

UK Biobank Ethics and Governance Council Induction Meeting

Meeting at Wellcome Trust
215 Euston Road London NW1 2BE

Monday 29 November 2004 at 10.30am

Agenda

1. **Introductions**
(Professor Alastair V. Campbell, EGC Chair)
2. **Role of the Ethics and Governance Council**
(Professor Campbell; Ms Jo Sumner, Wellcome Trust)
3. **Role of the Council Secretariat**
(Ms Sumner, Wellcome Trust)
4. **An introduction to UK Biobank: vision, scientific rationale, structure, and establishment**
(Professor John Newton, Chief Executive, UK Biobank; Professor John Bell, Chair UK Biobank Science Committee, Oxford University)
5. **Questions and discussion**
6. **An introduction to the Ethics and Governance Framework**
(Dr William W. Lowrance, Chair UK Biobank Interim Advisory Group on Ethics and Governance; Ms Sumner, Wellcome Trust)
7. **Principles of the Intellectual Property and Access Policy**
(Ms Camm, Wellcome Trust)
8. **Discussion**
9. **Close**

UK Biobank Ethics and Governance Council First Meeting

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215 Euston Road London NW1 2BE

Monday 30 November 2004 at 10.30am

Agenda

1. **Housekeeping arrangements and Apologies**
2. **Chair's introduction**
3. **Ethics and Governance Council policies and operating procedures**
4. **Ethics and Governance Framework – items outstanding or for clarification**
5. **Council Workplan for 2004/2005**
6. **Dates and locations for Council meetings for 2004/2005**
7. **Any Other Business**

**UK Biobank Ethics and Governance Council
Induction and First Meeting**

**29 and 30 November 2004
Wellcome Trust, London**

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

In attendance: Ms Jo Sumner (joint acting EGC Secretary), Ms Tara Camm (joint acting EGC Secretary), Dr William Lowrance (former Chair, Interim Advisory Group on Ethics and Governance).

Observers: Professor John Bell (Chair, UK Biobank Science Committee), Dr Joan Box (MRC), Ms Adrienne Hunt (EGC Secretary designate), Professor John Newton (UK Biobank CEO), Mr Martin Sexton (Wellcome Trust).

The first day was an induction session on UK Biobank and its Ethics and Governance Framework. The Council received presentations from Professor John Newton (Chief Executive Officer, UK Biobank), Professor John Bell (Chair, UK Biobank Science Committee, UK Biobank) and Dr William Lowrance (Chair, Interim Advisory Group on Ethics and Governance), and had the opportunity to raise questions and points for clarification.

The main items discussed during the meeting proper were as follows:

EGC working procedures

Council members made declarations of their interests. These have been compiled into a register and published in summary form on the EGC website.

A process was agreed for appointment to the post of Vice-Chair.

It was agreed that the Council would meet in private initially. The question of meeting in public would be revisited at the fourth meeting of the Council in June 2005.

Relationship with UK Biobank

The Council was committed to establishing effective relationships with the various parts of UK Biobank, in particular the Board of Directors and the Science Committee.

It was acknowledged that there could be tension between the Council's oversight and advisory functions, particularly in the initial development phase, with the former requiring independence and distance and the latter drawing the Council in to a closer relationship with the project. Discussion suggested that there might be

a relevant difference in how the Council related to the Board on the one hand and the Science Committee on the other. Further discussions will be held with the Board and the Science Committee.

Issues arising from the Ethics and Governance Framework (EGF)

The Council began its consideration of the EGF by looking at two issues that were of particular interest to UK Biobank:

Provision of health information to individual participants.

The Council were firm in their view that the recruitment process for UK Biobank should not be described as a 'health check'. This would obscure UK Biobank's fundamental character as a long-term research resource and could be construed as an inducement to participate.

The Council recognised nevertheless that there were various stages at which UK Biobank might obtain information of possible health relevance to individuals. These have previously been described in the draft UK Biobank Ethics and Governance Framework (EGF) as being: at enrolment, as a result of baseline analyses before samples are stored and as a result of future research.

The Council recognised that it would be impractical and inappropriate to conceal some of the measurements taken in the enrolment interview from participants (e.g. height, weight, blood pressure). This raised the question of whether the recruiters should give these data to participants and/ or whether they should offer any commentary or interpretation of them. Other problems could be anticipated in UK Biobank's target age range, such as indications of possible elder or other domestic abuse or problems such as melanoma or diabetes. Following the enrolment process itself, there were baseline measurements that could also reveal signs of disease (e.g. white blood cell counts could indicate leukaemia).

A uniform approach of not providing feedback could work in many cases, but there were bound to be difficulties as UK Biobank was aiming to include individuals with prevalent disease. Some members felt that it would be insufficient (legally and ethically) for UK Biobank simply to assert that it did not owe a duty of care by virtue of its being a research project.

The Council will advise UK Biobank on the development of a policy on what, if any, of this information could be fed back to participants.

The Council requested full details from UK Biobank of the tests and measurements that would be carried out, in order to identify those that could pose problems for its proposed policy on feedback.

Recontact of participants

The Council recognised the three main reasons why UK Biobank would need to recontact participants as described in the draft EGF:

- To collect new information or samples for inclusion in the resource.
- To seek consent to proposed new uses that have passed scientific and ethical review but do not fall within the existing consent.
- To ask participants whether they would be willing for researchers to contact them to discuss possible involvement in a study requiring new data or samples or new engagement (e.g., an interview).

A clear distinction had to be made between studies that fell within the terms of the original consent to participate in UK Biobank and which would not involve any new intervention such as collection of further data or samples (which could go ahead without further reference to the participants) and studies that required consent to a new use not falling within the original consent or to a new intervention.

The Council made a number of initial observations on these questions. If a particular use of UK Biobank is deemed to require further consent in addition to the original consent to participate, then participants will have to be given appropriate information on the new study. This consent process has the potential to reveal health-related information that participants had been led to expect would not be provided. For example, an individual may acquire new knowledge of their genotype if this is the basis for re-contact.

It was agreed that it would be difficult for the Council to make detailed prescriptions at this stage. Instead, it should give careful consideration to the consent materials drawn up by UK Biobank for the pilot phases to satisfy itself that the information being given to participants gave a fair indication of the decisions they might have to make in future. For example, UK Biobank's pilot consent form and process should deal as openly as possible with the circumstances under which participants could be re-contacted. UK Biobank would also have to develop a strategy to deal with the possibility of repeated approaches to particular participants. Finally, under UK Biobank's policy on access, any approach to participants for additional consent would require the Council's prior approval (as well as approval from a research ethics committee).

EGC workplan

The main tasks for the Council over the coming year will be:

- 1.1. To provide commentary on the protocols for the various pilot stages of UK Biobank, and the full scientific protocol;
- 1.2. To advise UK Biobank's Funders on the revision of the Ethics and Governance Framework, taking account of the scientific development of the

project and policy decisions taken since the publication of the first version of the Framework.

The Council will also begin to develop its strategy for engagement with participants and the public.

Future meetings

The next meetings of the EGC will take place on 14 February 2005, 14 March 2005¹, 6 June 2005, 19 September 2005 and 29 November 2005.

¹ The third meeting of the UK Biobank Ethics and Governance Council will now take place on 4 April 2005, not 14 March 2005.