

UK Biobank Ethics and Governance Council Twenty Fifth Meeting

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

Monday 6 December 2010 at 10.30am

Agenda

1. **Apologies**
2. **Minutes** of twenty fourth meeting held on 27 September 2010
3. **Matters arising**
 - (i) Tracking of requests to UK Biobank
 - (ii) Subgroup reporting as necessary
 - (iii) Researching the socio-economic determinants of health
 - (iv) EGC review – outcomes and funding
4. **International Scientific Advisory Board meeting report**
5. **EGC recruitment update**
6. **Closed discussion on topics to discuss under item 7 - 8**
7. **Update from UK Biobank** (Professor Rory Collins, Chief Executive Officer, UK Biobank)
 - (i) General update on developments and recommendations from EGC24
 - (ii) Biannual report on enquiries and complaints received by UK Biobank
 - (iii) Biannual report IT and data management strategy
8. **UK Biobank's draft access and intellectual property procedures** (Professor Rory Collins and Mr Jonathan Sellors, Company Secretary, UK Biobank)
9. **Closed discussion of matters arising under items 7 - 8**
10. **Communications activities**
 - (i) External speaking opportunities
 - (ii) External enquiries to the EGC
11. **Report on meetings attended**
 - (i) Board of Directors meeting 01/10/10
 - (ii) Sheffield Institute of Biotechnological Law and Ethics 'Feedback workshop' 05/10/10
 - (iii) International Scientific Advisory Board meeting 11-12/10/10
 - (iv) Taiwan biobank meeting on public engagement 12-14/10/10
 - (v) Review Board meeting for the German Ministry of Education and Research, National Biobank Initiative 12/11/10
12. **Any other business**
13. **Date of next meeting** 14 March 2011 - Council meeting, London

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

**6 December 2010
Wellcome Trust, London**

Present: Professor Graeme Laurie (Chair), Professor Ian Hughes, Professor Martin Richards, Professor Roger Higgs, Professor Heather Widdows, Dr Roger Moore, Mrs Margaret Shotter and Dr Jonathan Hewitt.

In attendance from EGC Secretariat: Ms Adrienne Hunt.

Observers: Ms Beth Thompson (Wellcome Trust) and Dr Catherine Moody (Medical Research Council) for the whole day. Professor Roger Brownsword (incoming Chair) for items 7 – 13.

Speakers: Professor Rory Collins (Principal Investigator and Chief Executive, UK Biobank) and Mr Jonathan Sellors (Company Secretary, UK Biobank) for items 7 – 8.

1. Apologies

Apologies were received from Professor Paolo Vineis, Mr Andrew Russell and Ms Tracey Phillips for the whole day and Dr Jonathan Hewitt for the morning only.

2. Minutes of twenty fourth meeting held on 27 September 2010

The Council approved 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

Communications – The EGC's Communications strategy has been revised in light of the Review Panel's recommendations (including the proposal that the EGC does not need to place as much emphasis on public engagement in future). The Council will no longer continue its series of annual public meetings but will instead assess the need for such events on a case-by-case basis as issues arise. In addition, it will be important for the EGC to retain its ability to propose public attitude research on specific issues as and when required.

ACTION: The Communications strategy will be posted on the EGC website after some minor revisions. [AH]

Information Security – The subgroup has not met since the last Council meeting. An update is expected from UK Biobank colleagues later in the day.

Access and IP (AIP) – The AIP subgroup met with Professor Collins and Mr Sellors in November to discuss the second draft AIP procedures. UK Biobank aims to open the resource for some access in the second quarter of 2011. The November AIP meeting had been constructive and included discussion of the governance arrangements, including the remit and constitution of the Access Committee. This went some way to addressing concerns that had previously been raised by Council about the tightness of the UK Biobank timetable and the need to address key issues relating to governance of access decisions. Subsequent to the November AIP meeting the Chair requested further information from UK Biobank, including its timetable for the final stages of the development of the procedures. The procedures and timetable were discussed further under item 8.

Researching the socio-economic determinants of health

The Council considered a third draft of Professor Vineis and Ms Phillips's paper that reflects on the concept of 'representativeness' in population studies and proposes a number of strategies for enhancing the socio-economic data collected by UK Biobank. The Council's discussion was also informed by a background paper, prepared by the Secretary, that provided an overview of the socio-economic-related data that have already been collected by UK Biobank at the baseline assessment visit and the data that the project aims to collect through its strategies for enhancement and follow-up.

Members agreed that the Council is walking a fine line between advocating specific research use (and data collection) and its more appropriate role in making recommendations to UK Biobank about enriching the resource in order to assure the EGC that the resource is sufficiently constituted to address the fullest range of research uses (including research into the socio-economic determinants of health) and in line with the stated purpose of UK Biobank. The Council agreed that the locus for any recommendation relating to the collection of socio-economic-related data should be clarified and tied to the EGC's role in relation to the EGF. Members considered this subject to be appropriate for the EGC's attention because UK Biobank receives public money and as such the EGC is keen to see the resource being used for the broadest public benefit (including research into the socio-economic determinants which contribute to significant health inequalities in society).

The Council agreed to raise this topic with Professor Collins later in the meeting.

ACTION: Professor Vineis will meet and discuss this topic with Professor Collins in the new year. [PV]

EGC review – outcomes and funding

Following the recent, positive review of the EGC, funding has been confirmed at the current level for the next three years. The Review Panel made a number of

recommendations, the implementation of which will be discussed with the funders and UK Biobank.

ACTION: The EGC review final report will be published on the EGC website. [AH]

4. International Scientific Advisory Board (ISAB) meeting report

Professor Martin Richards represented the EGC at the October ISAB meeting where discussion focused on UK Biobank's enhancement and access and IP proposals. Professor Richards provided a report of the meeting and a paper that reflects on UK Biobank's policy on the provision of health information to participants in light of the enhancement proposal. This topic was raised with UK Biobank colleagues later in the day and conclusions were formulated under item 9.

ACTION: The funders offered to give the EGC sight of the meeting note of the Wellcome Trust's workshop on incidental findings in research. [BT]

5. EGC recruitment update

Professor Roger Brownsword has been appointed Chair of the Council with effect from the 1 January 2011. Interviews for up to three new members will take place in January 2011.

6. Closed discussion on topics to discuss under item 7 – 8

Topics were raised under items 3 – 5.

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

General update on developments and recommendations from EGC24

Re-contact and re-assessment visits

Participants have consented to be re-contacted by UK Biobank for a number of reasons, including to undertake a repeat of the baseline assessment visit. Contact details have been collected to facilitate such re-contact but experience from other cohort studies has shown that these details become non-valid over time. In order to mitigate this effect, UK Biobank is developing a web-based system through which participants can easily update their details.

UK Biobank is currently considering how best to structure the repeat baseline assessment visit and intends to pilot its approach to re-contact in the first instance. Initial plans involved re-assessments in all 20 of the previous recruitment locations through use of the mobile unit. However, UK Biobank is now investigating the possibility of having fewer, fixed location centres that will be open for longer. This

approach would have the advantage of providing the required space to undertake the full range of measurements (unlike the mobile unit which has constrained space).

Human Tissue Authority audit

The Human Tissue Authority (HTA) was set up to regulate the removal, storage, use and disposal of human bodies, organs and tissue for a number of Scheduled Purposes, including research. As part of the regulatory framework the HTA licenses establishments and undertakes inspections to assess compliance with expected standards. The Council had sight of the HTA's site inspection report for UK Biobank, which judged the project to fully meet all of the HTA's standards (under such high-level headings as consent, governance and quality, premises, facilities and equipment, disposal).

The UK Biocentre

The Council received an update on UK Biobank's plans to establish the UK Biocentre to provide centralised services and facilities for other researchers (including support during participant recruitment, sample processing and sample storage). The initiative was borne from the high level of demand from other research groups to learn from UK Biobank's experience and expertise. It does not involve the data and samples held by UK Biobank.

ACTION: The Council recently received a participant enquiry regarding the UK Biocentre and its relationship with UK Biobank. The Secretary will seek the enquirer's permission to share the letter with UK Biobank. [AH]

Biannual report on enquiries and complaints received by UK Biobank

UK Biobank has received very few enquiries and complaints since the end of recruitment in July 2010. The first participant newsletter will be circulated in hard copy in January 2011 and is expected to generate a number of enquiries.

ACTION: The newsletter will be sent to the EGC for information. [RC]

Biannual report IT and data management strategy

Dr Tim Peakman, UK Biobank's Executive Director, has been working with the Clinical Trial Service Unit (CTSU) to implement the recommendations of the information security systems auditors. At the conclusion of this process Dr Peakman will prepare a paper that details CTSU's actions against the recommendations. Professor Collins offered to give the EGC sight of this paper. In the long term UK Biobank will arrange regular, repeat audits of CTSU's systems.

Having recently received confirmation of funding for the period 2010 – 2015, UK Biobank is now able to commit to the development of its IT systems, in particular those systems that relate to providing access to the resource. Other IT-related developments have been pushed back in order to give the access systems the necessary priority (e.g. the repeat assessment visits will now take place at the end of 2011).

Researching the socio-economic determinants of health

Professor Collins confirmed that research into the socio-economic determinants of health represents a major part of the aims of UK Biobank. The project has already collected a range of socio-economic-related data through the baseline visit (e.g. socio-demographics; lifestyle exposures; early life exposures; psychological state; cognitive function; family history of illness; and medical history and general health) and plans to enhance the collection of this type of data through its proposed strategies for enhancement (e.g. web-based questionnaire on environmental exposures; further data on residential and occupational history) and follow-up (e.g. by linking to records that relate to occupational workplace screening; social services; education and environment).

The Council fully supports the collection of a wide variety of socio-economic data whilst recognising that retrospective data might be more difficult to acquire (useful contacts might include the MRC Social and Public Health Science Unit in Glasgow and the Social Dimensions of Health Institute at the University of St Andrews). The Council fully endorses the further consideration that UK Biobank will give to the collection of socio-economic data through its follow-up and enhancement strategies.

ACTION: Recognising that the question of balancing data-collection priorities and needs should fall to UK Biobank and its scientific advisory committees, the Council agreed to send a revised copy of the Secretary's paper to the International Scientific Advisory Board for consideration. [AH]

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

The Council had a detailed discussion on Access and IP (AIP) issues with Professor Collins and Mr Sellors and recognised that this came at a time before the UK Biobank Board had had an opportunity to air its views and decide on future directions. The Council reiterated its advice to drill down on detail and to firm up plans if the current timetable is to be met.

An AIP consultation phase is planned for March – April 2011 during which UK Biobank will invite comments from the scientific community, participants and the public. An awareness-raising meeting will be held in March during which members of the scientific community will be consulted on the AIP procedures in addition to being informed about the availability and content of the resource. Participants will be alerted to the upcoming consultation via the newsletter and will be advised by text or email once the consultation document has been posted on the project's website.

The Council recommended that UK Biobank's AIP consultation document could usefully include examples of different potential users of the resource (including commercial and overseas) and uses which are considered to fall clearly within the purpose of UK Biobank. Also, the consultation provides an opportunity to give examples of research that does not fit the purpose of UK Biobank and to highlight uses that UK Biobank considers to be potentially controversial and how these will be handled. UK Biobank would be advised to highlight how use of the resource will

serve the public interest, for example by pointing to clear examples of benefit sharing.

ACTION: The Council will provide UK Biobank with a list of examples of different potential users and uses of the resource to be included in the consultation document. [AIP subgroup, AH]

The Council welcomed sight of UK Biobank's current timetable for the development of the AIP procedures (which envisages opening the resource for some access in the second quarter of 2011). The Council expressed concern about how realistic the timetable is based on progress to date but was assured that access will not be granted until robust procedures have been developed and subjected to adequate stakeholder and public engagement.

ACTION: Two AIP subgroup meetings will be arranged as per the timetable. [AH]

9. Closed discussion of matters arising under items 7 – 8

Access and IP

It will be important for UK Biobank to communicate that it is guided by a strong, principled framework for access (in addition to the more operational set of procedures). The Council therefore recommends the development of a scientific strategic framework for use of the resource including at least the following elements: (1) an explanation of the variety of uses of UK Biobank data and samples; (2) a description of when UK Biobank might be 'ready' for certain disease research (i.e. the disease timetable); (3) an overview of the types of users that might use the resource (including commercial and international); (4) an explanation of how UK Biobank will manage research applications which seek to address similar goals (i.e. how/if collaboration between users will be promoted); (5) an indication of how the scientific robustness of an application will be evaluated in a broad sense and (6) an explanation of how the depletability of samples will be managed.

The Council briefly considered the question of whether it should request observer status on the Access Committee and agreed to revisit the question once the access process has been more fully defined.

It will be essential for the Council to continue to work closely with UK Biobank as it aims to finalise its procedures within the new tight timetable. The incoming EGC Chair, Professor Brownsword, will serve on the AIP subgroup, in place of Professor Laurie, once his appointment commences on the 1 January 2011.

ACTION: As a further initiative to expedite matters the Council recommends that Professor Laurie assist UK Biobank with the drafting of the procedures after he steps down as Chair on the 31 December 2010. Professor Laurie will write to the Chair of the Board with this recommendation and to offer the Council's reflection on the role of the Access Committee. The AIP subgroup's November meeting note will also be sent for the Board's attention. [GL, AH]

Communications

The Council agreed to request an update on UK Biobank's communications strategy for its 14 March 2011 meeting, including sight of the proposed AIP consultation document, an update on the project's website redevelopment and an update on UK Biobank's plans to establish virtual participant panels. In the shorter term, the Council would welcome sight of UK Biobank's first participant newsletter.

UK Biocentre

The UK Biocentre has the potential to benefit the research community by offering centralised services and facilities. However, the UK Biocentre also has the potential to adversely affect the UK Biobank project if communication to participants is not handled appropriately (in terms of both timing and content). The Council recommends that the relationship between UK Biobank and the UK Biocentre should be communicated to participants. Such a notice could usefully include a clarification of the relationship between the two organisations; the accountability of the UK Biocentre; who will manage the UK Biocentre; who is expected to benefit from the UK Biocentre's activities (including benefits to researchers but also how potential profits will be used) and implications, if any, for participants and their samples/data.

EGF revision

As previously requested, the Council would hope to review a revised EGF once the AIP procedures have been finalised. At that time the EGF should also be revised to clarify the issue of participant re-contact and the need for REC approval for research for audit (either by the funders or UK Biobank) (see recommendations from EGC22).

Feedback policy and the EGF

The Council is charged to advise UK Biobank on revisions to the EGF which may be required to respond to changes in the development of ethics. Some members have reported an increasing tendency in the ethics literature towards support for participants being provided with feedback of their research measurements (in particular in the field of MRI). To the extent that this represents a shift in culture and expectations – which will require careful monitoring – this might also have implications for UK Biobank, not least with respect to its proposed enhancement measures.

At present the EGF describes a number of stages at which UK Biobank might provide feedback to participants and details reasons for and against such feedback. In his note to Council, Professor Richards describes that there are now several proposals for enhancement which represent new possibilities for feedback, in particular given their predictive clinical nature. These assessments are currently not included in the EGF considerations but should be taken into account during the upcoming EGF revision (if the enhancements are funded).

UK Biobank is likely to undertake a number of future enhancements and so too it is likely to continue to face the related question of whether or not to provide feedback. Given this, the Council recommends the development of a framework of principles

from which to decide whether or not feedback should be provided. This framework will assist UK Biobank to make consistent and justifiable decisions on feedback by providing a benchmark against which each new measure/technology is judged. For example, the results of the measurements may have to meet certain criteria before feedback is considered, such as clinical validity and utility. In the main, the above considerations will relate to UK Biobank's enhancement measures. However, UK Biobank would also be advised to re-evaluate its baseline (repeat) assessment measurements against the framework of principles, if only to affirm that the current policy is still appropriate.

ACTIONS: Professor Richards's paper will be sent to Professor Collins and Mr Sellors for information. [AH] The Secretary will review the literature for recent initiatives concerning feedback of individual health information in a research setting. [AH] The issue of feedback will be discussed further once the Council has had sight of UK Biobank's enhancement proposal. [All]

Related to the question of feedback, the Council would be interested to learn how often incidental findings were made, and escalated to senior management, during the recruitment process. The Council recommends that incidental findings should continue to be handled and recorded appropriately during the repeat baseline and any future enhancement visits.

CTSU audit

The Council would welcome sight of Dr Peakman's concluding report of the CTSU audit actions, once available.

10. Communications activities

External speaking opportunities

There are no upcoming speaking opportunities.

External enquiries to the EGC

The EGC received an enquiry from a participant concerning the UK Biocentre (see items 7 and 9).

11. Report on meetings attended

Board of Directors meeting 01/10/10

Professor Richards attended the Board of Directors meeting where discussion focused on the AIP procedures.

Sheffield Institute of Biotechnological Law and Ethics (SIBLE) 'Feedback workshop' 05/10/10

Professors Laurie and Richards attended the SIBLE workshop on feedback, some papers from which may appear in a special issue of the Journal of Law, Innovation and Technology.

International Scientific Advisory Board (ISAB) meeting 11-12/10/10

Professor Richards attended the October ISAB meeting, as reported under item 4.

Taiwan biobank meeting on public engagement 12-14/10/10

Professor Laurie attended a meeting in Taiwan where he shared the outcomes of the EGC workshop on public involvement.

Review Board meeting for the German Ministry of Education and Research, National Biobank Initiative 12/11/10

Mrs Margaret Shotter recently sat on a review board for The German Ministry of Education and Research. The Board considered proposals submitted in response to the Ministry's launch of a National Biobank Initiative aimed at merging currently fragmented biobanking activities at universities and other research institutions in the country.

12. Any other business

The June 2011 EGC meeting date was changed to the 6 June.

Professor Laurie's four and a half year term of office ends in December 2010. The funders thanked him for his wisdom, good judgement and consistent approach during his time in office. Professor Laurie thanked the funders for what he considered as a very enjoyable and productive time with a tremendous committee that has made a significant contribution to the UK Biobank project. Professor Laurie thanked the members for their constructive input over the years and thanked the Secretary for all her support.

13. Date of next meeting 14 March 2011 - Council meeting, London