

**Summary of decisions and recommendations from
the Eighteenth Meeting of the UK Biobank Ethics and Governance Council
(16 March 2009)**

1. The Chair welcomed new member Dr Jonathan Hewitt, a Consultant Geriatrician at Portsmouth NHS Trust.
2. The Council approved the circulated minutes and the summary of decisions and recommendations of its seventeenth meeting.
3. The paper 'Advising on the public interest and the public good' has been revised in light of members' comments. Members approved the document with two minor changes. The paper will be revised and published on the Council's website. [AH]
4. Two meetings of the new Information Security subgroup have taken place since the Council's last meeting including a meeting with UK Biobank colleagues at the co-ordinating centre in Cheadle to discuss the project's data security provisions. The subgroup found the meeting to be very encouraging while also agreeing to follow-up on a number of areas that require further clarification from UK Biobank (including the nature of its relationship with the Clinical Trial Service Unit).
5. The Access and IP (AIP) subgroup met with Mr Jonathan Sellors in January to discuss the development of the AIP procedures. While encouraged by the ongoing dialogue with UK Biobank, members expressed some concern over a degree of slippage from the previously advised timetable for drafting procedures and noted that it may take more time than currently anticipated. Members agreed that UK Biobank might benefit from additional resources (for example, hiring an expert consultant to provide input from an ethics and social science perspective to expedite the research and drafting process). The Council considered that it may wish to communicate its observations regarding the timetable to the Board of Directors but agreed to await the outcomes of UK Biobank's update later on in the meeting and of the AIP subgroup's meeting with Mr Sellors in March.
The Council previously compiled a list of questions that it recommends UK Biobank address during the development of its AIP procedures. The document will be posted on the EGC website as an indication of its thinking in relation to the key elements of the procedures. [AH]
6. The Communications subgroup has approached UK Biobank about the possibility of running a joint session at the Manchester Science Festival.
7. A new format was adopted for the Cardiff public meeting held on 12 February 2009. The introductory presentations were followed by small group discussions with two Council members in each group to facilitate the discussion. Feedback from attendees was very positive, although numbers for the event were lower than previous meetings and the attendees were predominantly from related disciplines rather than interested members of the public. In relation to the poor attendance, it was noted that recruitment in Cardiff ended in summer 2008 so participants could not be invited to the meeting through the assessment centre. The Council agreed that it is important to be able to target participants directly and that future meetings should be held in cities where UK Biobank is actively recruiting. In light of the new format used in Cardiff, the Council agreed to review the format of future meetings while also re-visiting the meetings' history and purpose. [AH and Communications subgroup]
8. The EGC workplan for 2009–2010 includes a proposal for a workshop on the pros and cons of seeking to achieve participant representation in biobanking

activities. Members agreed that the proposal should be developed further and brought to the next meeting for consideration. [AH]

9. The Council received presentations from expert radiologists Professor Paul Griffiths and Dr Nigel Hoggard. They spoke of their experience of working in an Academic Unit of Radiology which undertakes a combination of 'blue sky' and clinically-based research with a large number of clinical and non-clinical collaborators and where the majority of the research involves brain magnetic resonance (MR) imaging. They described the frequency with which the MR imaging results in an incidental finding and how these findings are managed within their Unit.¹
10. The Council agreed to carry out a diversity and equality impact assessment of its activities. [AH]
11. It was agreed that Mr Andrew Russell will join Professor Martin Richards and Dr Roger Moore on the EGC's Communications subgroup.
12. Ms Andrea Cook has resigned from the Council with effect from March 2009. The Chair thanked Ms Cook for her contribution to the Council and in particular for having Chaired the Communications subgroup over the previous four years. The Council wished Ms Cook well for the future.

Recommendations and requests to UK Biobank

13. Equality and diversity impact assessment

Professor Collins advised that UK Biobank has not undertaken a diversity and equality impact assessment of its recruitment process. Considering that such an assessment would assist UK Biobank in identifying the barriers and enablers to participation the Council recommended that UK Biobank should undertake an equality and diversity impact assessment of its activities. A recommendation will be drafted and the Council will provide UK Biobank with contact details of people who can help with such an assessment. [TP and AC respectively].

Subsequent to the meeting the following recommendation was made:

- a. That UK Biobank should publish a formal policy document confirming the inclusion and exclusion criteria for the project, which includes reference to the underpinning rationale, e.g. the policy should explain that the project does not seek to be statistically representative of the UK population and why.
- b. This formal policy document should identify who within the UK Biobank is responsible for equality and diversity (E&D).
- c. Notwithstanding that, for scientific reasons, the project does not seek to be statistically representative, the policy document should confirm the stance of the UK Biobank towards E&D, e.g. a commitment to ensure that all people meeting the inclusion criteria have an **equitable** opportunity to participate and the steps taken to bring this about.
- d. The Council recommends that UK Biobank should prepare and implement an Equality and Diversity Impact Assessment (E&DIA) tool. The E&DIAs should identify the barriers and enablers to participation in the project and nominate responsibility for any actions required, with timescales, to meet the UK Biobank's stated commitment to E&D.
- e. The Council recommends that UK Biobank should implement a comprehensive E&D monitoring form for participants and

¹ N Hoggard, G Darwent, D Capener, I D Wilkinson and P D Griffiths 'The high incidence and bioethics of findings on magnetic resonance brain imaging of normal volunteers for neuroscience research' Journal of Medical Ethics. 2009 35:194-199

employees/potential employees to build an accurate picture of the make-up and diversity of participants, employees and those applying for jobs.

Notes

- i. Please note the use of the word *equitable* rather than *equal*.
- ii. E&D does not only apply to Black and Minority Ethnic communities, it applies to everyone and the E&D policy should take into account race, gender, class, marital status, age, disability, sexual orientation, religion or belief).
- iii. E&D does not only apply to participants, it also applies to employees and job applicants.
- iv. An equality & diversity impact assessment is not a 'one off' activity; these assessments should be carried out for each stage of the project and encompass all activities. Whenever a proposal is made to change the project, for whatever reason, an E&DIA should be considered.

14. *UK Biobank's proposal for enhanced phenotyping of participants*²

UK Biobank recently sought legal advice which was that there may be found to be an irreducible duty of care as between the radiographer and the participant and that, as a consequence of this, a limited feedback protocol for reporting serious and modifiable incidental findings should be developed. In light of this UK Biobank will now move to develop a draft protocol by which scans would be reviewed and incidental findings considered serious and modifiable might then be reported to participants. Subject to a positive funding decision, UK Biobank plans to investigate the practicalities of the imaging visit during the second half of 2010, including how the measures will be performed and an assessment of the participants' expectations of the re-assessment visit. A pilot of the imaging re-assessment visit is planned for 2011.

The Council discussed UK Biobank's enhancement proposal broadly (i.e. including baseline and re-assessment measures) and with a particular focus on the MR imaging. The following recommendation resulted from the discussion.

Three initial points should be noted:

First, the Council recommends that UK Biobank should consider how its current policy on feedback at baseline will apply to any enhancement measurements, i.e., which measurements will be routinely relayed to participants arising from any enhancement procedure (including those measures that UK Biobank proposes to add to the baseline assessment and those measures that comprise the re-assessment visit).

Secondly, the Council recommends that UK Biobank should consider how its current policy on feedback of incidental findings will apply to any enhancement measurements (including those measures that UK Biobank proposes to add to

² See the EGC15 meeting report for details of the categories. For more detail of the discussion at this meeting see the full EGC18 meeting report. Both reports are available at www.egcukbiobank.org.uk/meetingsandreports).

the baseline assessment and those measures comprising the re-assessment visit).³

Thirdly, irrespective of whether enhancements proceed, the Council recommends that UK Biobank revisit the terms of its current SOP on incidental findings at baseline in light of the comments below.

Recommendation on Enhancements and Incidental Findings

1. The Ethics and Governance Council (EGC) would begin by re-iterating the fundamental purpose of UK Biobank which is to create a research resource for the benefit of future generations. It is not to provide a mechanism for giving participants routine health information nor to provide them with a health check. This is made perfectly clear both in the Ethics and Governance Framework and all participant information materials.
2. The EGC considers that a number of issues, detailed below, should be tested during any pilot phase for enhancements and reserves its position on whether or not any or all enhancement data should ultimately be collected, for example, because feedback proves to be unworkable and/or because no acceptable mechanism can be developed.
3. The starting premise for this recommendation with respect to a pilot phase is to ask whether UK Biobank's existing policy on feedback of incidental findings at baseline can be applied to the proposed enhancements; more specifically, the EGC would expect more detail to appear in any pilot SOPs across the range of enhancements and with respect to the following details:
 - a. Which criteria will be applied to determine the "seriousness" of any suspected underlying condition or finding, for example, will these be by reference to established clinical guidelines? If none exist, what will be used?
 - b. What role, if any, should "treatability" play in the determination of whether or not feedback should be given? It may be useful to consider the reasons why a participant may wish to receive feedback of information on a condition which is not treatable, for example, to allow the individual to prepare for the onset of disease emotionally, socially, financially etc.
 - c. To whom would feedback be given, for example, only to the individual or to the individual and his/her GP and/or to any other party?
 - d. Will UK Biobank make provision to allow for an individual's "right not to know", that is to allow a participant to refuse all feedback? Would UK Biobank allow a participant to refuse to allow feedback to be passed on to their GP while receiving it him or herself?
4. What is the overall balance of "harms", e.g., for the individual, for GPs, for the NHS, for families etc, and how do these compare with the "benefits" of conducting the enhancements in the first place?

³ With reference to the proposed MRI this document proceeds on the understanding that measurements and any procedures involving feedback of incidental findings would involve a radiographer and a radiologist (who might have a role in verifying findings and deciding on whether feedback should be given).

5. The Council strongly believes that any move to adopt enhancements and to institute SOPs for incidental findings must proceed on the basis of a sound evidence-base. This should include:

- a. Satisfactory evidence of the scientific merits of carrying out the enhancements at all;
- b. Evidence of the full range of potential harms associated with enhancements *and* of any particular feedback policy that is adopted (see above);
- c. Evidence of procedures and processes that can be satisfactorily adopted to reduce/minimise said harms;
- d. Evidence of robust mechanisms to respond to incidental findings, for example, clarity of relationships between the professional making the initial observation of potential incidental findings and the appropriate clinical specialist, clarity and acceptability of criteria for escalation within this relationship, clarity and acceptability of circumstances and format in which information will be given to an individual (and his/her GP or other party, if relevant), clarity and acceptability of the timescales involved with respect to the above;
- e. Evidence of robust information materials. Given that this will be the first experience of re-contact for many participants the information materials will need to clearly address issues such as why a particular individual has been chosen, what the new involvement may entail and what they are consenting to and clarity about such issues as the implications (or lack of them) that declining a re-assessment may have on their continued engagement with UK Biobank.

The materials might also address the possibility that incidental findings may be made (1) at the point at which the data are collected or (2) later, as a result of researchers analysing the images. The materials might indicate that the implications of any incidental finding may be uncertain (and for whom). In order to illustrate the likelihood and relevance of making an incidental finding in case (2), the materials could usefully include an indication of how the new data are likely to be used (e.g. that data will not be systematically analysed at the point of collection but will be used on a case-control basis) and the implications of this type of use (e.g. that analysis of the measurements or images will only occur many years after collection, that any incidental finding made at this stage will likely be less relevant to an individual than if the analysis had been performed at the point of collection and that any such analysis will relate only to a proportion of the whole population.).

- f. Evidence that there will be appropriate training of the professionals involved in the measurement and feedback processes, including potential issues of counselling individuals receiving feedback;
- g. The pilot should include *both* quantitative and qualitative evidence, for example, quantitative figures about the levels of incidental findings, false positives etc, as well as qualitative findings about the experiences of professionals and participants in any feedback procedures. On this last point, the Council recommends that the input of a sociologist should be sought.

6. Finally, and with respect to the design of the pilot, the Council recommends that UK Biobank be prepared to consider the full range of issues related to participation in enhancement, for example, the contents of an invitation letter, the likely impact or expectations of receiving such a letter, and the management of participants' expectations more generally. Furthermore, the pilot might be used to test differing approaches to feedback, for example, comparing (a) always involving an appropriate clinical specialist (e.g. a radiologist for MRIs), as opposed to (b) training the professional making the initial observation of potential incidental findings to escalate cases of concern to a clinical specialist (e.g. in the case of MRI the radiographers escalating cases of concern to a radiologist).