

UK Biobank Ethics and Governance Council Forty-second Meeting

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

Monday 9 March 2015 at 10.30am

Agenda

1. **Apologies**
2. **Minutes** of forty-first meeting held on 8 December 2014
3. **Matters arising**
 - (i) Tracking of requests to UK Biobank
 - (ii) Funders' review of the EGC
 - (iii) Subgroup reporting: EGF revisions
 - (iv) Subgroup reporting: Access oversight role and access reports
4. **Closed discussion on topics to discuss under item 5**
5. **Update from UK Biobank** (Professor Rory Collins, Chief Executive Officer)
 - (i) Report on applications
 - (ii) Review of the access process
 - (iii) Imaging pilot
 - (iv) Other enhancements (genotyping, web questionnaires etc.)
 - (v) EGF revisions
 - (vi) Any other developments and outstanding recommendations from EGC41
6. **Closed discussion of matters arising under item 5**
7. **Communications activities**
8. **Report on meetings attended**
 - (i) Public Health Genomics Foundation seminar, 'Using data in healthcare: policy and practice' 09/12/14
 - (ii) Board of Directors meeting 19/12/14
 - (iii) UK Biobank's participants' meeting 27/01/15
 - (iv) Interview with SATORI researcher (Stakeholders Acting Together On the Ethical Impact Assessment of Research and Innovation) 28/01/15
 - (v) Nuffield Council on Bioethics report launch: 'The collection, linking and use of data in biomedical research and health care: ethical issues' 03/02/15
9. **Any other business**
10. **Date of next meeting** 8 June 2015 – Wellcome Trust, London

**UK Biobank Ethics and Governance Council
Forty-second Meeting**

**9 March 2015
Wellcome Trust, London**

Present: Professor Roger Brownsword (Chair), Mr Andrew Russell, Dr Sheelagh McGuinness, Ms Tracey Phillips, Mrs Margaret Shotter, Dr Jonathan Hewitt, Dr Susan Wallace and Mr David Walker.

In attendance from EGC Secretariat: Ms Adrienne Hunt.

Observers: Dr Jon Fistein (Medical Research Council) and Ms Katherine Littler (Wellcome Trust) for the whole meeting.

Speakers: Professor Rory Collins (Principal Investigator and Chief Executive, UK Biobank) for item 5.

1. Apologies

Apologies were received from Professor Nils Hoppe, Professor Søren Holm and Mr Jonathan Sellors.

Member noted that Dr Sheelagh McGuinness and Professor Søren Holm have successfully applied for renewal for a further three year term.

Due to other commitments, Professor Kate Hunt has decided not to seek renewal. The Council recorded its appreciation and thanks to Professor Hunt for her immense contribution to the Council's work.

2. Minutes of forty-first meeting held on 8 December 2014

The Council approved the circulated minutes.

3. Matters arising

Tracking of requests to UK Biobank

Members noted the outstanding requests to UK Biobank.

Funders' review of the EGC

The Review Panel met on the 17 February and, in the morning session, interviewed Professor Rory Collins, the EGC Chair, Mr David Walker and Dr Roger Moore.

The Review Panel Chair and the EGC Chair have subsequently spoken and the Panel's current thinking was conveyed.

Four participant focus group sessions were commissioned by the funders as further evidence for the review. The report of this work will be shared with the EGC once the review process is complete.

The EGC should be advised of the outcomes of the review in late April.

The current EGC Chair, Professor Roger Brownsword, will step down in September. The post will be advertised once the outcomes of the review are known, with a view to the new Chair attending the EGC's September meeting. To accommodate the review timetable, members agreed to move the next meeting to June 1 and the Secretary will explore the possibility of moving the subsequent meeting to late September¹.

Subgroup reporting: EGF revisions

See item 5.

Subgroup reporting: Access oversight role and access reports

Members reviewed the new-look high level access summary reports. Mrs Lorraine Gillions and her colleagues had clearly gone to great efforts during the preparation of the reports in order to make them as informative as possible (in the light of the new oversight and reporting requirements). Members asked the Secretary to pass on their thanks.

Members proposed minor revisions to the reports, which the Secretary will feedback.

The Council agreed that there is still some ambiguity regarding the stage at which an application would be escalated to the EGC (e.g. a re-contact); this should be clarified with UK Biobank during future discussions on the access process.

4. Closed discussion on topics to discuss under item 5

Members agreed on topics to raise with Professor Collins.

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

Report on applications

There continues to be a significant increase in the rate of submitted applications and an increasing number of registrations and preliminary applications from non-UK

¹ Post meeting note: In the event, Professor Roger Brownsword agreed to serve as Chair through to the end of 2015 in order to accommodate a slight delay in the review process. The Chair vacancy will be advertised in September with a view to the new Chair attending the EGC's December meeting.

researchers. There are, however, still very few applications from researchers in the commercial sector.

A new access oversight model was recently adopted. The model includes the reporting of 'salient' access applications. Professor Collins updated the EGC on the following:

The Access Sub-Committee (ASC) has discussed an application that proposes to recruit UK Biobank participants into another study; the proposal is analogous to an earlier proposal to conduct an interventional trial, but there are no feedback issues. Under the re-contact rules the application will be escalated to the EGC in due course. (The earlier application proposed to select participants on the basis of the heel ultrasound measurement. While the question of feedback was discussed, this was not considered to be an issue; participants routinely received their heel ultrasound measurement at the end of the baseline assessment visit and so recruitment to the new study would be based on information that is already known to the participant.)

All proposals for sample use are considered by the ASC on a case by case basis. For example, the ASC has discussed a proposal to measure telomeres using the left-over samples from the genotyping project (the samples would otherwise be discarded). The ASC concentrated its discussion on issues of quality control; there is no international standard for telomere measurement. Through consideration of this and other applications, the ASC is building up its experience of sample adjudication and aims to develop the criteria under which samples can be used. The ASC is also planning to develop a strategy for release of data for nested case control studies.

UK Biobank recently learnt that an application proposing linkage to another research resource will not be pursued. Although this particular application may not progress, UK Biobank will further explore the generic issue of linkage to research resources recognising that this situation may arise again in future.

Review of the access process

UK Biobank is in the process of reviewing and revising its access process and its Access Procedures. The overall objective, in light of the ever-increasing number of applications, is to streamline the access process and simplify the Access Procedures (particularly for data-only applications) whilst retaining an appropriate level of scrutiny for applications. Members discussed a document from Mr Jonathan Sellors (Company Secretary) outlining the proposed changes and timetable for the review.

At present researchers are required to complete both a Preliminary and Main Application. In general, Dr Naomi Allen reviews the Preliminary Applications (once the access team has performed the administrative checks). Professor Collins or Dr Cathie Sudlow review the Main Applications and provide an in principle decision for the ASC's consideration. In the long term UK Biobank hopes to move towards a single application process for the majority of applications.

The streamlining will necessitate changes to the access systems (including the application portal, the review system and the Data Showcase). UK Biobank is developing a tender for the access systems rebuild. Amongst other things, the tender will include reporting requirements; the current access reports have to be prepared manually and are very time consuming.

It was agreed that a small group comprising UK Biobank, EGC and funder representatives should meet to discuss the review process and proposed changes; ideally this will take place before the systems re-build is put out to tender.

The funders advised that the Expert Advisory Group on Data Access will soon publish a report that is relevant to the access process review discussion.

Imaging pilot

18 participants are being assessed at the imaging centre per day, seven days a week with the aim of recruiting 6-8,000 participants during the pilot. A response rate of 20% is required for the main phase project to come in under budget, based on a three centre model recruiting 100,000 participants. Modelling has been undertaken with a view to deciding where best to locate the three centres (looking at where participants are now living). The modelling suggests Manchester, Newcastle and Reading.

While the desired response rate was achieved when recruiting close to the assessment centre, the rate falls below 20% when recruiting from greater distances. In order to improve the response rate UK Biobank is:

- sending repeat invitations (having recently received REC approval to do this).
- planning to run a number of participant events in Manchester to generate interest in the imaging visit.
- reviewing the exclusion criteria (half of the exclusions are due to recent joints/implants which, rather than there being a safety issue for the participant, have an impact on the DEXA scan).

A member asked if participants could self-select if they had not received an invitation to take part. Participants can do this, however, it is anticipated that all participants from the Manchester area will receive an invitation.

UK Biobank, the funders and EGC representatives will meet on the 23 March for a progress report, including an update on the imaging feedback protocol and social science research.

Other enhancements (genotyping, web questionnaires etc.)

Repeat invitations for the cognitive function web questionnaire are being sent out with a view to increasing the response rate.

An occupational history web questionnaire has been finalised and will be sent out once the cognitive function questionnaire has been completed and after a suitable delay.

The recently re-convened Enhancement Working Group will consider further web questionnaire topics. It is anticipated that some proposals will come from the research community, for example, UK Biobank has received a proposal to conduct a questionnaire on eating behaviours. The Working Group will need to be selective as there is a limit to the number of web questionnaires that can be performed.

The Working Group is also looking at enhancements related to environmental exposures. Such enhancements were explored by the previous Group but at that stage it was not clear how best to address the issue. Coming back to the issue now was probably the right choice as the increasing use of smart phones might facilitate the assessment of environmental factors.

UK Biobank is considering the feasibility of assaying infectious disease biomarkers. In addition, consideration is being given to assays of immune function. Two options are being explored: (i) Samples were collected during the baseline assessment with a view to creating immortalized cell lines for producing extra DNA. Given current technology for genetic assays, these samples are not likely to be required for this purpose. Consequently, UK Biobank is exploring the potential of using these samples for measuring immune markers. (ii) Alternatively, or perhaps as well, samples could be collected as part of the main phase imaging visit in a way that is optimized for these assays.

Genotyping

The genotype analysis and quality control work is being undertaken in collaboration with colleagues from the Wellcome Trust Centre for Human Genetics (WTCHG). Preparation of these data for the research community will include imputation work involving the 820,000 measured markers; at least 50 million markers can be imputed.

The first tranche of genotyping data for 150,000 participants was due to be released in the first quarter of 2015. However, while the remaining data transfer and quality control issues are being addressed, these data are now expected to be released in the second quarter of 2015.

Dr Colin Freeman and Professor Peter Donnelly from the WTCHG are preparing a document to help researchers understand the structure of the genotypic data. There are already many applications waiting on the release of these data.

Once released, UK Biobank is considering hosting a communications event to advertise the availability of the data and to stimulate interest. Initial discussions have taken place with the Science Media Centre.

EGF revisions

UK Biobank had planned to circulate a revised draft EGF by the end of January 2015. More recently, however, it has become clear that it would be premature to revise the EGF given that the outcomes of the imaging pilot are unknown (and that the outcomes will have implications for what is said in the EGF). Professor Collins

proposed that UK Biobank could proceed to revise certain sections of the EGF (that are not affected by the imaging work) in order to test the proposed approach and he welcomed further input from the EGC.

Any other developments and outstanding recommendations from EGC41

Professor Collins agreed to follow-up on a number of earlier discussions, namely:

- the possibility of undertaking an external audit of the Cardiff University systems that deal with UK Biobank data. An update will be included in the next biannual report.
- last year's UK Biobank, EGC and funder discussions on feedback and UK Biobank's proposal to write a note for participants. The note would re-state the project's policy on feedback and relate the policy to the recent enhancements.
- plans to prepare a re-contact monitoring report, based on the central log of re-contacts. Professor Collins proposed to discuss with Mr Andrew Trehearne (Head of Communications) how best to report on the variety of re-contacts; this could be incorporated into Mr Trehearne's biannual communications report.

The Nuffield Council on Bioethics (NCoB) recently launched its report 'The collection, linking and use of data in biomedical research and health care: ethical issues'. Professor Collins raised for the EGC's consideration the process by which members of the EGC had been involved in the NCoB's Working Group. The EGC discussed and reaffirmed its conflicts policy; members who intend to serve on another committee in their individual capacity should declare such interests so that it can be managed appropriately.

6. Closed discussion of matters arising under item 5

Members briefly discussed what questions to raise with UK Biobank during the proposed meeting on access.

7. Communications activities

The EGC Annual Review has been finalised; hard copies will be distributed and the electronic version is available on the EGC website.

A report of the EGC's 10-year anniversary public lecture and two day international conference will be finalised shortly. Availability of the hard copy report will be disseminated via various biobanking social media platforms. The electronic version of the report will be available on the EGC website and will contain links to the conference videos. Videos from the conference are available on the EGC's YouTube channel² and will also be available on a new dedicated page on the EGC website.

² www.youtube.com/channel/UChESOGb8EqJp8M1Zizfiouw

8. Report on meetings attended

Public Health Genomics Foundation seminar, 'Using data in healthcare: policy and practice' 09/12/14

The EGC Secretary attended the Public Health Genomics Foundation's seminar on data use in healthcare. This was the first in the Foundation's series of Life Sciences and Society seminars.

Board of Directors meeting 19/12/14

The EGC Chair attended the December Board meeting.

UK Biobank's participants' meeting 27/01/15

Members noted a report from Mrs Margaret Shotter who attended UK Biobank's second participant event in Edinburgh.

Interview with SATORI researcher (Stakeholders Acting Together On the Ethical Impact Assessment of Research and Innovation) 28/01/15

SATORI is 'a platform for the consolidation and advancement of ethical assessment in research and innovation. The 4-year project aims to develop a common framework of ethical principles and practical approaches so as to strengthen shared understandings among actors involved in the design and implementation of research ethics'.³ The EGC Chair and Secretary were interviewed by a SATORI researcher as part of the project's initial work to create an inventory of current practices and principles in ethics assessment.

Nuffield Council on Bioethics report launch: 'The collection, linking and use of data in biomedical research and health care: ethical issues' 03/02/15

A number of EGC members and the EGC Secretary attended the launch of the Nuffield Council on Bioethics' most recent report.

³ <http://satoriproject.eu>