

**Summary of decisions and recommendations from
the Fifteenth Meeting of the UK Biobank Ethics and Governance Council
(9 June 2008)**

1. The Council approved the circulated minutes and the summary of decisions and recommendations of its fourteenth meeting subject to one clarification.
2. Vacancies for new EGC members will be posted in the Guardian on 3 September 2008. Members were asked to contact the Secretary with suggestions of how the advert might be disseminated. [All] The Secretary will investigate and compile a list of dissemination methods and will request that the advert be posted on UK Biobank's website and in its assessment centres. [AH]
3. Professor Ruth Chadwick, Distinguished Research Professor at Cardiff University and Director of CESAGen, will join the Council as a guest speaker at its December meeting. Members were asked to contact the Secretary with suggestions of further guest speakers. [All]
4. The Council reviewed the revised draft of the commissioned report 'UK Biobank: public attitudes to third party access and benefit sharing' and agreed a further and final list of specific points to feedback to Professor Webster.
5. The Council agreed to be aware of, and where appropriate seek, opportunities to present its work at external meetings and events. The Secretary will maintain a list of opportunities and will bring the list to each Council meeting for consideration. [AH] The Secretary will circulate a standard presentation and speaking notes to members for future reference. [AH]
6. The Secretary reported on two external enquiries that have recently been received by the Council concerning UK Biobank's policies. It was agreed that all enquiries received by the EGC relating to UK Biobank policy should be sent to UK Biobank for information and/or comment (including where the enquiry relates to the Council's opinion only). The Secretary will only pass the enquirer's contact details and actual email to UK Biobank with the enquirer's permission. If there is no permission the Secretary will only include an outline of their query along with the full EGC response.
7. A member informed the Council, and offered to provide details of, an academic paper by an ethicist and a sociologist in which they describe and comment on an experience of being recruited to UK Biobank.
8. Council meetings currently take place on a Monday. One member requested that an alternative day be considered in future. This change will be considered for the 2010 meeting schedule.
9. The EGC review is expected to take place in 2009. It is expected that the Funders will require from the Council, in time for the September EGC meeting, a document outlining how it has met its remit. This document will be circulated to members before being submitted to the Funders. [AH]
10. Professor Chris Wild resigned from the Council in light of his election as Director of the International Agency for Research on Cancer, the specialised cancer agency of the WHO located in Lyon, France. The Chair thanked Professor Wild for his commitment and input to the EGC

Recommendations and requests to UK Biobank

11. *UK Biobank's intellectual property and access policy.*

- The Chair and Secretary recently attended a P3G meeting at which access issues were discussed. The Chair suggested sharing a paper with UK Biobank which was prepared by Dr Jane Kaye for this meeting. The Secretary will ask Dr Kaye if the paper can be shared with UK Biobank. [AH]
- Mr Sellors has prepared a tentative timetable for the development of the access and intellectual property procedures. The Secretary will request sight of this timetable [AH]

12. *UK Biobank's IT and data management strategy.*

The Council was re-assured to read a report on the outcomes of penetration testing of the UK Biobank network at Cheadle and the Manchester assessment centre. It was recommended that information about the external testing could be made available on UK Biobank's website, thereby also providing re-assurance to participants and the public.

13. *UK Biobank's biannual report on enquiries and complaints.*

The Council welcomed UK Biobank's second biannual report on complaints and enquiries and was grateful that its earlier suggested additions to the report had been incorporated. On reviewing the report the Council congratulated UK Biobank on the low numbers of complaints and enquiries it has received. The following requests were made with respect to future reports:

- The report as submitted was helpful in detailing escalated queries but 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 requested 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 of the people who enquire or complain about an aspect of the study actually go on to participate. For example, the report cites this figure for the subject of commercial use of the resource, where 30 – 40% of those who raise this concern do not go on to participate. The Council requested that this figure is provided for all categories in the table of escalated enquiries or complaints in future reports.
- UK Biobank has received 110 requests to be withdrawn from the project during the 6-monthly reporting period and 146 in total during the first year of recruitment. The Council is interested to learn how soon during or after recruitment participants withdraw. The Council requested a breakdown listing the number of participant withdrawals set against duration of time from the assessment centre visit.
- The 'miscellaneous' category contains 151 responses (a significant proportion of the total 625 escalated complaints and enquiries). The Council asked if this category can be broken down any further. Professor Collins reported that there are generally only one or two complaints or enquiries in each subcategory of this category and this is why they are reported together. Professor Collins offered to review this category to see if there are any significant subcategories that should be reported separately and agreed to show the Council the breakdown nonetheless.
- The Council recommended the use of a participant satisfaction survey and was interested to learn that UK Biobank plans to conduct a post-visit survey, one of the aims of which will be to assess participant satisfaction. Professor

Collins also highlighted that participants are able to leave anonymous comment cards at the assessment centre. He proposed that UK Biobank could provide, and the Council agreed that it would welcome, a summary of the key messages arising through these report cards to be part of future complaints and enquiries reports.

14. *Proposals for enhanced phenotyping of participants.*

UK Biobank has developed a proposal for enhanced phenotyping of participants. Professor Collins presented the proposal, seeking the Council's view both generally and specifically on the implications of the proposal for the project's policy on the feedback of health information to participants. As a result of the subsequent discussion a framework was devised within which to consider the implications of the proposal for UK Biobank's policy on feedback. The Council proposed that UK Biobank should develop a paper on the legal and ethical implications of its enhancement proposal on the feedback policy, informed by the devised framework, to be considered by the Council at its September meeting. The Council will consider the issue further, and offered to review and provide input on UK Biobank's paper as it is developed over the summer.

Framework of considerations:

- 1) Re-affirm the basis of the original advice to UK Biobank regarding feedback.
- 2) From what is being proposed, what falls within the existing policy?
- 3) What, if anything, is ethically or legally different about what is proposed?
- 4) What is being done elsewhere (in other biobanks) and what is comparable to UK Biobank?
- 5) What, if anything, has changed?
- 6) What, if anything, should change?

In the longer term, if the proposals are funded, the Council would hope to review and provide input on certain operational aspects involved with the adoption of the new measures and questionnaires (e.g. the consent form, information leaflet, issues surrounding gender privacy etc).