

**Summary of decisions and recommendations from
the Twentieth Meeting of the UK Biobank Ethics and Governance Council
(7 September 2009)**

1. The Council approved the circulated minutes and the summary of decisions and recommendations of its nineteenth meeting.
2. The majority of invited speakers have confirmed their availability for the EGC's 8th December 2009 workshop on public involvement. Members endorsed Professor Heather Widdows' offer to sit on the discussion panel at the conclusion of the workshop.
3. The Communications subgroup will meet in November to discuss the March 2010 public meeting format and content.
4. The Secretary has undertaken three initial equality and diversity impact assessments which will be discussed with Ms Tracey Phillips and Professor Graeme Laurie: the Council's published material, its public meetings and the process by which members are recruited.
5. A decision regarding the Council's funding beyond September 2010 will be informed by a review of the EGC's activities by its funders, the Wellcome Trust and the Medical Research Council. As part of this review the Council will be required to submit a workplan for 2010 and beyond. Members reviewed the Council's progress against its current workplan and discussed future initiatives.
6. The Council agreed to write a series of papers on key ethical and governance issues as one element of its future workplan. The papers could draw together the Council's analysis and discussion on specific topics in a single place and in an accessible format. The Council agreed that, in the shorter term, it would be useful to write a paper on the use of MR imaging, potentially for publication in an academic journal (e.g. The Journal of Medical Ethics). The paper could describe the ethical issues involved and how these might be addressed (e.g. elements of consent, feedback protocol etc) rather than offer a position statement. The Council hopes that such a paper would be of value to other organisations that are addressing this issue (for example, two of the birth cohort studies are planning to pilot MR imaging studies). Dr Jonathan Hewitt, Professor Martin Richards and Professor Widdows expressed an interest in authoring the paper. Members should confirm with the Secretary if they are also interested in writing the paper.
[All]
7. A meeting of the Council's Access and Intellectual Property subgroup will be arranged to coincide with the release of the draft procedures paper to the EGC (see below). [AH, MS, HW and GL]

Recommendations and requests to UK Biobank

8. Request – UK Biobank information systems

The Council's Information Security subgroup requests a meeting with Dr Tim Peakman to be held at the Clinical Trial Service Unit (CTSU) in Oxford along with those individuals from CTSU who are responsible for the security of UK Biobank's data. The purpose of the visit is for the subgroup to refine its queries with Dr Peakman to arrive at the level of reassurance about data security that it and

participants might expect. The Council agreed that the meeting could usefully include discussion of the following:

- The governance arrangements between UK Biobank and CTSU and in particular the lines of responsibility and accountability. Specifically, the Council will request a diagram that describes the governance relationship between CTSU and UK Biobank and elaborates on the lines of accountability and responsibility (including at the level of the individual).
- The nature of the relationship (e.g. contractual) between UK Biobank and CTSU and how this relationship might change over time.
- CTSU's data processing and storage mechanisms and the related security provisions.
- The proposed audit of CTSU (including timetable, who is conducting the audit etc) and of the planned penetration testing of CTSU.

9. Request – Access and IP (AIP)

UK Biobank will meet with its funders on 24th September to discuss the project's draft AIP procedures (i.e. outline of planned content which will be expanded during future development) and will request that the procedures be released to the EGC as soon as possible (subject to any amendments required by the funders prior to distribution). The Board of Directors will also be asked by email (rather than wait until the next Board meeting, currently timetabled for December) to approve the distribution of the procedures to the EGC for initial comment in the short term.

The Council considers the AIP procedures to be fundamental to the principle of UK Biobank and its model of broad consent and that it is essential for UK Biobank to give the necessary time to the process of consultation (with the EGC and UK Biobank's other stakeholders). The Council agreed to write to the funders to ask that they look favourably on UK Biobank's request that the procedures are released to the EGC in the earliest possible timeframe.

10. Question and recommendation – Equality and diversity

- *Disability Discrimination Act* - At its last meeting the Council requested confirmation that the UK Biobank assessment centres, including the mobile unit, are compliant with the Disability Discrimination Act (DDA). Professor Rory Collins confirmed that he has passed this query to the developers of the mobile unit and offered to provide further information regarding DDA compliance of the mobile unit after the meeting.
- *UK Biobank's communication strategy*– The Council recommended that UK Biobank consider its proposed long-term communication strategy in terms of equality and diversity issues (for example making materials available in large print version and streamlining the availability of hard copy newsletters).
- *UK Biobank's web-based diet questionnaire* – The web-based questionnaire will be conducted during the initial assessment centre visit of the last 110,000 participants, before being rolled-out to the remaining approximately 390,000

participants who will be re-contacted by text and email and, if no such contact details were provided, by letter. The Council queried the accessibility of participation in UK Biobank's diet questionnaire for the re-contacted participants. A concern was expressed that the socio-economic response to the questionnaire may not be representative of the cohort as a whole as it is likely that the less wealthy cohort members may not have ready internet access. This may limit the amount of information UK Biobank receives regarding poorer diets and related health outcomes. Professor Collins proposed that UK Biobank could assess access issues by investigating the determinants of who does and does not complete the questionnaire.

11. Recommendation and request – *Post-visit survey*

UK Biobank has previously utilised a post-visit survey to investigate participants' experience of the recruitment process. Subsequent to this survey the Council had recommended that UK Biobank move to undertake a more detailed investigation of participants' understandings and expectations of their future involvement with the project. The Council reviewed a revised post-visit survey which UK Biobank intends to conduct at the last six assessment centres.

Members considered that the revised survey stands on its own terms and that it has the potential to provide useful insights regarding the participant experience. However, as drafted and presented, the Council did not think that the proposed survey responds fully to its previous recommendation. The Council had suggested that what is required is not the addition of further questions to the previous post-visit questionnaire because, although this may tell us more about the frequency of misunderstandings, it cannot tell us how or why participants come to make whatever assumptions they may have about participation in UK Biobank. Instead the Council recommended a more in-depth qualitative methodology (e.g. focus groups or interviews).

The Council noted that UK Biobank intends to conduct a number of telephone interviews as a follow-up to the revised survey and that this might provide the more nuanced approach as described above. However, no information was provided regarding the telephone interviews and so members were unable to comment further on the approach.

Professor Collins offered to provide the Council with a cover letter which sets out the context of the survey and the follow-up interviews (something that will likely be required for the project's MREC submission). The letter may address the questions raised by members during the discussion, including:

- When will the revised survey take place? (The Council has previously recommended that the survey would ideally take place some time after the assessment visit so that participants have had some time for reflection.)
- How many people will be surveyed and how many follow-up interviews will be conducted?
- How will UK Biobank choose who to contact with regards to the follow-up interview?

- How will the follow-up interviews be structured and what questions will be asked?
- How will the data from the survey and follow-up interviews be stored and used?

The Council is keen to offer advice on the structure and content of the proposed follow-up interviews as and when they might be made available.

Specific comments regarding the draft survey will be compiled by the Secretary and sent to Professor Collins and Dr Tim Sprosen. [All]

12. Request – *Meeting between Professor Collins and Professor Laurie*

The Council wished the degree of frustration amongst some members regarding the timetable for the provision of information from UK Biobank to be noted. Members are aware, and understand, that UK Biobank has competing priorities (for example the slippage in the AIP timetable for development resulting from other aspects of UK Biobank's operations having taken priority, notably the enhancements). Notwithstanding, the Council is keen to mitigate any sense of frustration, now and in the future, and to work hard at maintaining its excellent relationship with UK Biobank. To this end, the Council proposed a meeting between Professor Laurie and Professor Collins to discuss the relationship between UK Biobank and the EGC, including how this has been managed in the past and how relations and communications might be best managed in the future.

13. Request – *Assessment centre visit*

The Council requests a site visit to the Sheffield assessment centre prior to its public meeting on 15th March 2010.