

UK Biobank Ethics and Governance Council Third Meeting

Meeting at Wellcome Trust
215 Euston Road London NW1 2BE

Monday 4 April 2005 at 10.30am

Agenda

1. **Apologies**
2. **Minutes** of second meeting held on 14 February 2005
3. **Matters arising**
 - (i) UK Biobank CEO transition arrangements
 - (ii) Appointment of second Vice-Chair
4. **External enquiries submitted to the Ethics and Governance Council**
5. **Report on meetings attended**
6. **UK Biobank Communication Strategy**
(Shaun Griffin, Head of Communication, UK Biobank)
7. **Presentation and discussion of issues arising from the Ethics and Governance Framework and main protocol**
(Tim Sprosen, Chief Scientific Officer, UK Biobank)
 - (i) Recruitment
 - (ii) Understanding and consent
 - (iii) Confidentiality
 - (iv) Family based studies
8. **Any other business**
9. **Next meeting**

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

**4 April 2005
Wellcome Trust, London**

Summary of Meeting

Matters arising

UK Biobank CEO transition arrangements

The Council briefly discussed the CEO transition arrangements and noted that the advertisement for, and terms of appointment of, the new UK Biobank Chief Executive Officer gives recognition to the relationships with the Ethics and Governance Council (EGC).

Appointment of second Vice-Chair

Professor Higgs was appointed as second Vice-Chair with effect from the 1st April 2005.

Implications of the Freedom of Information Act 2000 for the EGC

The EGC as a whole is not subject to the Act because it is not listed as a public authority in the Act and is not a wholly owned subsidiary of a public authority. Some members of the EGC are employees of organisations that are public authorities under the Act (e.g. universities). However, because they serve on the EGC in their personal capacity the Act does not apply to them individually.

There may be an indirect effect when EGC documents are shared with other bodies that are subject to the Act (e.g. standing observers from the Medical Research Council). Relevant exemptions under the Act were discussed, namely, confidentiality.

It was felt that no immediate change was required to current EGC procedures.

External enquiries submitted to the UK Biobank EGC

When considering its role in responding to external enquiries the EGC agreed that it needs to distinguish between what is its responsibility and what is UK Biobank's. For example, directly assessing the scientific validity of the project is not within the EGC's remit nor is the EGC suitably constituted to act in this way. However the EGC does need to be assured of the efficacy of UK Biobank's decision making regarding the science.

The EGC had received a communication from the Pesticide Action Network UK (PAN UK) and the World Wildlife Fund (WWF). The communication addressed the public interest and accountability in UK Biobank.

Two concerns were raised that are of particular relevance to the EGC's remit:

- The concern that the public may be misled by descriptions of UK Biobank as 'the world's largest study of the role of nature and nurture in health and disease'. The EGC discussed the fact that the clarity and accuracy of UK Biobank's communications about the resource's potential will be essential to giving the public realistic expectations. The EGC will continue to monitor UK Biobank's communication strategy and advise accordingly.
- The concern that UK Biobank's Intellectual Property and Access (IPA) policy does not prevent access by industry. Under the IPA policy the EGC has a role in advising UK Biobank on the strategies, processes and criteria for prioritising requests for access to samples. These mechanisms and criteria will be directed by the purpose of the UK Biobank resource. The EGC's role with respect to access will be clarified in the response letter to PAN UK and WWF.

Actions: The Secretary will ask UK Biobank to comment on the issues which PAN UK and WWF have raised. A draft response to PAN UK and WWF will be drafted by the Secretary and distribute to the EGC.

UK Biobank Communications Strategy

UK Biobank's current Communication Strategy is based on three strands with key anticipated overlapping 'audiences' for each strand. These were presented in addition to an outline of the main challenges and the main activities in each area to date:

- Corporate communications (main audiences – internal and external stakeholders, funders, EGC, parliamentarians, healthcare professionals, general public)
- Recruitment communications (potential and actual participants, media, parliamentarians, healthcare professionals)
- Business-to-business (potential and actual users of the resource; sources of funding)

The EGC discussed the strategy and views were expressed that:

- Throughout the strategy a clear distinction should be drawn between activities which 'engage' and those which 'communicate' with the selected audience.
- The choice of language is an important method of facilitating clear communication with different groups, this will be a key consideration when writing the recruitment communications material.
- The tight timetable between the initial publication of the scientific protocol and recruitment may restrict the possibility of significant scientific input at this stage. The EGC did note, however, that the draft scientific protocol has been published and that further protocols, for example the sample storage and processing protocol, will continue to be published as appropriate.

Presentation and discussion of issues arising from the Ethics and Governance Framework and main protocol

Dr Sprosen, Chief Scientific Officer, UK Biobank presented an update on the development of the main study protocol and associated activities. The session was structured around the key elements of the 'Relationships with Participants' section of the Ethics and Governance Framework (EGF).

Recruitment

Specific recruitment strategies are under development with two main methods of identification being explored. The methods are underpinned by two principal options for invitation where a letter of invitation is either sent by the Chief Executive Officer of UK Biobank or by the individual's GP. Advantages and disadvantages are currently recognised for both invitation methods. This will be a primary issue addressed in detail in the Phase 2 integrated pilot.

The EGC briefly discussed whether or not an individual could be rejected from participation in UK Biobank despite fulfilling the project's recruitment criteria. If so UK Biobank should develop a protocol for explaining in a sensitive manner the reasons for rejection to those who are rejected. UK Biobank currently has no policy in this area.

Action: The EGC will return to the issue of rejection from participation when a full description of the assessment visit, including any protocols for exclusion, becomes available.

Understanding and consent

While recognising the ongoing right of withdrawal the EGC discussed three different models of consent where:

- **No provision for opting-out of specific types of research is provided either during the assessment visit or throughout participation.**
- **Participants are given the option, during the initial assessment visit, to decline participation in certain types of research.**
- **Participants who so chose would be kept informed of specific projects to be conducted using the UK Biobank on a case-by-case basis.**

The EGC had agreed generally with the broad consent approach during its second meeting. This is the model endorsed in the EGF, and it assigns to UK Biobank and the Council the task of ensuring appropriate uses of the resource in addition to the project by project approval of an NHS research ethics committee.

As discussed at the EGC's second meeting, providing the possibility of opting-out during the assessment visit was seen as problematic for a number of reasons, including the difficulty of predicting the possible types of research, the associated

difficulty of adequately describing these possibilities to participants, and the fact that views of what is culturally or ethically acceptable may change over time.

The third model responds to this difficulty in predicting future research proposals or areas of research. Information could be provided in parallel to the process of project approval by UK Biobank, the relevant ethics committees and the EGC. Participants would be able to indicate an objection to being part of a study at that time and this could be flagged on the database so that they were not included in that particular study. This would have the advantage of participants making decisions about specific studies, rather than the broad areas that could be highlighted in the preceding model.

The final two models present a number of logistical problems, including that of creating subsets within the UK Biobank population of those willing for their data or samples to be included in, or to be re-invited to take part in, certain types of research but not others. It was suggested that an advantage to Biobank in allowing this kind of selective withdrawal – as opposed to the “all or nothing” situation of the current protocol – would be that it would limit loss from the cohort as a whole.

Action: The Secretary will ask UK Biobank to comment on the possibility of flagging participants’ data in this way, of other logistic problems of offering them either the upfront or the project-by-project opt-out and the impact, if any, on study design of doing so.

Re-contact

The EGC states that the initial consent to participate in UK Biobank will include consenting to re-contact in specified circumstances. The EGC has an important role to play in monitoring policies and procedures for re-contact.

Confidentiality

The EGC will be discussing issues relating to confidentiality at their June 2005 meeting.

Action: EGC members should submit comments or questions relating to confidentiality to the Secretary before the June meeting.

Family based studies

The EGC briefly discussed the scope of conducting family based studies and questioned what types of information UK Biobank would seek concerning the relatives of participants. Dr Sprosen proposed that these issues are discussed at a future meeting of the UK Biobank Science Committee and recommendations presented to a future meeting of the EGC.

Provision of health information to participants

The UK Biobank Science Committee proposed four general principles:

1. *Recruitment to UK Biobank should not be presented to potential participants as a general health check;*
2. *Participants should give individual and specific consents for them to receive feedback on health information and for such information to be communicated to their GP (participants could decline either or both feedback options, but still participate);*
3. *Health information fed back to participants should be limited to;*
 - a) *non-genetic information;*
 - b) *clinically meaningful at an individual level;*
 - c) *amenable to effective modification, including lifestyle changes and readily available therapies.*
4. *Health information should be communicated to participants without interpretation, but with enough supporting information to be meaningful.*

The EGC supported the key principle that UK Biobank should not be perceived as a health check. Also a participant should be able to give or withhold consent in relation to the supply of information to them directly or to their GP.

The EGC discussed the criteria proposed in the third principle and expressed the view that:

- During the consent process individuals should be clearly informed about what information will and will not be fed back to them. This should prevent the misconception that ‘no news is good news’. The meaning of the terms ‘non-genetic’, and ‘clinically meaningful’ should also be clearly explained.
- How will clinical relevance be determined and what will the benchmark level of accuracy be, beyond which feedback is provided? Has UK Biobank taken advice on the liability implications of providing clinically meaningful data?
- Are the criteria equally weighted? For example, if genetic information concerning an individual is found to be clinically meaningful should this be fed back or not? If not, what is the justification for not feeding back such information?

The EGC brought the discussion back to the EGF by commenting that there are three stages at which the above information could be fed back:

- *Baseline measurements* at enrolment (such as height, blood pressure, etc)

The proposal to report standard ranges as a comparator for measurements taken was seen as a useful tool. This should provide the participant with enough information to give meaning to the measurements taken but without providing individual interpretation.

- *Baseline analyses* before samples are stored

The EGF states that in general UK Biobank will not provide health information to participants but that it will develop a policy on provision of information in exceptional circumstances where a reading in the baseline laboratory analyses might indicate a serious illness for which intervention is possible. The EGC noted that the proposal to provide feedback of baseline analyses is a clear departure from this policy.

Action: The Science Committee will be asked to describe in greater detail the reasons justifying such a change in policy.

- *Later findings* as the results of research

The EGF states that UK Biobank will not provide participants with information, genetic or otherwise, derived from examination of the database (or samples) by research undertaken after enrolment. The EGC support this position in the EGF. The Human Genetics Commission response to the first published version of the Ethics and Governance Framework 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. The Commission commented further that 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.

Criteria for mental capacity

The EGC considers the management of mental incapacity an important issue for UK Biobank and will return to this subject at a future meeting.

Next meeting

The next meeting of the UK Biobank Ethics and Governance Council will take place on 6th and 7th June 2005 in Manchester.

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 Chris Wild, Professor Roger Higgs.

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.

Apologies: Professor Ian Hughes, Dr Sandy Thomas.

Speakers: Dr Tim Sprosen (Chief Scientific Officer, UK Biobank) and Dr Shaun Griffin (Head of Communications, UK Biobank) attended for part of the meeting.