UK Biobank Ethics and Governance Council
Fourth Meeting

Meeting at Nowgen (The North West Genetics Knowledge Park)
29 Grafton Road Manchester M13 9WU

Monday 6 June 2005 at 10.30am

Agenda

1. **Apologies**

2. **Minutes** of third meeting held on 4 April 2005

3. **Matters arising**
   (i) External enquiries submitted to the EGC
   (ii) Draft paper on capacity to consent

4. **Chairman's introduction**

5. **Report on meetings attended**

6. **EGC Communication Working Group**
   (i) Media Policy
   (ii) Public Engagement Strategy
   (iii) Public report of third meeting held on 4 April 2005

7. **Confidentiality and UK Biobank: IT and information management**
(Mr Steve Walker, Chief Information Officer, UK Biobank and Mr Andy Harris, Systems Architect, UK Biobank)

8. **Phase I pilot progress report**
(Dr Tim Sprosen, Chief Scientific Officer, UK Biobank)
   (i) Participant feedback
   (ii) Amendments to Phase I

9. **Phase II pilot**
(Dr Tim Sprosen, Chief Scientific Officer, UK Biobank, Dr Ron Hsu, Department of Health Sciences, University of Leicester and Dr Darren Shickle, School for Health and Related Research, University of Sheffield)
   (i) Recruitment- proposed process of invitation
   (ii) Research proposal for the evaluation of UK Biobank participant materials

10. **Facilities and operations update**
(Dr Tim Peakman, Acting Chief Executive Officer, UK Biobank)

11. **Any other business**

12. **Next meeting**

UK Biobank Ethics and Governance Council
Fourth Meeting

6 June 2005
Nowgen Centre, Manchester

Summary of Meeting

Matters arising

Draft paper on capacity to consent

The law concerning the definitions of incapacity in the United Kingdom and the requirements for the inclusion of adults who lack capacity in research is not simple. For example The Adults with Incapacity (Scotland) Act 2000 and the Mental Capacity Act 2005 (England and Wales) define capacity differently. While assessing capacity may rarely be a practical problem for UK Biobank, those who seek consent will need to be familiar with the law including the consequences of finding a lack of capacity.

The EGC discussed:

- In a standard clinical environment determining an individual's capacity to consent is often the responsibility of the doctor in charge of the individual's care. In this situation the doctor will generally have direct knowledge of the individual and their medical history. During the UK Biobank recruitment process, however, the assessment centre staff will have no previous knowledge of the individual and may have limited experience of adjudicating on these issues. UK Biobank will need a protocol describing who will be responsible for judging capacity and how it will be judged.
- The fact that a participant may lose capacity during the study represents a challenge given that the law in this area is not clear. UK Biobank will need to consider the enduring nature of consent and the rights of the next of kin in light of the Mental Capacity Act 2005.

Action: The Secretary will draft a briefing note with input from certain EGC members. The briefing note will advise UK Biobank of the importance of creating a clear policy on the management of issues relating to mental incapacity and a protocol describing how capacity will be assessed. The briefing note and the EGC paper on capacity to consent will be sent to UK Biobank.

Chairman's Introduction

Professor Campbell raised with three policy issues:

- *Role of the EGC:* The EGC's role is that of an advisory and oversight body. The Council should avoid taking on responsibilities, outside of its remit, that rest with the MREC or in any way appear to function as a "pre-MREC" for the EGC by looking at incomplete or provisional drafts of documents.

- *Use of individual EGC members:* It is considered inappropriate for individual members of EGC to be asked to provide comments on draft materials or to provide individual advice to the Company as it develops its policies and protocol materials. This could lead to confusion between EGC decisions and individual members' opinions or advice.

- *UK Biobank Ethics and Governance Framework (EGF).* The main revisions to the EGF will be made when the phase 2 integrated pilot is available. The Wellcome Trust and the Medical Research Council ("the Funders") currently own the EGF. However, it is understood that UK Biobank Ltd. ("the Company") will adopt the document prior to commencement of full study recruitment.

EGC Communication Working Group

Media Policy

The policy has two main objectives; to specify the key principles guiding the EGC's media relations and to provide a clear protocol for members of the EGC if they are contacted by the media. The Chair will be the principal spokesperson for the EGC and all media enquiries should be referred to his representative, Barry Taylor of Bristol University, in the first instance.

The draft Media Policy was approved subject to a minor amendment.

Public Engagement Strategy: Meeting in public/ public meeting

The EGC is keen to develop a long term strategy for public engagement, one immediate aspect of which is to hold a meeting with the public. In the first instance this will take the form of a public meeting at which the EGC will report on its activities. The strategy will be developed according to future needs.

Actions: · The Secretary will establish a suitable date for a public meeting.
· EGC members may provide opinions to the Secretary regarding the feasibility and practicality of both 'public meetings' and 'meeting in public'.
· The Secretary will investigate the cost implications associated with both options and bring these to a future meeting.

*Public report of third meeting held on 4 April 200*5

Another aspect of the public engagement strategy is the public reporting of EGC meetings. The reports aim to be consistent with the Minutes; briefer for ease of understanding and exclude confidential information.

Confidentiality and UK Biobank: IT and information management

The current UK Biobank information management strategy is based on a one-way flow of information where storage is in a central facility to which only designated people have access (for example assessment centre staff will not have access to the central information). Data will be generated at various points in the process, for example pre-clinic (recruitment/booking), assessment clinic, laboratory data and follow up health care records. The EGC was introduced to the principles of operation and standards being applied in addition to the physical architecture.

The EGC was concerned about security against hackers and was reassured to learn that this aspect of UK Biobank will be tested in October 2005 when the Company plans to invite people to try to gain access to the system. This test will then be repeated on an annual basis.

The EGC emphasised that the language used in the participant information sheets will be key to conveying effective messages about the system.

The proposed use of electronic signatures during the consent process was seen as an efficient way to prevent a paper trail during the life of UK Biobank and may also set a norm for future research.

It was noted that personal information would not need to be removed from back-up tapes (in the event that an individual withdraws from UK Biobank) providing that participants have been clearly informed about the role of back-ups, how and when the tapes may be used and that any withdrawals would be activated if the tapes are used.

Phase 1 pilot progress report

The amendments to the Phase 1 pilot protocol include the introduction of an Electrocardiogram (ECG) measurement to the assessment visit. It was agreed that this could be problematic given the need to undress to the waist. The acceptability of the new measure will be judged by the pilot participants' feedback.

Phase 2 pilot

Recruitment: proposed process of invitation

The Regional Collaborating Centres (RCCs) will be responsible for the initial contact with the Primary Care Trusts (PCTs) and for seeking access to potential participants' data (including contact details). In turn the PCT will indicate which lists may be used as the basis for contact. The legal implications of obtaining potential participants' data were raised: An employee of the PCT will act as the data controller for the purposes of the Data Protection Act. Given that UK Biobank will not be accessing the lists themselves the Information Commissioner had confirmed to UK Biobank that acquiring the information in this way was a legitimate use under the Act. UK Biobank has also contacted the Patient Information Advisory Group (PIAG) for advice.

Research proposal for the evaluation of UK Biobank participant materials

The Patient Information Leaflet (PIL) will be evaluated according to these three aspects of the participant's experience:

- What did the participant think of the invitation letter?
- What was the participants' expectation of the assessment centre visit?
- Was there any aspect of the assessment visit that the participant had not anticipated and/or had been surprised by?

The EGC suggested that it would be valuable to compare the proposed method of evaluation with other published methods. It was also recognised that further evaluations of the main study consent materials will be required given that many contentious issues will not be present in the phase 2 integrated pilot (for example long term use of the resource). The EGC is strongly of the opinion that these areas will require careful consideration when the final protocol consent materials are written.

When writing the PIL the authors should take full account of the draft Ethics and Governance Framework with particular reference to the bullet point list in Section B1 of the draft Framework setting out elements of the consent. The materials could also be checked by the Plain English Campaign.

There is a possibility of using data from the phase 2 integrated pilot in the main study. The EGC recognised implications for the type of information received by the pilot participants. For example, when will they be informed of the possibility of joining the main study?

Facilities and operations update

Dr Tim Peakman, Acting Chief Executive Officer, UK Biobank presented an update on the facilities and operations to the EGC.

The operations are being designed in line with the published UK Biobank sample handling and storage strategy. The individual samples will be divided and stored separately at two Manchester sites. The system is being built to respect the security commitments of UK Biobank at the level of the sample. The only information on the sample tube will be a 2D barcode label. Decoding of this barcode would only be possible if an individual was able to break into the computer storage system.

The EGC briefly discussed the need for security on the site.

The possibility of samples being misfiled was raised and the EGC was reassured to learn that this has been a significant consideration for UK Biobank as they have developed their Laboratory Information Management Systems. The system has been designed to promote continuity of the data trail including, for example, there being only one interface and by minimizing human involvement.

Any other business

The scientific and ethical peer review comments of the UK Biobank draft protocol have been published on the MRC website.

Next meeting

A provisional meeting would take place on 4th July 2005 only if the integrated pilot protocol becomes available for comment, otherwise the next Council meeting would be held on 19th September 2005.

Appendix A:

Present: Professor Alastair Campbell (Chair), Ms Andrea Cook, Miss Jayam Dalal, Baroness Finlay (morning only), Ms Clara Mackay, Professor Sheila McLean, Miss Sally Smith, Professor Ian Hughes, Professor Sandy Thomas.

In attendance from EGC Secretariat: Ms Adrienne Hunt.

Observers: Dr Joan Box (Medical Research Council), Ms Jo Sumner (Wellcome Trust) and Ms Tara Camm (Wellcome Trust) for the whole meeting. Dr Shaun Griffin (Head of Communications, UK Biobank) attended for items 9 and 10 only.

Apologies: Professor Roger Higgs, Professor Chris Wild.

Speakers: Dr Tim Sprosen (Chief Scientific Officer, UK Biobank) and Dr Tim Peakman (Acting Chief Executive Officer, UK Biobank) attended for items 7 to 10 only. Mr Steve Walker (Chief Information Officer, UK Biobank) and Mr Andy Harris (Systems Architect, UK Biobank) for item 7 only. Dr Ron Hsu (Department of Health Sciences, University of Leicester) and Dr Darren Shickle (School for Health and Related Research, University of Sheffield) for items 8 and 9 only.