

UK Biobank Ethics and Governance Council Thirty-fifth Meeting

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

Monday 20 May 2013 at 10.30am

Agenda

1. **Apologies**
2. **Minutes** of thirty-fourth meeting held on 4 March 2013
3. **Matters arising**
 - (i) Tracking of requests to UK Biobank
 - (ii) Subgroup reporting: Access – EGC access oversight role
 - (iii) Funders' response to the EGC work plan
4. **Draft feedback report**
5. **Closed discussion on topics to discuss under item 6**
6. **Update from UK Biobank** (Professor Rory Collins, Chief Executive Officer, UK Biobank)
 - (i) Report on access
 - (ii) Imaging pilot
 - (iii) Genetics strategy
 - (iv) Health outcome linkage and adjudication report
 - (v) Participant and public involvement biannual report
 - (vi) IT and data security biannual report
 - (vii) Any other developments and outstanding recommendations from EGC34
7. **Closed discussion of matters arising under item 6**
8. **Communications activities**
9. **Report on meetings attended**
 - (i) Wellcome Trust/MRC feedback framework legal meeting 11/03/13
 - (ii) UK Biobank Board of Directors meeting 15/03/13
 - (iii) EGC access oversight role meeting 15/03/13
 - (iv) P3G Privacy Summit 'Data sharing and cloud computing' 03/05/13
 - (v) Emerging Science and Bioethics Advisory Committee Forum 13/05/13
10. **Any other business**
11. **Date of next meeting** 9 (dinner) & 10 (meeting) September 2013 – Royal York Hotel, York
12. **Dates for 2014** 10 March, 2 June, 2 September, 8 December

**UK Biobank Ethics and Governance Council
Thirty-fifth Meeting**

**20 May 2013
Wellcome Trust, London**

Present: Professor Roger Brownsword (Chair), Professor Martin Richards, Dr Roger Moore, Mr Andrew Russell, Ms Tracey Phillips, Dr Sheelagh McGuinness, Professor Søren Holm, Professor Heather Widdows, Mrs Margaret Shotter and Dr Jonathan Hewitt.

In attendance from EGC Secretariat: Ms Adrienne Hunt.

Observers: Dr Katherine Giles for the whole day (MRC). Ms Katherine Littler for items 1 – 7 only (Wellcome Trust).

Speakers: Professor Rory Collins (Principal Investigator and Chief Executive, UK Biobank) for item 6 only.

The Chair opened the meeting by welcoming the new MRC observer, Dr Katherine Giles. The Chair thanked the previous MRC observer, Dr Catherine Moody, for all the support and sound advice that she has offered the EGC over the years.

1. Apologies

Apologies were received from Professor Kate Hunt.

2. Minutes of thirty-fourth meeting held on 4 March 2013

The Council approved the circulated minutes.

3. Matters arising

Tracking of requests to UK Biobank

Members noted the outstanding requests to UK Biobank and the Chair highlighted the key topics for the day's discussion: the EGC's responsibilities in relation to access, the EGC's feedback report and the proposal to hold a conference in 2014.

The EGC having reiterated its concern that the Ethics and Governance Framework (EGF) should be up-to-date and fully connected to the span of the project's activities, the funders advised that they will discuss a timetable for revision of the EGF with UK Biobank.

Subgroup reporting: Access – EGC access oversight role

In March members of the EGC, Ms Tara Camm (UK Biobank's Access Sub-Committee Chair), Professor Rory Collins and the funders had a constructive meeting, the purpose of which was to understand and identify how best each party can fulfil their respective responsibilities in relation to access. A key discussion concerned how the parties understand the scope of the EGC's access oversight responsibilities.

Members discussed the note of this meeting, including the possibility of the EGC's oversight responsibilities moving towards an 'audit' (or 'scrutiny') model where the emphasis of the EGC's oversight would be largely of an *ex post* nature. This would be in contrast to the present arrangement whereby, the EGC relies principally on the lay summaries to keep itself informed about applications as they progress through the adjudication process. It was emphasised, however, that any evolution of the EGC's oversight responsibilities must be compatible with protecting the interests of participants.

In this context, and mindful of the (above) proviso, members agreed that they have no wish to engage in parallel review; and there was a shared sense that the 'direction of travel' needs to be towards an 'audit' (or 'scrutiny') model. However, before the EGC could move towards such an auditing role, there is a need to build confidence in the access procedures, in particular regarding the Access Sub-Committee (ASC) process of decision-making, its deliberations and decisions and how it develops policy to guide future decisions. To this end, members welcomed the proposal that Ms Camm and Mrs Lorraine Gillions (UK Biobank's Research Access Administration Manager) will attend the September EGC meeting in order to demonstrate the entire process, end-to-end, including the work of the ASC.

One of the longer term issues for the EGC is how to engage with novel classes of governance or ethics issues that arise through the applications; how they might be identified and flagged up; and how the EGC might cooperate with UK Biobank in addressing such issues. It was noted that only one application has been escalated to the EGC during the first year of access – namely, an application for re-contact which under the terms of the EGF must be escalated for the EGC's advice.

Funders' response to the EGC work plan

Members discussed the funders' response to the EGC's revised 2-year work plan. While broadly supportive of the plan the funders requested clarification on three points before they could be in a position to approve the work and the 2-year pro-rata extension of the existing funding envelope.

The first point related to the ongoing discussions regarding the EGC oversight responsibilities in relation to access; members agreed that the clarification should be informed by the day's discussion.

The second point related to the proposed re-development of the EGC website and whether the site should contain a section dedicated to participants (e.g. advising them on aspects of the imaging visit). On reflection, members agreed that this would

not be an appropriate role for the EGC as an independent committee. Moreover, this conclusion is in line with the outcomes of the quinquennial review of the EGC's activities that recommended the EGC should step back from its direct engagement work (i.e. its public meetings).

The third point related to the proposed 10-year anniversary conference. It was agreed that the event should be refocused to highlight to the research community what lessons can be learnt from establishing the EGC and to think about governance oversight mechanisms and the emerging ethical issues in biobanking.

The work plan (including conference proposal) will be revised and resubmitted to the funders.

4. Draft feedback report

The Council discussed the latest draft of its report on feedback with a view to having this ready to sign-off at the September EGC meeting and deliver to UK Biobank's Board of Directors in the autumn. The report will be shared with Professor Collins in advance of the September meeting.

5. Closed discussion on topics to discuss under item 6

Members highlighted a few matters to raise with UK Biobank under item 6.

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

Report on access

A number of streamlining measures are being implemented in light of UK Biobank's internal management team review of the access process. Professor Collins offered to provide the EGC with a summary of the measures and the rationale for change. Noting that a further review is planned, as required by the funders, 12 – 18 months into the access process, the EGC will be interested to discuss how and when it might engage with UK Biobank during this review process.

Members noted that some applicants are taking a staged approach to their research whereby their application for access highlights that the proposed research will be expanded once other data become available e.g. the genotyping data. Professor Collins advised that in such circumstances UK Biobank would only approve the research use proposed in the initial application, although it would review the proposal as a whole. At a later date, for example when the genotyping data become available, it may be possible for an amendment to the initial application to be submitted and to be reviewed by the ASC in an expedited manner.

Members indicated an interest in learning about the ASC's thinking in terms of controlling the use of the depletable resource, including how sample requests are

judged and prioritised in order to optimise the informativeness of the resource in the long-term. Whilst advising that there have been few requests for use of the depletable resource to date, Professor Collins confirmed that UK Biobank plans to draft a policy to address these issues.

Imaging pilot

Professor Collins provided an update on the imaging plans, including the decision to open the imaging assessment centre in early 2014. The imaging assessment visit will include all elements of the baseline assessment visit, except the fitness test and the eye measures. Additional questions on cognitive function will be included, along with an electrocardiogram (ECG).

UK Biobank has asked participants attending the repeat assessment visit whether they would be willing to take part in a 4 – 5 hour imaging assessment, with 95% saying they would. The repeat assessment visit attendance rate is 30% which suggests UK Biobank should be able to reach its target of 100,000 participants for the imaging visit.

While no participant materials were provided at this meeting, the Council looks forward to receiving the imaging timetable and draft materials in due course and to working with UK Biobank as it prepares for the imaging pilot.

Genetics strategy

Professor Collins reported that UK Biobank has started to extract DNA from the samples in preparation for the genotyping, and the design of the chip is being finalized. The genotyping will be performed by Affymetrix in California in a process that is expected to run through to the end of 2014. The EGC requested a further update on this work at its September meeting by which time a number of outstanding details should have been finalised (e.g. how and where the genotyping data will be stored). The Council also asked for clarification regarding whether Affymetrix will be required to destroy the data once it has been passed on to UK Biobank.

A video interview with Professor Collins was posted on the UK Biobank website very soon after the genotyping was announced¹. Members consider this a good example of keeping participants informed about UK Biobank's progress. Noting that UK Biobank has received an application for whole genome sequencing (WGS) of a few hundred participants the Council asked if UK Biobank planned to inform participants about this particular use of the resource (e.g. what is WGS and what are the implications, both benefits and risks of such analyses?). Professor Collins agreed to follow this up with UK Biobank's Head of Communication, Mr Andrew Trehearne.

Ms Katherine Littler advised that the Wellcome Trust is considering how to communicate advances in genomics to participants and the public. Discussions are also taking place at the Department of Health, in the context of the 100,000 Genomes Project. The Council was reassured by this; it is entirely appropriate that funders should take a lead as this issue is by no means unique to UK Biobank.

¹ See www.ukbiobank.ac.uk/2013/03/genetics-study-targets-serious-disease (accessed 04/06/13)

Health outcome linkage and adjudication report

The Council received a comprehensive update on UK Biobank's progress with the checking, processing and incorporation of linked data into the UK Biobank database and its preparation for display to researchers within the UK Biobank Data Showcase.

Data on deaths and cancers registered in England and Wales have already been incorporated into the Data Showcase, while information on deaths and cancers registered in Scotland should be incorporated during Q3 2013. An updated timetable for incorporation of other linked data (including hospital episode data and primary care data) has been made available on UK Biobank's website and will be updated regularly.

Participants are also being followed-up through the use of questionnaires. A web-based questionnaire on cognitive function is being finalised and will be sent out during 2013. Mental health and occupational questionnaires are currently in development while the content of further questionnaires is being considered by UK Biobank's outcomes working group and steering committee.

Four outcome adjudication pilot studies are ongoing to develop methods for adjudication of cancer, diabetes, stroke and cardiac disease outcomes. An initial aim of the pilots is to provide advice to help researchers make best use of the coded information available from the linked health data. A longer term aim is to develop more detailed procedures for the sub-classification of confirmed health outcomes. Proposals for a second wave of outcome adjudication pilots are under development for a range of other health outcomes (including mental health and ocular).

Participant and public involvement biannual report

Members considered an informative report on UK Biobank's recent communications activities, that also included a number of participant comments received in response to the annual newsletter.

The report gave details of the number of participants who have opted to withdraw from the project for each of the three options, 'no further contact', 'no further access' and 'no further use'.² Experience has led UK Biobank to subcategorise the 'no further contact' options so participants can choose (1) no further contact for any reason or (2) contact for updates on the project's activities but no contact for any other reason (i.e. no longer receiving requests to provide more information etc.). The Council found this to be a sensible and helpful distinction.

IT and data security biannual report

The Council congratulated UK Biobank on its successful audit and resulting Certification for the international quality standard ISO 27001:2009 (Information management and security). All aspects of the operations at the UK Biobank Coordinating Centre were scrutinised as part of the audit, covering not just IT

² See the Ethics and Governance Framework Section I.B.6 for a description of each option. Available at: www.ukbiobank.ac.uk/resources

systems but all aspects of the operation that relate to the security of the data and samples.

Cardiff University provides a number of functions for the UK Biobank project, including the operation of the Participant Resource Centre (PRC) and development and hosting of the cognitive function web questionnaire. During the imaging pilot, the PRC will also administer a pre-visit check to ensure that participants are eligible for involvement in the imaging assessment. Members queried who has responsibility for the data security provisions of the Cardiff University systems that deal with UK Biobank data and whether their systems fall within the scope of UK Biobank's recent Certification. Professor Collins offered to confirm this after the meeting.

Any other developments and outstanding recommendations from EGC34

UK Biobank's web questionnaire on cognitive health has received Research Ethics Committee (REC) approval. The Council was provided with UK Biobank's REC submission and the REC approval letter, for information. Professor Collins advised that the final checks are now taking place after which the questionnaire will be rolled out to participants.

As the UK Biobank cohort ages, an increasing number of participants may not have the capacity to consent to new data/sample collections. The Council asked if UK Biobank had considered referencing the results of the cognitive function questionnaire at the time when it goes back to participants (i.e. if there is a very low score this may indicate a loss of capacity). Professor Collins made the related point that as cognition declines, fewer participants will complete the questionnaire and so UK Biobank will potentially underestimate the level of cognitive decline across the cohort. Professor Collins is due to meet Professor John Gallacher (who developed the cognitive function questionnaire for UK Biobank) to discuss these issues, including how to assess cognitive function within the cohort and what other assessments could be obtained.

7. Closed discussion of matters arising under item 6

EGC access oversight role

It is anticipated that UK Biobank's ASC Chair, Ms Camm, and UK Biobank's Research Access Administration Manager, Mrs Gillions will attend the EGC's September meeting to demonstrate the end-to-end access process (see item 3). The EGC agreed that, in the intervening time, it would be helpful for the EGC Chair to have a further meeting with Ms Camm, Professor Collins and the funders to update them in detail on the EGC's discussion. Professor Mike Parker could also be invited to attend the meeting (who through a contract with the Ethox Centre provides advice to UK Biobank on the ethics issues raised by individual applications).

The EGC access subgroup will also meet over the summer.

8. Communications activities

A planned visit to the Estonian Genome Center and The Centre for Ethics in Tartu, to learn about their feedback policy and practice, had to be postponed and is now expected to take place in autumn.

9. Report on meetings attended

Wellcome Trust/MRC feedback framework legal meeting 11/03/13

The Wellcome Trust and the MRC are developing a Framework on feedback of health related findings. The EGC Chair and Dr Sheelagh McGuinness attended the latest in a series of meetings that will inform this work, focusing on the legal aspects of feedback.

UK Biobank Board of Directors meeting 15/03/13

The EGC Chair observed the March Board of Directors meeting, which focused on discussion of the genotyping work.

EGC access oversight role meeting 15/03/13

An update on this meeting was provided and discussed under item 3.

P3G Privacy Summit 'Data sharing and cloud computing' 03/05/13

Members of the EGC attended an informative P3G Summit on data sharing and cloud computing. The Council agreed that it should learn more about informatics, including the possibilities, benefits and risks of using cloud computing to store data. To this end the Council will invite speakers to its December meeting to address this topic. In the meantime, a briefing note will be drawn up, including a set of questions that the EGC would like to have addressed.

Emerging Science and Bioethics Advisory Committee (ESBAC) Forum 13/05/13

The Secretary attended the Forum meeting of ESBAC, the main UK advisory body on emerging healthcare scientific developments and their ethical, legal, social and economic implications. Sponsored by the Chief Medical Officer for the Department of Health, England, ESBAC comprises approximately 22 members covering a variety of areas (including social sciences, humanities and economics, law, industry, science in society, biosciences and biotechnology).

The Forum was presented as a unique opportunity for attendees to help shape the future direction of ESBAC's emerging work plan, including the Committee's approach to horizon scanning and its draft proposals in three areas:

- The implications of emerging technology in the diagnosis of dementia
- Exploring the use of emerging technologies to optimise treatment

- Governance related issues in the context of the regulation of emerging technologies in healthcare.

10. Any other business

The Wellcome Trust Monitor is a unique survey of UK adults' and young people's views of science, biomedical research and science education. The aim of this tracking survey is to build a high-quality evidence base that explores trends and variations across time on both general scientific themes and specific societal issues. Repeated every three years, the second wave of the survey has just been launched and contains many questions of relevance to the EGC.³

11. Date of next meeting

9 (dinner) & 10 (meeting) September 2013 – Royal York Hotel, York

12. Dates for 2014

10 March, 2 June, 2 September, 8 December

³ For more information: www.wellcome.ac.uk/About-us/Publications/Reports/Public-engagement/WTX058859.htm