

UK Biobank Ethics and Governance Council Second Meeting

Meeting at MRC Headquarters
20 Park Crescent London W1B 1AL

Monday 14 February 2005 at 10.30am

Agenda

1. **Apologies**
2. **Minutes** of the induction and the first meeting held on 29 and 30 November 2004
3. **Matters arising**
4. **Report on meetings attended**
5. **Update on development of scientific protocols**
(Tim Sprosen, Chief Scientific Officer, UK Biobank)
 - (i) Update on submission of Phase I pilot protocol for MREC review
 - (ii) Workplan and milestones
6. **Consent to participate in UK Biobank**
7. **Provision of health information to participants**
8. **Recontact for future studies where selection is based on genotype**
(John Todd, Cambridge/UK Biobank Science Committee)
9. **Reducing barriers to participation by ethnic minorities**
(Mark Caulfield, Queen Mary/Chair, UK Biobank Ethnic Minorities Sub-group)
10. **Next meeting**
11. **Any other business**

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

14 February 2005

Medical Research Council Headquarters, London

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

In attendance from EGC Secretariat: Ms Jo Sumner, Ms Tara Camm, Ms Adrienne Hunt.

Observers: Dr Colin Blakemore (CEO, Medical Research Council), Dr Tony Woods (Head of Medical Humanities, Wellcome Trust) for first session only; Dr Joan Box (Medical Research Council), Mr Martin Sexton (Wellcome Trust) for the whole meeting.

Apologies: Professor Roger Higgs.

Speakers: Dr Tim Sprosen (Chief Scientific Officer, UK Biobank). Professor John Todd (University of Cambridge, UK). Professor Mark Caulfield (Queen Mary's School of Medicine and Dentistry, UK).

Summary of Meeting and Decisions

Minutes of the last meeting held on 29-30 November 2004

The Council approved the circulated unconfirmed minutes with the following clarification: The Council will revisit the issue of meeting in public at the 4th meeting. This will therefore occur in June 2005 rather than September 2005 given the recent addition of a meeting in Spring 2005.

Council website

A new website (www.egcukbiobank.org.uk) is currently under construction. When the site becomes active it will contain information relating to the remit, constitution, operating procedures and work of the Council.

Appointment of Vice-Chair

The Chair proposed, and the Council agreed, to the appointment of Ms Andrea Cook with effect from the 1st March 2005. The Council further agreed to appoint two Vice Chairs with a view to drawing on the breadth of knowledge and skills available on the Council. The remaining Vice-Chair position would remain vacant for the time being.

Relationships between UK Biobank, the Funders and the Council

The following arrangements were noted:

Relationship with the UK Biobank Science Committee –

- The Council will have observer status on the Science Committee.
- The Council will have a joint meeting with the Science Committee.
- The Council will have the opportunity to review all protocols prior to MREC submission.

Relationship with the UK Biobank Board of Directors –

- The Chair of the Council will receive all Board agendas and minutes.
- With agreement from the Chair of the Board, the Council Chair (or his nominee) should be able to attend Board discussions which he believes might be of direct relevance to the work of the Council.

In addition the EGC Council Chair will be invited to attend UK Biobank Board of Directors meetings every six months to review the relationship between the Council and the Board and to discuss key issues of policy and strategy which impact on the Council's term of reference.

Update on development of scientific protocol

Dr Sprosen briefly outlined the role, remit and constitution of the Science Committee and the sub-groups.

Dr Sprosen highlighted the upcoming milestones in the scientific plan of UK Biobank including the start of Phase1 pilot recruitment in March 2005. In order to inform the development phases of the scientific protocols it was agreed that the Council would be supplied with relevant documents in a timely fashion and that an extra meeting of Council would be scheduled for July to be used if required.

Consent to participate in UK Biobank

The Council had a wide-ranging discussion during which the meaning, feasibility and practicality of both broad and limited consent were discussed. The Council agreed generally with the broad consent approach.

Further clarity on the nature of risks associated with UK Biobank was sought, in particular relating to the need to ensure security of data and samples. UK Biobank was asked to provide a briefing on this.

The Council agreed on the need for transparency about the system that will be put in place for making decisions about access to the resource. For example, the consent document should state clearly that not all subsequent uses can be predicted and explain who would make decisions on access and on what basis. The Council agreed that general information should be provided on the possible types of research that it is anticipated will be undertaken. This would be for illustrative purposes and should not be construed as specific consent to those types of research. Indeed, it would be important for UK Biobank to recruit participants who understand and are comfortable with the broad ranging terms of the consent. Further, the Council briefly discussed the use of the term authorisation rather than consent (recognising the extent of the unknown factors at the point of enrolment). However, while the concept had much merit the Council agreed that it would be necessary to use terms that are familiar, including to the MREC.

The Council agreed that it would return to this issue at the June 2005 meeting once UK Biobank have issued the participant materials.

Provision of health information to participants

The Council remained firm in their view that the recruitment process for UK Biobank should not be described as a health check and that participation in UK Biobank should not be perceived as a healthcare venture.

The UK Biobank Science Committee is engaged in ongoing discussions on this subject. The Council felt that the formulation of a policy on provision of health information and the practicalities of encouraging participation should be clearly separated. The Council agreed to comment further following formulation of a policy on the provision of health information by UK Biobank.

In further discussion the Council recognised four distinct categories of information that might be fed back:

- *Baseline measurements* at enrolment (such as height, weight, blood pressure, etc)
- *Incidental additional observations* at enrolment (such as melanoma, signs of abuse)
- *Baseline analyses* before samples are stored
- *Later findings* as the results of research

The Council agreed that this issue should be considered further. A member of the Secretariat offered to explore precedents for this strategy (which is believed to have been used by the NHANES study in the US).

The Council agreed that results of later research discoveries should not be fed back to participants on an individual basis, but that UK Biobank should provide general information on findings of research using the resource as part of its strategy for

ongoing engagement with participants and the public. This position was supported by the comments submitted by the Human Genetics Commission in response to the first published version of the Ethics and Governance Framework. The Commission stated that in their view the only individual health related information that UK Biobank should consider feeding back should be that gathered from the enrolment meeting; were research derived from UK Biobank to discover that a number of participants were at risk of a particular condition, this should be reported in general feedback to all participants, and the public and medical community at large (the Commission's response is available in full from its website www.hgc.gov.uk).

The broad principle of not feeding back later research discoveries reflects the principle that UK Biobank should not be perceived as providing the individual participant with healthcare advice.

Recontact for future studies where selection is based on genotype

Professor Todd outlined the scientific rationale and structure of the recently established Cambridge BioResource. The BioResource reflects a number of governance and ethical issues raised by UK Biobank including recontact of participants on the basis of specific genotypes.

Reducing barriers to participation by ethnic minorities

Professor Caulfield presented the constitution, remit and work of the Ethnicity Recruitment Subgroup of the UK Biobank Science Committee. The subgroup was established in the light of historically poor rates of recruitment of ethnic minorities into comparable studies in the UK. The subgroup will report to the Science Committee, identifying practical issues and influencing the pilot design, for example by the inclusion of additional measures and materials.

The Council felt the work of the subgroup to be of great value and agreed to maintain close links with it.

Communications

In order to pursue various communication issues raised by the Council, it was agreed to set up a Communications Working Group. A first task will be to develop a draft Media Policy for the Council. A second task will be to develop ideas for the Council's public engagement strategy. The Working Group will report to the June 2005 meeting of Council.

Next meeting

The third meeting of the UK Biobank Ethics and Governance Council has been rescheduled to follow the rescheduled meeting of the Science Committee. It will be held on 4 April 2005.