

UK Biobank Ethics and Governance Council Fifth Meeting

Meeting at Wellcome Trust
215 Euston Road London NW1 2BE

Monday 19 September 2005 at 10.30am

Agenda

1. **Apologies**
2. **Minutes** of fourth meeting held on 6 June 2005
3. **Matters arising**
 - (i) Public report of third and fourth meeting held on 4 April and 6 June 2005
 - (ii) Public engagement strategy
 - (iii) Email discussion list- update
 - (iv) Briefing paper on capacity to consent
4. **Report on meetings attended**
5. **Chairman's introduction**
6. **Vision Paper**
7. **Chairman's UK Biobank Update**
8. **Revised timetable and structure of UK Biobank**
(Professor Rory Collins, Chief Executive, UK Biobank)
9. **Participation in biobank research resources: Risks of harm**
10. **EGC annual report proposal**
11. **Public meeting**
12. **Next meeting**
13. **Any other business**

**UK Biobank Ethics and Governance Council
Fifth Meeting**

**19 September 2005
Wellcome Trust, London**

Summary of Meeting

Matters arising

Public engagement strategy

Several items on the meeting agenda raise issues that relate to both the public engagement and broader communications strategy. Discussions throughout the day will be used to inform the next phase of development of these strategies.

Briefing paper on capacity to consent

A briefing note and the Council paper on capacity to consent has been sent to UK Biobank. A response has been invited.

The Council re-iterated the need for UK Biobank to be mindful of the implementation of the Act in the development of its policies on mental capacity. The Council noted that although the Act does not make specific provision for advanced statements in relation to research (eg positive decisions about remaining a participant when capacity is lost), statements in Parliament during the passage of the legislation made clear that consent to research given when a person has capacity could endure his or her loss of capacity.

In this regard, the Council reminded UK Biobank of the importance of the following requirement in the EGF. The participants' consents must be based on an understanding of the intention to keep them in Biobank after they lose capacity or die.

Chairman's introduction

Policy on inviting observers to attend Council meetings

Don Chalmers, Professor of Law, Dean of Faculty of Law and Head of Law School at the University of Tasmania, was invited to join the Council as an observer for the afternoon business. The Chairman invited Professor Chalmers on his own initiative but suggested that the Council discuss the criteria he should use in issuing such invitations in the future.

It was agreed that if a member of Council has a proposal for an observer this should be submitted to the Chair in the first instance. Observers are envisaged to include, but not be limited to, academics with an interest in the field.

The Chair will consider observer requests on a case-by-case basis. It is anticipated that the EGC would accept observers on an occasional rather than a frequent basis. The Chair will be responsible for briefing observers as to the confidential nature of EGC meetings.

Vision Paper

The Wellcome Trust and the Medical Research Council ('the Funders') convened a meeting with EGC representatives at which they discussed the progress of the EGC. At this meeting it was agreed that three 'set up' documents should be developed. These were described as a Memorandum of Understanding, to be written by the Funders; a vision statement, which Professor Campbell agreed to draft for the EGC, for comment by the Funders ('Vision paper'); and a more operational description of the interface between UK Biobank, the EGC and other parties as required, to be developed in due course once the Council had become fully operational ('Relationships paper').

The Memorandum of Understanding will provide the foundation required for the Council to meet the objectives outlined in the Vision paper. The Relationships paper will describe at a systems level how these objective are delivered.

Initial discussions focussed on the development of ideas for the Vision paper. Key aspects of the EGC's remit were discussed including: the EGC's understanding of the phrase 'independent guardian'; what types of advice it would be appropriate for the Council to give and how this advice should be timed; how the EGC can fulfil its remit to monitor activities of UK Biobank that relate to the EGF and how the Council can meet its public reporting responsibilities. The Council also discussed which values should underpin the work of the EGC.

Actions: The Chair and Secretary will prepare a draft Vision paper for discussion at the November Council meeting.

Revised timetable and structure of UK Biobank

(Professor Rory Collins, Chief Executive and Principal Investigator, UK Biobank)

(Professor Don Chalmers joined the meeting as an observer for this and all subsequent items.)

Professor Collins provided an update on UK Biobank operations.

Discussion

The Council is interested in the development and the evaluation of the participant materials and is keen to review the materials and provide input within the current timetable. The materials will have to explain key elements of the projects design including, for example, that during participation there will be an ongoing link to the full medical record. (A more complete list is given in the draft EGF.) Evaluation will

be necessary to test the adequacy of these materials in terms of the participants understanding. It will be important for those writing the materials and those formulating the evaluation questions to be aware of the law in this field. Professor Collins informed the Council that the wider consortia of Regional Collaborating Centre have contacts with experience in the legal and ethical field that can be applied to the development and evaluation of the consent materials and other issues.

The Council enquired about the progress being made by the ethnic minorities subgroup and asked when consent materials for ethnic minority groups will be developed. (The ethnic minorities subgroup has completed its work to date and so has stepped-down.) UK Biobank will be focusing its immediate activities on demonstrating the feasibility of the study model. The participant materials will firstly be produced in English and be evaluated during the Integrated Pilot. Feedback from this process will inform revision of the materials. Translation will occur after this point.

The Council recommended that UK Biobank should enter into a dialogue with ethnic minority groups and be explicit about this proposed strategy for staggered recruitment. Otherwise there may be a possibility of disenfranchising them from the beginning by not giving them an equivalent priority from the start of the project.

The Council agreed that it would be helpful to have more detail on studies which incorporate similar design elements to the UK Biobank project (for example where future uses of the resource is unknown and where individuals should anticipate a level of follow-up).

Action: A paper will be prepared on other studies which incorporate similar elements to UK Biobank. This subject will be revisited at a future meeting.

Participation in biobank research resources: Risks of harm

Due to time constraints this agenda item was postponed until the next EGC meeting.

EGC annual report proposal

The Council approved the draft public annual report proposal. This document will report on EGC activities between November 2004 and December 2005 and annually thereafter. Five key sections are envisaged:

- How and why the EGC was established;
- The role of the EGC;
- Meetings in the first year;
- The way forward: challenges ahead;
- Communications.

The report will also include members biographies, full terms of reference, Memorandum of Understanding, the public register of member's interests, EGC

expenditure and a report on external activities (including press releases, articles prepared for journals, national and international meetings attended by members).

Public meeting

It was agreed that the EGC public meeting will be held on 28th November 2005 between 4-6pm at the Royal College of Physicians, 11 St Andrews Place, Regent's Park. The Chair and Vice Chairs will present on behalf of the EGC. Presentations will include information on the background of UK Biobank and the EGC, the EGC's work to date and the future work of the Council.

Action: The Secretary will investigate methods of dissemination and possible groups to whom invites will be sent.

Next meeting

The sixth meeting of Council will be held at the Wellcome Trust on the 29th November 2005.

Any other business

Individual advice by Council members

The minutes of the fourth Council meeting state that 'it would not be appropriate for individual members of Council 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, since this could lead to confusion between Council decisions and individual members' opinions or advice.'

It was questioned whether this policy may be unduly restrictive. It was clarified that when a member is asked their opinion they should be explicit about their role to avoid confusion. If the Council has expressed an opinion on the matter this can be stated. If the Council has not previously considered the matter the member should be clear that any opinion they express is their own. If appropriate, the member can then bring the matter to the Council's attention.

Appendix A:

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

In attendance from EGC Secretariat: Ms Adrienne Hunt.

Observers: Dr Joan Box (Medical Research Council) and Ms Jo Sumner (Wellcome Trust) for the whole meeting. Ms Tara Camm (Wellcome Trust) for parts of the meeting. Dr Tim Sprosen (Chief Scientific Officer, UK Biobank) for agenda item 8 only. Professor Don Chalmers (Professor of Law, Dean of Faculty of Law and Head of Law School at the University of Tasmania) for agenda items 8-11 only.

Speakers: Professor Rory Collins (Chief Executive and Principal Investigator, UK Biobank) for agenda item 8 only.