UK Biobank Ethics and Governance Council
Sixth Meeting

Confidential

Meeting at Wellcome Trust
215 Euston Road London NW1 2BE

Tuesday 29 November 2005 at 10.30am

Agenda

1. **Apologies**

2. **Minutes** of fifth meeting held on 19 September 2005

3. **Matters arising**
(i) Public meeting feedback from members
(ii) Public report of fifth meeting held on 19 September 2005
(iii) Tracking of requests to UK Biobank
(iv) 'Uniqueness of Biobanks' paper

4. **Report on meetings attended**

5. **EGC expenditure**

6. **UK Biobank integrated pilot update**
(Professor Rory Collins, Chief Executive, UK Biobank)

7. **Chairman's report**
(i) Attendance at Regional Investigators Group (UK Biobank Steering Committee)
(ii) Development of the Relationships paper
(iii) Integrated Pilot Materials

8. **Discussion of the draft Vision paper**

9. **Access to collections of data and materials for health research**

10. **Participation in biobank research resources: Risks of harm**

11. **Dates of meetings for 2006**

12. **Any other business**
(i) EGC register of disclosable interests
(ii) Future EGC consultations
(iii) EGC first year annual report to the Wellcome Trust and the Medical Research Council
(iv) Integrated pilot: Observation invitation

UK Biobank Ethics and Governance Council
Sixth Meeting

29 November 2005
Wellcome Trust, London

Summary of Meeting

Matters arising

Public meeting feedback from members

The Council held a public presentation and discussion on 28 November 2005 at the Royal College of Physicians, London. The Chair and Vice Chairs made presentations on behalf of the EGC. Presentations included information on the background of UK Biobank and the EGC, the EGC's work to date and the future work of the Council. After the presentations the Council invited attendees to share their thoughts concerning the EGF and the Council during a question-and-answer session.

The Council was very encouraged by the number of attendees and by the interest shown in its work and the work of UK Biobank. A number of issues were raised during the question-and-answer session including questions about the EGF position on the feedback of health information to participants; the possibility of access to the resource by commercial companies; the possibility of patenting human gene sequence and the 'power' of the EGC including the sanctions at its disposal.

Some attendees of the public meeting raised issues relating to UK Biobank's communication strategy. In particular, attendees requested more information regarding UK Biobank's protocol developments along with greater stakeholders consultation. The Council took the opportunity to raise this point with Professor Collins at the closed Council meeting.

The public meeting highlighted the need for clarity regarding the roles and responsibilities of the various parties involved with the UK Biobank project. For example, UK Biobank is responsible for the development of the Ethics and Governance Framework while the Council's role is to advise on revisions to this document.

The meeting was seen by Council members as a positive step towards future engagement activities.

Action: The Secretary will write a report of the meeting for publication on the EGC website.

EGC expenditure

The total spend on EGC operations in 2004/5 was approximately 80% of the budget equating to a spend of approximately £64,000.

UK Biobank Integrated Pilot Update

Strategy for identifying potential participants

Professor Collins presented UK Biobank's proposed strategy for the identification of potential participants. Under the proposal the UK Biobank co-ordinating centre would:

- Obtain name, title, sex, address, date of birth and possibly GP details for people aged 40-69 from the NHS Agency/Primary Care Trust (PCT) covering a particular study assessment centre.
- Process these data on behalf of the NHS Agency/PCTs, and select particular individuals for invitation (based on age, sex, deprivation index and distance from the centre) (UK Biobank acting as the data processor and the NHS Agency/PCT being the data controller under the Data Protection Act.)
- Generate letters on behalf of the NHS Agency/PCTs inviting people to attend specific appointments at the assessment centre (with repeated rounds of invitation letters sent in order to fill all appointment slots).
- Deal with telephone and mail requests to confirm, change or cancel appointments (which requires knowledge of invitees), and answer any questions about the study.

UK Biobank has sought advice on whether the proposed model for acquiring identifying information is in conformity with the Data Protection Act (DPA) and the common law duty of confidence. This advice was sought from the Office of the Information Commissioner (OIC) and the Secretariat of the Patient Information Advisory Group (PIAG).

The Council was informed that the OIC advised that the model did not cause problems in relation to the DPA. However, discussions with PIAG are ongoing while consideration is given to the question of whether the identifying data constitutes confidential patient information under Section 60 of the Health and Social Care Act 2001. If this is the case UK Biobank will be required to submit an application to PIAG for a Section 60 exemption.

While discussions are ongoing, UK Biobank has submitted a request to PIAG proposing that the methods of identifying potential participants may be carried out in a single assessment centre starting in January 2006 using limited release of contact details from the local NHS Agency (e.g. name, address, sex and year of birth; but not necessarily date of birth, NHS number or GP details). Results from this pilot would inform future revisions of the protocol, including the proposed method of identification and invitation, based on participants' feedback. The Council was asked to consider supporting this request in a letter to PIAG.

This pilot represents a significant step toward the full implementation of the UK Biobank project as a resource managed for the public good. Based on the understanding that: the relationship between data controller and processor should be a true agency relationship and that it should be clearly described in the participant information leaflet; that only limited contact details may be obtained for this pilot proposal from the local NHS Agency and that further discussions between PIAG and

UK Biobank are required; the Council agreed to endorse the proposal that the methods of identifying potential participants may be carried out in a single assessment centre starting in January 2006.

Action: The Secretary will write to PIAG explaining the Council's position with respect to UK Biobank's request.

Invitation to observe procedures at the integrated pilot assessment centre

Initial recruitment for the integrated pilot is expected to begin during the second half of March and run for two months. At the height of recruitment UK Biobank hopes to see 100/150 people per day, with the aim of recruiting 2000-3000 people in total. This will take place at one assessment centre based in Altrincham.

UK Biobank has invited members of the EGC to observe procedures at the integrated pilot assessment centre, subject to potential participant's consent. This would be a valuable exercise and provide first hand experience of how the recruitment process is managed.

Integrated Pilot Materials

The Council will shortly receive the integrated pilot materials from UK Biobank. A working group was established to discuss the Council's comments and formulate a response to UK Biobank.

Actions:

- The Secretary will circulate the integrated pilot materials to Council members.
- Council members will send comments to the Secretary by 19 December 2005.
- The Secretary will establish a suitable date for the working group meeting.

Access to collections of data and materials for health research

The Wellcome Trust and the Medical Research Council commissioned Dr Bill Lowrance, an independent consultant and formerly Chair of the Interim Advisory Group, to review the issues surrounding research access to population-based collections of data and materials that the two organisations sponsor in the UK. Dr Lowrance presented his findings to the Council, making special reference to the UK Biobank project and the EGC's role in monitoring conformity of the resource with the EGF.

Dr Lowrance described a number of negotiable terms of access agreements. He drew particular attention to the terms which the EGC, given its remit, may concern itself with, including mechanisms or criteria for screening of scientific merit; consent; purpose limitation; confidentiality; linking; recontacting; intellectual property rights; and transborder enforcement.

Dr Lowrance suggested a number of reasons for establishing oversight of collections of data and materials for health research. Such an oversight body can take a broader view than the collections' custodians; it can bring to bear a diverse set of

experiences and perspectives when providing guidance; it may be able to help resolve conflicting claims on the resource; and it can provide reassurance both to various publics and to the Funders.

Dr Lowrance concluded by listing a number of roles regarding access that, in his opinion, the EGC can serve with respect to UK Biobank, including:

- Monitoring the pattern of applications;
- Reviewing unusual applications;
- Reviewing and advising on special complaints or appeals;
- Scanning the horizon and brainstorming, to anticipate access problems, consider them, and advise UK Biobank.

Among the general access issues that the EGC may wish to consider, in the near term is the possibility of linking the core UK Biobank database to other databases. In the longer term the EGC may wish to consider the implications of access requests by researchers outside of the UK legal jurisdiction. The Council briefly discussed both of these areas and the "agreement to co-operate" that UK Biobank has recently entered into the "Biobanks for Health" at the Norwegian Institute of Public Health and the Bristol Avon Longitudinal Study of Parents and Children

Action: The Secretary will ask UK Biobank to clarify the practical significance of "agreements to co-operate" with respect to data flow and access. The Council will also ask UK Biobank to provide further information on which resources the Company is forming agreements or links with; the criteria the Company uses when deciding which projects/institutes to form agreements and links with; and the practical significance of such relationships.

The Council then discussed the role it may play in an appeals process for two different types of complaint: complaints by researchers wanting access but having difficulty getting it, and objections by participants or others about particular access issues such as purposes. Final decisions regarding access rest with the Board of Directors of UK Biobank. The Council does not anticipate that its remit will require regular involvement in the research-access complaints procedure.

The handling of complaints more generally, for example by participants, will primarily be the responsibility of the UK Biobank Company and ultimately the Board of Directors. Under the EGF the Council has a responsibility to review UK Biobank's handling of complaints to ensure that an appropriate and effective process is in place, and to monitor the pattern and themes of complaints.

Participation in biobank research resources: Risks of harm

Potential participants of UK Biobank should be informed of both the risks and benefits of participation. The Council discussed the risks of harm associated with participation in research biobanks with a particular focus on UK Biobank.

Individual risks may be difficult to define or quantify where the potential harm is linked to an individual's personal beliefs (for example, certain types of research may

be acceptable to some people but not to others). Broadly, the main risks of participation identified by members included: the taking of a blood sample; an individual being asked a question during the assessment centre visit that they are uncomfortable answering (although in the context of UK Biobank the questionnaire has been built in such a way that an individual may choose not to answer certain questions); and of a breach in confidentiality (be it an 'intentional' breach, e.g., access to data by police through a court order for criminal investigation or an 'unintentional' breach, e.g., hackers).

Members recognise that the risks to UK Biobank participants should be considered in light of the likelihood of harm occurring. Also the risks should be balanced against the overall benefit anticipated from the long-term use of UK Biobank. The Council considered the risks identified above to be minimal.

Action: Council members will review the participant materials of the Phase 2 integrated pilot in the light of this discussion.

Dates of meetings for 2006

13 March 2006 - MRC, London
12 June 2006 - London (tbc)
25 September 2006 - London (tbc)
4 December 2006 - London (tbc)

Any other business

EGC register of disclosable interests

The EGC conflicts policy states that members should confirm their disclosable interests on a yearly basis.

Action: Members will confirm their disclosable interests to the Secretary. The Disclosure Register will be revised by the Secretary on the basis of members current disclosures. A summary of the information held within the revised Register will be published on the EGC website in due course.