

**Summary of decisions and recommendations from  
the Seventeenth Meeting of the UK Biobank Ethics and Governance Council  
(8 December 2008)**

1. Four new members were welcomed by the Chair and all attendees introduced themselves. The new members are: Tracey Phillips, Business, policy and strategy consultant; Margaret Shotter, formerly Associate Director for Research Ethics at the University of British Columbia, Canada; Andrew Russell, Chief Executive of the Association for Spina Bifida and Hydrocephalus; Paolo Vineis, Chair of Environmental Epidemiology at Imperial College London (in absentia).
2. The Council approved the circulated minutes and the summary of decisions and recommendations of its sixteenth meeting.
3. The paper 'Advising on the public interest and the public good' summarises the findings of the EGC commissioned reports in the context of their application to its activities. The Council discussed a version of the paper which had been updated with information from the recently commissioned public attitude study. The paper will be revised to take account of members' comments and will be included in papers for the next Council meeting. An approved version of the paper will then be published on the Council's website. [AH]
4. The Wellcome Trust and Medical Research Council ('the Funders') recently reviewed the Council resulting in further funding being confirmed until September 2010 and in a letter containing a number of recommendations. The Funders recommended that the Council should obtain additional expertise in the area of bioinformatics and IT. The Council discussed a number of strategies by which this could be achieved and agreed to establish a new subgroup to examine the area in more detail. At the Funders' request an EGC workplan for 2009 – 2010 will be developed and submitted to them by 12 January 2009. [AH]
5. The Council received a presentation from Professor Ruth Chadwick, Distinguished Research Professor in Bioethics at Cardiff University and Director of the ESRC Centre for Economic and Social Aspects of Genomics. Her talk addressed questions around how the concepts of the public interest and public good might be interpreted and used in the context of biobanks.
6. The EGC communications subgroup has agreed to investigate the possibility of participating in the 2009 Manchester Science Festival. [AH]
7. Members noted that the total spend on EGC operations in 2007/2008 was approximately £156,925 (82% of the budget). This figure includes the cost of the commissioned public attitude survey at £56,248.
8. EGC subgroups. It was agreed that:
  - Ms Margaret Shotter will join Professor Graeme Laurie and Dr Heather Widdows on the EGC's access and intellectual property subgroup
  - Ms Tracey Phillips, Professor Ian Hughes and Dr Roger Moore will serve on the IT/Security subgroup. A meeting will be arranged at which the subgroup will consider its remit and workplan. [AH]
9. Professor Anneke Lucassen resigned from the Council with effect from March 2009. The Chair thanked Professor Lucassen for her contribution to the Council and wished her well for the future.

## **Recommendations and requests to UK Biobank**

### *10. UK Biobank's roll-out timetable for assessment centres*

The Council reviewed UK Biobank's roll-out timetable and noted that the project does not plan to recruit in Northern Ireland. Dr Sprosen explained that UK Biobank relies on collaborations with local researchers who are willing to take an active role in the local recruitment process. While UK Biobank has been in contact with researchers in Northern Ireland, no collaborator has been identified. The Council recommended that UK Biobank might re-assess the possibility of finding a local collaborator, and opening an assessment centre, in Northern Ireland.

### *11. UK Biobank's access and intellectual property (AIP) procedures*

UK Biobank is consulting with a number of experts with a view to producing draft AIP procedures, ancillary documentation and a draft Material Transfer Agreement in the latter part of 2009.

The Council considers that the development of the AIP procedures represents a significant quantity of work which will inevitably require consideration of a number of ethical issues. A number of these issues have been highlighted by the Council in a list of questions sent to UK Biobank subsequent to the last Council meeting. The Council strongly recommended that UK Biobank dedicate sufficient time to the task of developing the procedures in advance of the completion of recruitment in Summer 2010. The EGC's AIP subgroup offered to meet with Mr Sellors to discuss the Council's list of questions and to offer advice on the procedures. A meeting will be arranged between Mr Sellors and the EGC's AIP subgroup in January 2009. [AH]

### *12. UK Biobank's proposals for longitudinal follow up of participants*

The Council pointed to a discrepancy between the EGF and the participant materials which state, respectively, that UK Biobank will seek access to 'health-relevant' and 'health-related' records. The Council recommended that UK Biobank amends the materials so that they are consistent. UK Biobank would be advised to give full consideration to which phrase to adopt as there may be consequences over the difference in interpretation of the two phrases.

### *13. UK Biobank's post-visit participant questionnaire*

The Council reviewed the final results of UK Biobank's post-visit survey which involved a total of 298 participants from three different assessment centres (Stockport, Leeds and Newcastle). While informative for its purpose, the Council considered the results of the current post-visit survey to provide limited depth and therefore re-iterated a previous recommendation that UK Biobank might now move to conduct a more robust, discursive survey of participants' understandings and expectations. Dr Sprosen confirmed that UK Biobank will re-draft the previous questionnaire with a view to conducting subsequent telephone interviews with specific participants to gain greater understanding.

### *14. Biannual report on enquiries and complaints received by UK Biobank*

The Council welcomed UK Biobank's third biannual report on complaints and enquiries and was grateful that the majority of its suggested additions to the report had been incorporated. The Council re-iterated:

- a request that while the report as submitted was helpful in detailing escalated queries, it would also be helpful to have some reporting on the more standard

enquiries and complaints that are raised at the assessment centres. The Council requests some reporting of these standard enquiries and complaints in future reports (categorised, for example, by different aspects of the visit 'language problem', 'waiting times', 'staff behaviour' etc.). The Council is interested to learn how many individuals had a bad experience, how this was resolved and what was their experience. Dr Sprosen offered to analyse the comment cards from each assessment centre and to include additional information in the next report to Council.

- the point that the miscellaneous category contains a high proportion of responses. It would be helpful if this category could be reviewed on an ongoing basis to see if there are any significant subcategories that should be reported separately. This is important in assisting the Council to monitor complaints and enquiries over time.

#### *15. UK Biobank's proposal for enhanced phenotyping of participants*

The Council discussed UK Biobank's enhancement proposal with a particular focus on the category 3 enhancements (e.g. MRI) and the question of what information, if any, should be fed back to participants.<sup>1</sup>

UK Biobank's proposal is that there is a choice to be made between providing a certain level of incidental feedback and providing no feedback. There are pros and cons of both approaches and although UK Biobank management were leaning towards the no feedback option, it may be the case that both alternatives could be more extensively tested during the proposed pilot phase.

The Council felt that the first consideration should be the scientific validity of the enhancement proposals, in particular the category 3 enhancements. This review process is being conducted by UK Biobank's International Scientific Advisory Board and through the usual funding peer-review process. All further discussions, e.g. regarding UK Biobank's feedback policy, follow from the scientific validity of what is proposed.

In moving forward, UK Biobank said that it would explore the landscape for analogous situations (including those studies which incorporate MRI but do not necessarily compare to UK Biobank in scale). The Council supported this proposal and recommended that UK Biobank could also explore whether or not the Standard Operating Procedures (SOP) for handling incidental findings made during the baseline assessment visit can be adopted for the proposed category 3 measures, and if not to explain clearly why these SOPs are not analogous or applicable to the current situation.

Finally, Mr Sellors' paper states that preliminary evidence suggests that with full body MRI the false positive rate could be up around the 25% mark. The Council recommended that UK Biobank investigates whether or not there is any literature that provides an accurate, reliable percentage incidence of false positives in scanning research, in particular for brain and heart MRI, in addition to whole body MRI.

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<sup>1</sup> See the EGC15 meeting report for details of the three categories. For more detail of the discussion at this meeting see the full EGC17 meeting report. Both reports are available at [www.egcukbiobank.org.uk/meetingsandreports](http://www.egcukbiobank.org.uk/meetingsandreports)).