subgroup reviewed the history, purpose and format of the Council's public meetings and agreed that public meetings should take place in locations where UK Biobank is actively recruiting. The subgroup recommended to Council that the March 2010 public meeting should be held in Sheffield with a focus on issues around access to the resource.
3. At its last meeting the Council agreed to undertake an equality and diversity impact assessment (EDIA) of its activities. Members considered and endorsed a draft EDIA policy and tool which were prepared by the Secretary (with one minor change). The Council agreed to undertake three initial assessments; its published material, its public meetings and the process by which members are recruited. Ms Tracey Phillips and the Chair will assist the Secretary in undertaking the assessments and all assessments will be circulated to the full Council. [AH, TP, GL]
4. In their review letter of 12<sup>th</sup> November 2008, the funders acknowledged that the Council had developed and implemented a strong public engagement programme within the UK while noting that 'for the future, it will be important for the EGC to consider which mechanisms of engagement and communication with the public are best undertaken by the EGC, which by Biobank directly and which by the funders'. The Council discussed a proposal to host a workshop which aims to address this issue through a series of expert testimonies from practitioners who have worked with certain methods of public involvement (including participant panels or one-off deliberative democracy exercises) and academics who have proposed certain models in theoretical terms. The Council agreed to hold the workshop (with minor changes to the proposal) and to investigate dates in December 2009. [AH]
5. The Council noted the external enquiries received by the Council since its last meeting. In particular, the Council discussed a recent enquiry which sought clarification regarding the EGC's opinion on whether or not 'consent to participate in UK Biobank' might reasonably be thought to include the creation of human or human admixed embryos from participants' samples. In summary, the creation of human and human admixed embryos was not considered by the Council to be clearly ruled out in the broad consent model. The Council is not in favour of making a categorical statement regarding a hypothetical use of the resource which is currently unforeseen. The Council expects to monitor the types of research proposals that arise and to make recommendations while reflecting on the prevailing ethical, legal and social context and the public interest.<sup>1</sup>

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<sup>1</sup> For a more detailed description of this discussion please see the full minute of this meeting ('EGC19 agenda and report' available at [www.egcukbiobank.org.uk/meetingsandreports](http://www.egcukbiobank.org.uk/meetingsandreports)).

## Recommendations and requests to UK Biobank

### 6. *Proposal for enhanced phenotyping of participants*

Members re-iterated the main recommendations from the last Council meeting including, overarchingly, the need for a consistent policy for the full suite of proposed enhancements in terms of the way in which incidental findings will be managed and which measures will be routinely fed back to participants (e.g. as with the routine reporting of blood pressure at the end of the current baseline assessment visit).

Further, the Council recommends that:

- it will be important for UK Biobank to create a communication loop back from the radiologist to the radiographer as part of an education process which should, over time, assist the radiographers in becoming more experienced at identifying potentially significant incidental findings.
- appropriate training is provided for those undertaking the scans to enable them to deal sensitively with participants (while noting that it is not the responsibility of the individual who takes the scan to provide feedback to the participant).
- UK Biobank gives full consideration to the position of the GP in the feedback process (including how information is fed back to GPs and how a GP might address the finding with the participant). A 'buddy system' might be appropriate whereby specific UK Biobank staff (e.g. the radiologists) have responsibility for communicating with GPs. The Council noted the enhancement Review Committee's recommendation that UK Biobank will need to model the predicted numbers of incidental findings arising from MRI scans in order to evaluate the cost implication to the NHS of clinical follow-up.
- UK Biobank would be advised to keep alert to the language being used regarding the re-assessment visits and how this might – or might not – be understood by participants. For example, the term 'false positive' is open to interpretation even within the scientific community and may not be readily understood by participants. The Council recommends that UK Biobank uses non-technical language. UK Biobank might also give consideration as to whether or not it should continue to call the imaging visit a 're-assessment' as this might wrongly imply that participants are being invited to a repeat of their initial baseline assessment (rather than undergoing new measurements).

### 7. *UK Biobank information systems*

The EGC Information Security subgroup recently requested information from UK Biobank regarding the nature of its relationship with the Clinical Trial Service Unit (CTSU) and regarding the steps taken by UK Biobank to assure itself that CTSU meets the project's own security standards (specifically, compliance with ISO 27001). This issue was discussed along with the UK Biobank Board's recent decision that the development of the database (which will eventually contain participants' assessment and follow-up information) and the associated user interfaces will be outsourced to academic collaborators through a tendering process which is expected to complete in the last quarter of 2009.

The Council agreed to address the following points to UK Biobank:

- The Council endorsed UK Biobank's proposal to commission an independent external audit of CTSU's security provisions. The Council would welcome further information regarding the scope of the audit and which person/organisation will be commissioned to undertake the audit process.
- In relation to the outsourcing of the database, the Council endorsed UK Biobank's plan to have an independent audit of the IT security systems of the tenders and that an IT security expert will sit on the Commissioning Panel. The Council requests further information regarding which procedures are/will be put into place in order to ensure appropriate data security during the transition phase from having an in-house IT team to outsourcing the database development. In addition, what procedures will be employed to ensure appropriate security during the downstream administration of the database? When will it be possible to answer the question of whether data will be held externally to UK Biobank (i.e. if UK Biobank decides that it would be an advantage for the database developer to also maintain the database) and what are the implications of this?
- How will the development of the database and user interface affect the timetable for access?
- Could UK Biobank clarify the nature of the relationships, in the medium and long term, between it and CTSU and between it and the external database developer. For example, will CTSU increasingly become a provider of services only?
- Given the role of CTSU in handling the participant invitation process and the proposed outsourcing of the database (including the uncertainty as to whether or not the management and maintenance of the database will also be outsourced), could UK Biobank clarify the scope of the ISO 27001 accreditation that it hopes to receive in September 2009, including the operations that are covered by the accreditation? Is this move to outsourcing likely to prejudice in any way the process for attaining ISO 27001 accreditation?

#### 8. *UK Biobank's access and IP procedures*

The Council reflected on its recent Cardiff public meeting and a concern amongst some attendees that international researchers might have access to UK Biobank. This topic is addressed explicitly in the participant information leaflet and a strong scientific case can be made for such access (including the ability to compare different populations). However, despite the apparent clarity in the information leaflet and consent material the Council considered that the reasons for concern might need to be teased out in more detail (e.g. to ascertain whether or not there is an underlying perception of a privacy risk for data used outside of the UK).

The EGC Access and IP (AIP) subgroup recently provided UK Biobank with a document which describes the 'Top 6' issues which the subgroup considers require immediate further investigation during the development of UK Biobank's AIP procedures. The Council agreed that it would be most helpful to UK Biobank and to the Council itself if it could receive a paper for its 7<sup>th</sup> September meeting that describes UK Biobank's proposed approach with respect to the 'Top 6' issues (including the proposed role of the EGC in the access process).

The Council recommended that Mr Andrew Trehearne (UK Biobank's Head of Communications) might usefully develop a method of consultation through which participants' views on the draft AIP procedures can be garnered with suitable attention to the limits of scale. It was considered advisable to factor in a stage of education prior to the consultation phase in order to promote informed views.

The Council plans to hold a public meeting on 15<sup>th</sup> March 2010 in Sheffield and proposes that UK Biobank's access provisions provide a focus for the meeting. Given this, the Council hopes that the current timetable for the development of the draft procedures by September 2009 will be maintained so that the materials can be used to inform its public discussion.

The Council noted in the feedback on the enhancement proposal that the funders encouraged UK Biobank to develop its AIP procedures "as a matter of urgency" and re-iterated that it is very happy to work with UK Biobank to ensure that the timetable is met and that a robust instrument is made available for wider consultation.

9. *Equality and diversity*

The Council was encouraged to learn about UK Biobank's progress with respect to equality and diversity impact assessments and that assessment centre staff are being surveyed for their views on how to improve the assessment process. An additional consideration arose for the Council as a result of this staff feedback: are the assessment centres compliant with the Disability Discrimination Act? The Council recommended a review of UK Biobank's operations in light of this Act, including the set-up of the proposed mobile assessment unit.

10. *Biannual report on complaints and enquiries*

The report indicated that there had been a rise in the small number of withdrawals (a total of 411 for all three options of withdrawal in the current reporting period in comparison to 193 in the previous six months). The Council and Professor Collins discussed whether or not there were geographic or other trends in relation to the withdrawals. Professor Collins confirmed that UK Biobank keeps a record of withdrawals and of people who have made enquiries or expressed concerns (e.g. regarding feedback of results or commercialisation), but that the project does not routinely link the two sets of information. The Council recommended that UK Biobank cross-reference these data sets to help shed light on the recent apparent increase in withdrawals.

The Council noted that the current biannual report does not contain reference to the Miscellaneous category of enquiries and complaints (which was a substantial category in previous reports). Professor Collins offered to seek clarification from Dr Tim Sprosen as to whether or not any enquiries and complaints should have been reported in this category.

11. *Post-visit survey*

At a previous meeting the Council strongly recommended that UK Biobank pursue the idea of a systematic post-visit survey to investigate participants' understanding and expectation of UK Biobank and their continuing involvement in the project. The Council has previously supplied UK Biobank with a proposed

structure and questions for the survey. Professor Collins advised that Dr Sprosen is now developing the survey which will focus on the issue of participants' understandings of consent. The Council agreed to re-send the EGC's detailed survey structure and questions to Professor Collins in order to re-iterate its earlier recommendation.

Professor Collins offered to give the Council sight of the new, draft post-visit survey before the end of July 2009 and prior to the survey being adopted and used.

12. *Ethics and Governance Framework (EGF)*

The Council recommends that UK Biobank make the necessary revisions to the EGF in time to reflect the introduction of the enhancement measures and development of the access procedures.