

UK Biobank Ethics and Governance Council Twenty Fourth Meeting

Meeting at Wellcome Trust
215 Euston Road, London, NW1 2BE

Monday 27 September 2010 at 10.30am

Agenda

1. **Apologies**
2. **Minutes** of twenty third meeting held on 7 June 2010
3. **Matters arising**
 - (i) Tracking of requests to UK Biobank
 - (ii) Subgroup reporting as necessary
 - (iii) Representation and representativeness
4. **EGC review**
5. **Closed discussion on topics to discuss under item 6 - 9**
6. **UK Biobank communications** (Mr Andrew Trehearne, Head of Communications, UK Biobank)
7. **Update from UK Biobank** (Professor Rory Collins, Chief Executive Officer, UK Biobank)
 - (i) General update on developments and recommendations from EGC23
 - (ii) Information systems development, CTSU audit
 - (iii) Biannual report on longitudinal follow-up of participants
8. **UK Biobank's draft access and intellectual property procedures** (Professor Rory Collins and Mr Jonathan Sellors, Company Secretary, UK Biobank)
9. **The National Information Governance Board** (Dr Alan Doyle, Director NIGB)
10. **Closed discussion of matters arising under items 6 - 9**
11. **Communications activities**
 - (i) External speaking opportunities
 - (ii) External enquiries to the EGC
12. **Report on meetings attended**
 - (i) Royal College of Radiologists and the SINAPSE Collaboration meeting 'Ethical Management of Research Imaging' 01/07/10
 - (ii) Making Connections III, 'Biobank Governance – Does Size Matter?' 25-26/07/10
 - (iii) The Centre for Law and Genetics, University of Tasmania, Biobanking workshop 4-5/08/10
 - (iv) The Argentinian Ministry of Science and Technology and the University of Buenos Aires, Fleni Institute Biobanking Seminar 10/08/10
 - (v) MRC Regulatory Support Centre conference, 'Sharing human tissue: New opportunities, new horizons' 15/09/10
13. **Any other business**
14. **Date of next meeting** 6 December 2010 - Council meeting, London

**UK Biobank Ethics and Governance Council
Twenty Fourth Meeting**

**27 September 2010
Wellcome Trust, London**

Present: Professor Graeme Laurie (Chair), Professor Ian Hughes, Professor Martin Richards, Professor Heather Widdows, Dr Roger Moore, Professor Paolo Vineis, Mrs Margaret Shotter, Ms Tracey Phillips, Dr Jonathan Hewitt and Mr Andrew Russell.

In attendance from EGC Secretariat: Ms Adrienne Hunt.

Observers: Ms Katherine Littler (Wellcome Trust) for the whole day, Dr Catherine Moody (Medical Research Council) for the afternoon only and Ms Beth Thompson for item 7 (i) only.

Speakers: Professor Rory Collins (Principal Investigator and Chief Executive, UK Biobank) and Mr Jonathan Sellors (Company Secretary, UK Biobank) for item 6 - 9 only. Mr Andrew Trehearne (Head of Communications, UK Biobank) for item 6 only. Dr Alan Doyle (Director, National Information Governance Board for Health and Social Care) for item 9 only.

1. Apologies

Apologies were received from Professor Roger Higgs for the whole day and Dr Jonathan Hewitt for the afternoon only.

2. Minutes of twenty third meeting held on 7 June 2010

A shorter minute has been produced in response to the EGC Review Panel's recommendation. In light of this the 'Summary of decisions' document was considered to be redundant and will no longer be produced. The Council approved the new style and the circulated minutes.

3. Matters arising

Tracking of requests to UK Biobank

Members noted the outstanding requests to UK Biobank, the majority of which were raised later in the day.

Subgroup reporting as necessary

Information Security – The Council reviewed (1) the outcomes of an audit of the IT systems and procedures within the Clinical Trial Service Unit (CTSU) that relate to UK Biobank and (2) CTSU's response to the findings. Members were encouraged by the audit which found no critical events but did find a few

weaknesses. It will be important for UK Biobank to carefully consider CTSU's response and ensure that all appropriate measures are taken to address the findings and to have mechanisms in place to demonstrate that the issues have been adequately addressed.

Communications – The EGC Review Panel recommended that the role of the EGC in public and participant engagement activities should be clarified in relation to the expectation of the funders. The Panel considered that the EGC's legitimacy does not lie in its engagement work but in its very existence. With this in mind, the Panel proposed that the EGC does not need to place as much emphasis on public engagement in future. Members re-iterated that any EGC engagement activity ought to assist the Council to fulfil its remit and ought not be, or be seen to be, part of UK Biobank's own engagement work or as advocacy for the project.

ACTION: The subgroup will meet to consider the implications of the Panel's recommendations for the EGC's Communications strategy. [AH]

Access and IP (AIP) – The AIP subgroup, Professor Collins and Mr Sellors met in July to review the first draft AIP procedures. This productive meeting informed the development of a second draft which was presented to the Council for consideration. Members were pleased to note that the majority of the subgroup's recommendations have been incorporated into a second draft and agreed on aspects to raise under item 8.

Representation and representativeness

Members agreed that the second draft of the paper, which aims to investigate the concept of 'representativeness' in population studies, should be further developed with a focus on the following considerations:

- In what way, if any, should the Council's 'Advising on the public interest and public good' document be revised in light of the paper's findings?
- What specific recommendations ought the Council make to UK Biobank regarding:
 - What aspects might form the basis of a recommendation from Council for inclusion in the Access and IP procedures.
 - Whether the socio-economic status data for the current cohort can be enhanced.

ACTION: Professor Paolo Vineis and Ms Tracey Phillips will meet in October to discuss the further development of paper. [PV and TP]

4. EGC review

The EGC Review Panel's recommendations were circulated to members in draft form. The recommendations will be ratified by the funders in due course, after which the implications will be discussed fully with the EGC. The Council found the review to be fair and constructive.

5. Closed discussion on topics to discuss under item 6 - 9

Members agreed on issues to raise under items 6 – 9.

6. UK Biobank communications (Mr Andrew Trehearne, Head of Communications, UK Biobank)

UK Biobank's Communications strategy has two priority areas: the re-development of the project's website and the preparation and dissemination of the first newsletter.

The re-designed website will be primarily geared to participants and scientists while recognising the need to ensure that members of the public are also able to be involved. UK Biobank aims to make the website an interesting experience that visitors will choose to return to frequently. Key features of the website might include:

- A database of the scientists who use the resource, and for what purpose – to include a lay summary, links to published articles and press releases, perhaps searchable by disease, researcher and location;
- Video interviews of scientists explaining what they hope to gain from using UK Biobank;
- Feedback and reply system;
- Who's who;
- Potential to engage in polling, live Questions and Answers, streaming of press (and other) conferences, or edited highlights;
- A section for the research community explaining how to use the resource.

It will be some years before the findings of research based on UK Biobank come to fruition and can be publicised on the project's website. In the meantime, the website could be used to highlight scientific advances in other biobanks and other fields as a way of exemplifying how UK Biobank might be used in the future. Such information should be aimed at the general public, rather than at the scientific community, and might help promote the public understanding of science. Such scientific horizon scanning might serve the additional purpose of informing UK Biobank's risk management strategy (for example, by identifying what are perceived to be controversial research uses). The website might also be used to serve a broad public health purpose by promoting healthy living.

A key aspect of UK Biobank's communication strategy, and specifically its newsletter, is to maintain the validity of participants' broad consent. UK Biobank aims to maintain participation through the ongoing provision of information about how the resource is being developed and used and also endeavours to raise specific issues as and when they arise (e.g. potentially sensitive research uses). The Council recommended that UK Biobank consider carefully and seriously the content and conclusions of the EGC's workshop on public involvement during the further development of its communication strategy.

The discussion continued in closed session (see item 10).

7. Update from UK Biobank (Professor Rory Collins, Chief Executive Officer, UK Biobank)

The EGC Chair congratulated Professor Collins and his colleagues on the major achievement of completing the recruitment of 500,000 participants.

General update on developments and recommendations from EGC23

The main assessment centres are now closed and the mobile assessment centre, currently operating in Wrexham, will close in October. The final recruitment total is expected to reach approximately 504,000 participants.

UK Biobank is currently operating on bridging funding whilst it awaits the outcome of its 5 year funding renewal application. The UK Biobank Review Committee met in July to consider this application and to make a number of recommendations to the funders. While the funding decision is pending, some of the recommendations have already been acted on by UK Biobank, including the Committee's proposal that the EGC be represented at the International Scientific Advisory Board meetings.

Information systems development, CTSU audit

The Council was pleased to have sight of, and encouraged by, the CTSU audit outcomes. UK Biobank and CTSU colleagues will meet shortly to discuss CTSU's response to the audit, including its proposed action list. Professor Collins and the Council agreed that it will be important for UK Biobank to ensure formally that CTSU makes the changes that have been identified through the audit process.

Biannual report on longitudinal follow-up of participants

UK Biobank's main focus over the next six months is to link to major health outcomes data. The ongoing pilots in Scotland and Wales have shown the feasibility of linkage to a wide variety of electronic record systems, including mortality, hospital admission and primary care data. In England and Wales flagging on the central registry for death and cancer notification has been completed for around half the cohort (with the remainder to be flagged by the end of 2010) and the first monthly report providing details of participants who have died since participating has been received. The upcoming meeting of the Longitudinal Follow-Up Group will focus on options for linkage to the primary care record in England.

Having achieved the linkage to major health outcomes data, UK Biobank will move to investigate linkages to health-related records. For example, the project might link to environmental records or it may take a more direct approach by sending participants a device that measures atmospheric particles present in their homes. The latter approach would allow UK Biobank to measure certain exposures directly e.g. the levels of radon, which is the second leading cause of lung cancer.

8. UK Biobank's draft access and intellectual property procedures (Professor Rory Collins and Mr Jonathan Sellors, Company Secretary, UK Biobank)

The following aspects were discussed:

- The composition and role of the Access Committee (AC);
- The mechanism by which applications will be triaged and/or escalated;
- The respective legal and other responsibilities of the Board, the AC and Principal Investigator;
- The role of the EGC as an independent oversight body and the need to be clear that it is not part of the decision-making processes;
- The need for the procedures to be reviewed for internal consistency (e.g. in relation to anonymity commitments);
- The need for a wide-ranging participant and public consultation.

The discussion continued in closed session (see item 10).

ACTIONS: EGC members' comments on the second draft procedures will be compiled and circulated to UK Biobank. [AH] An AIP subgroup meeting with Professor Collins, Mr Sellors and Mr Trehearne will be arranged. [AH]

9. The National Information Governance Board (Dr Alan Doyle, Director NIGB)

Dr Alan Doyle presented the work of the National Information Governance Board for Health and Social Care (NIGB). NIGB provides leadership and promotes consistent standards for information governance across health and social care. It considers ethical issues; the interpretation and application of the law and policies; and provides advice on information governance matters at a national level.

Dr Doyle spoke about the NHS Information Centre and Research Capability Programme initiative to establish a series of Honest Brokers (HBs) with responsibility to facilitate secondary uses of patient identifiable data in a safe and secure environment; to develop and use pseudonymisation techniques to reduce the risk of disclosure and to develop best practice in Information Governance and security. HBs will be a trusted authoritative source of information which support data use for certain purposes that are in the public interest and will reduce the need for access to identifiable information. Such purposes could include the use of data in the management of health and social care; medical research; preventative medicine; the monitoring and audit of health related care and the surveillance and analysis of health and disease. The standards and criteria relating to the HBs are currently being developed and there may be an opportunity for UK Biobank to be involved in these discussions.

The NIGB's Ethics and Confidentiality Committee (ECC) administers applications under Section 251 of the NHS Act 2006 permitting the common law duty of confidentiality to be set aside in specific circumstances to allow patient information to be used without consent (where gaining such consent is impractical). The ECC's role is advisory only and as such it does not authorise use or disclosure of the patient information in question. This advice is provided to the Secretary of State for Health.

The ECC reviews approximately 130 applications per year, including both research and audit. An IT database is currently being established to facilitate the application process and a triage system is being introduced (allowing straightforward applications to be dealt with outside of the ECC committee meetings). The experience of the ECC may be informative to UK Biobank as it further develops its access and triage procedures.

10. Closed discussion of matters arising under items 6 - 9

UK Biobank information systems

The Council recommends that UK Biobank considers a possible external re-audit of CTSU every 3 years and that a process of internal auditing might take place on an annual basis.

Communications

The Council has previously recommended that UK Biobank participants should be included in the consultation phase of the AIP procedures. Members endorsed the proposal that the newsletter include mention of the consultation and that it direct participants to the website for further information. The Council strongly endorses a wide exercise in public engagement including groups that are likely to be unreceptive to the development of the AIP procedures.

Recognising that the newsletter will be the first re-contact with all participants, the Council recommended that UK Biobank develop a strategy and protocol for re-contact. The strategy might address: (a) how re-contact will be made and how frequency will be monitored and judged appropriate; (b) the need for re-contact to be phased over time and monitored to ensure that participants are not overburdened and (c) the fact that some participants might be ill at the point of re-contact or have died.

Access and IP

Members noted that the details of the procedures will be discussed at the upcoming Board of Directors meeting and reviewed by the International Scientific Advisory Board at its October meeting. Notwithstanding this and the considerable progress which had been made by UK Biobank in developing its procedures, members highlighted the following priority areas as requiring further consideration and development. Members expect that many of the details will be addressed in time, for example, in the 'Notes of guidance' for researchers.

- **Access Committee.** Membership of the AC should include people with sufficient expertise and experience to identify ethical concerns and to know which applications should be debated more widely. To this end, the Council recommends that members with ethical and/or legal expertise are full, permanent members of the Committee and that it may be helpful if at least one member has experience of ethical review of research proposals.

The AC's role – in the short and longer term – could usefully be elaborated whilst making it clear that the AC is responsible for the access process (under authority from the UK Biobank Board), even in cases where the responsibility for decision-making is delegated to management staff within UK Biobank.

- **Triage and escalation of applications.** The procedures should describe the mechanism by which applications will be triaged and/or escalated (including the criteria against which applications will be judged as requiring referral to the EGC). The guidance notes could usefully include details on the types of applications that UK Biobank would envisage the AC dealing with and the type that might be escalated to the EGC for advice.
- **Role of the Principal Investigator (PI) on the AC.** The Council understands that the UK Biobank Board and the funders will give further consideration to the proposed role, if any, that the PI might serve on the AC.
- **Risk identification and management.** The Council recommends adding a sentence to the preliminary application form to the following effect: 'Please include a statement of likely or possible risks to the participants, their families or communities, and/or to public interest and how these will be addressed and/or managed'. The purpose of this sentence is two-fold, first, to prompt the applicant to think about ethical risks broadly and at an early stage and, second, in turn, to assist UK Biobank during its consideration of the ethical risks association with the application. In particular applicants should be encouraged to consider threats to participants and/or public interest beyond those that relate to privacy or security risks.
- **Fees policy.** The Council understands that UK Biobank is giving ongoing consideration to the question of which cost calculations will underpin the access fees. The current draft procedures propose access on a cost-recovery basis but consideration might also be given to the question of the sustainability of the resource.
- **Principles of access.** The AIP procedures might usefully adopt the set of 'Principles of good regulation' outlined by Dr Doyle under item 9, namely: proportionality, accountability, consistency, transparency and fairness.

11. Communications activities

External speaking opportunities

The Chair will visit Taiwan in October to attend a meeting focusing on biobanking and public engagement. He will present the findings of the EGC's workshop on public involvement.

The German Ministry of Education and Research has launched a National Biobank Initiative aimed at merging currently fragmented biobanking activities at universities and other research institutions in the country. Proposals are being invited to systematically develop and implement a local biobank structure which will eventually

allow high-quality biobanking and integration into European research infrastructures. Mrs Margaret Shotter has been invited to sit on the review board which will consider the proposals.

External enquiries to the EGC

Enquiries have been received regarding the advertised EGC Chair appointment.

12. Report on meetings attended

Royal College of Radiologists and the SINAPSE Collaboration meeting 'Ethical Management of Research Imaging' 01/07/10

The EGC Chair presented a paper on the current UK legal and regulatory framework for research magnetic resonance imaging at the 'Ethical Management of Research Imaging' workshop organised by The Royal College of Radiologists and its partners. The meeting organisers are preparing a meeting report which will be published in due course.

Making Connections III, 'Biobank Governance – Does Size Matter?' 25-26/07/10

The Chair attended an interdisciplinary meeting in Singapore that looked at how best to apply governance principles - designed with large population biobanks in mind - to smaller scale institutions with smaller budgets (including governance structures, public consultation, consent, privacy and benefit sharing arrangements). The Chair spoke about UK Biobank and lessons learnt for smaller biobanks.

The Centre for Law and Genetics, University of Tasmania, Biobanking workshop 4-5/08/10

The Chair spoke about the EGC's experience at a meeting with the Principal Investigator of the proposed Tasmanian biobank and colleagues involved in the design of its governance mechanisms. The biobank aims to implement robust and upfront engagement with the community before the biobank is established and before the Tasmanian community is invited to participate.

The Argentinian Ministry of Science and Technology and the University of Buenos Aires, Fleni Institute Biobanking Seminar 10/08/10

The Chair presented a paper on the governance of UK Biobank and work of the Council at a meeting with colleagues from the Argentina Ministry of Science and Technology and the University of Buenos Aires, Fleni Institute.

MRC Regulatory Support Centre conference, 'Sharing human tissue: New opportunities, new horizons' 15/09/10

Mrs Margaret Shotter attended the MRC Regulatory Support Centre conference which focused on the use of human tissue, primarily in the context of smaller biobanks.

13. Any other business

The EGC writing group has received reviewers' feedback on its paper concerning the ethical implications of MRI in a biobanking context.

ACTIONS: The paper and reviewers feedback will be circulated to the Council and funders. [AH] The paper will be revised in light of the feedback, after the Council has had sight of UK Biobank's proposed scientific MRI protocols (which are currently being revised). Specifically, it may be necessary to supplement the paper with more background information and discussion and, in turn, to identify a journal that would accept a longer paper. [EGC writing group]

14. Date of next meeting 6 December 2010 - Council meeting, London