

# UK Biobank Ethics and Governance Council Forty-sixth Meeting

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

Wednesday 27 April 2016 at 9.30am

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## **Agenda**

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1. **Introductions and apologies**
2. **Minutes** of the forty-fifth meeting held on 7 December 2015
3. **Matters arising**
  - (i) Tracking of requests to UK Biobank
  - (ii) Implementation of the EGC review outcomes, including revised draft Memorandum
  - (iii) Draft paper on access to stored tumour tissue
4. **Report on the annual funder, UK Biobank and EGC planning meeting**
5. **Update from UK Biobank** (Professor Rory Collins, Chief Executive Officer)
  - (i) Report on access applications:
    - Access Sub-Committee Minutes
    - Access update reports
  - (ii) Review of the access process and systems
  - (iii) Imaging update
  - (iv) Other enhancements (genotyping, web questionnaires etc.)
  - (v) Revision of the EGF
  - (vi) Communications report
  - (vii) Annual General Meeting – draft programme
  - (viii) Health outcome linkage and adjudication report
  - (ix) IT and data security report
  - (x) Any other developments and outstanding recommendations from EGC45
6. **Follow-up from the discussion under item 5**
7. **Archiving of EGC materials at the Wellcome Library**
8. **Future work programme and format of meetings**
9. **Report on meetings attended and upcoming activities**
  - (i) UK Biobank participants' meeting, Leeds 01/03/16
  - (ii) UK Biobank Board of Directors meeting 31/03/15
10. **Any other business**
11. **Date of next meetings**      AGM, 13 June, Queen Elizabeth II Conference Centre, London  
EGC meeting, 3 October, Wellcome Trust, London

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

**27 April 2016  
Wellcome Trust, London**

Present: Baroness Helene Hayman (Chair), Dr Eric Meslin (Vice Chair), Dr Sheelagh McGuinness, Professor Søren Holm, Professor Nils Hoppe, Mr David Walker, Dr Susan Wallace, Mr Turlogh O'Brien, Dr Anton Enright and Professor Sally Macintyre.

In attendance from EGC Secretariat: Ms Adrienne Hunt.

Observers: Dr Natalie Banner for items 1-5 and Ms Katherine Littler for items 6-11 (Wellcome Trust).

Speaker from UK Biobank: Professor Rory Collins (Principal Investigator and Chief Executive, UK Biobank) for items 1-5.

1. Introductions and apologies

The new EGC Chair, Baroness Helene Hayman welcomed members to the meeting and everyone introduced themselves. This was the first meeting of the newly formed EGC, with five of the ten members being new to the Council.

Apologies were received from Dr Jon Fistein (MRC) for the whole meeting.

2. Minutes of the forty-fifth meeting held on 7 December 2015

The Council approved the circulated minutes.

The Minutes record that the funders agreed to re-consider the options with regard to performing an audit of the Ethics and Governance Framework (against metrics) and an audit of the access process (from the EGC's three strand oversight model) as part of the funders' existing audit of UK Biobank, looking in particular at the frequency and timings of the audits. Members noted that there was no update on this item.

**Action:** Dr Banner agreed to follow-up with funder colleagues regarding the audit.

3. Matters arising

*Tracking of requests to UK Biobank*

Members noted the confirmation from Professor Collins that, in future, the Access Sub-Committee (ASC) Minutes will be sent to the EGC shortly after the ASC meeting (rather than waiting to circulate them for the biannual EGC meetings).

### *Implementation of the EGC review outcomes, including revised draft Memorandum*

Three main tasks were recommended by the EGC Review Panel: (i) organisation of an Annual General Meeting (AGM) (ii) updating of the EGF and (iii) updating of the Memorandum between UK Biobank and the EGC. UK Biobank has taken the lead in relation to the AGM and EGF and the EGC is leading on the updating of the Memorandum. Members discussed a first redraft of the Memorandum and agreed on further revisions.

**Action:** The Secretary will revise the Memorandum and circulate to member. If members are content, the Memorandum will then be sent to UK Biobank for input.

### *Draft paper on access to stored tumour tissue*

At a previous meeting the EGC offered to provide UK Biobank with advice on the question of the extent to which stored tumour tissue (left over from clinical investigations) can be considered part of a participant's 'health-related record' (in terms of the consent given at recruitment).

Updating new members on the issue, Professor Collins explained that a small pilot took place in Newcastle, the purpose of which was: (i) to assess whether UK Biobank could identify the existence of tumour tissue from people participating in UK Biobank who had cancer and (ii) to see if, in principle, one could access the tissue (without actually accessing it). The pilot showed that UK Biobank can in principle identify the location of the tissue. The fact that UK Biobank participants are covered by a relatively small number of tertiary centres increases the feasibility of identifying the tissue.

Members considered a draft EGC paper on the issue, which focused on the interpretation of 'medical and other health-related records' in primary legislation and guidance documents (e.g. from the NHS). It was agreed that the paper should be re-structured and revised to focus not only on the legal aspects. Evidence should be sought from a literature search and through a consultation with UK Biobank participants e.g. via an online survey or through discussion at the participants' meetings. Members suggested that the topic could also be usefully discussed at the AGM.

#### 4. Report on the annual funder, UK Biobank and EGC planning meeting

The first annual planning meeting took place the day before this EGC meeting and was attended by the EGC Chair, Vice Chair and Secretary, the UK Biobank Chair, CEO, and Secretary and representatives from the Wellcome Trust and MRC. The meeting included a review of the previous year, discussion of the priorities for the year ahead and updating of the EGF. Agreeing that the meeting had been very positive, the group have agreed to hold the planning meetings biannually in future.

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

### *Report on access applications*

**Use of the resource for hypothesis-generating research:** This type of research looks for patterns or perturbations in the data which can then form the basis for a more specific hypothesis which can then be tested. The ASC has agreed that hypothesis-generating applications should have a definable purpose, scope and output and that such applications should not be a back-door route to undertake unspecified hypothesis-testing research. UK Biobank's approach will be published on its website and made available to all researchers.

**Sample strategy:** UK Biobank's strategy is (as far as it is possible) to produce common markers from the samples so that the samples are turned into non depletable data that can be made available to all researchers. This approach has been adopted for the common biomarkers and genotyping. UK Biobank is drawing up its approach to access to sample in light of its experience so far and, as part of this work, has agreed to implement calls for nested case control research (once there are sufficient incident cases for any given disease). The general approach would follow UK Biobank's approach to date i.e. funding will be sought for the conduct of the assays to be co-ordinated centrally by UK Biobank with release of the data to all researcher at the same time. However, some applications may involve assays that are novel or otherwise do not fit within the envisaged scheme. UK Biobank has agreed a number of factors to consider when judging how to proceed with such cases.

**Re-contact applications:** Members noted that a re-contact application at 'adjudication in progress' had not been alerted to the EGC prior to this meeting. As the EGC understand it, under the terms of the EGF and the EGC's three strand oversight model, all re-contacts should be alerted to the EGC at the earliest opportunity (even if advice is only sought at a later stage). Professor Collins confirmed that this is also his understanding, although there has been some difficulty in determining when applications should be escalated to the EGC for advice (e.g. whether before or after the ASC discussion).

### *Review of the access process and systems*

UK Biobank's new Chief Information Officer (CIO), Dr Mark Effingham, is scoping out a re-build of the access systems. The new systems will be more streamlined and will facilitate better access reporting.

While it is not the EGC's role to advise on how infrastructure should be built, the security issue is important and is an aspect that the EGC will look for assurance on, especially insofar as matters of privacy protection are concerned. Members agreed that the CIO should be invited to the next meeting to provide an update on the access systems review and on data security more broadly.

Members and Professor Collins discussed whether the preferences of participants could be factored into the systems re-build (e.g. through the creation of a participant

dashboard). UK Biobank is investigating ways in which to better visualise data, which will hopefully be a benefit to both participants and researchers.

### *Imaging update*

Funding for the imaging main phase has been approved and was announced in early April. UK Biobank has now moved to lease properties in Newcastle and Reading to house the new assessment centres.

The pilot quantitative and qualitative work suggested ways in which the imaging participant information materials could be improved. UK Biobank is working on the revision of these materials and will seek input from the EGC and funders before seeking Research Ethics Committee approval.

Members noted UK Biobank's imaging reputational risk protocol, which was developed at the request of the funders. The funders are now in the process of establishing a small oversight group who will meet annually to review UK Biobank's progress against set milestones.

A report of the results of the pilot phase is currently being prepared for publication; this will include Professor Cathie Sudlow's continuing work on the follow-up of participants who have received feedback.

**Action:** At the appropriate time, Professor Collins will seek input from the EGC on the revised imaging participant information materials and pilot report.

### *Other enhancements (genotyping, web questionnaires etc.)*

**Stool collection:** The imaging Review Panel responded positively to the proposal for stool sample collection but asked UK Biobank to prepare a more detailed submission regarding the collection protocol and its validation. While funding for this work is being sought UK Biobank will pilot the stool collection protocol as part of the imaging study. If funding is successful this additional element will continue during the imaging main phase.

**Cardiac rhythm:** A funding application will be submitted to British Heart Foundation that involves the collection of cardiac rhythm data. Under the proposal participants would be asked to wear a type of band aid for a period of 2 weeks, which incorporates a chip that records the data.

**Genotyping:** Following ongoing quality control work, and a completely new re-imputation on data for all participants using new algorithms, both measured and imputed data should be released in September 2016.

**Web questionnaires:** UK Biobank's general approach is to send out no more than two web questionnaires per year (including one reminder per questionnaire). The diet questionnaire was the exception; this was circulated four times. Some of the other questionnaires may be repeated – in order to see changes over time – but

there are currently no plans to do this. The next questionnaire to be circulated will be on mood, while a questionnaire on pain is under development.

A number of the EGC participant members mentioned that they had received very little communication from UK Biobank and regretted that they had not been contacted more frequently and asked to participate in the questionnaires. This raised a questions regarding the provision of up-to-date contact details. Professor Collins advised that the annual newsletter, which is sent out electronically and in hard copy to any participants without an email address, encourages participants to update their contact details, including the provision of any new email address. Further, UK Biobank recently received updated addresses from the NHS.

**Enhancement Working Group:** This group has been re-convened under Professor Paul Elliott and is assessing options regarding environmental exposure data (e.g. through personal monitoring) and biomarker assays.

#### *Revision of the EGF*

UK Biobank recognises that it would be helpful to expand on certain aspects of the Ethics and Governance Framework (EGF) for participants but is also aware that participants are not necessarily very familiar with the EGF. The current process of updating the EGF is being taken as an opportunity to draw attention to the EGF through specific examples where there has been an expansion of thinking e.g. incidental findings in relation to the imaging. These expanded areas will be made available on the UK Biobank website as a prompt for participants and will link through to the EGF so participants can see how current practice fits with the original document. Draft text will be made available to the EGC for its input in due course.

#### *Communications report*

Members noted UK Biobank's biannual report, agreeing that the participants' meetings are a good opportunity to draw attention to the role of the EGC. Professor Collins confirmed the EGC's standing invitation to attend and speak at the meetings; Dr Susan Wallace spoke at the March meeting in Leeds.

**Action:** Professor Collins will discuss with Mr Andrew Trehearne the EGC's suggestion of holding a live Q&A webcast and will report back.

#### *Annual General Meeting – draft programme*

The AGM will take place on 13 June at the QEII conference centre. Members reviewed and provided feedback on the outline programme, which will open with Fergus Walsh from the BBC interviewing a panel of participants. Other sessions will focus on the baseline data, the genotyping work, the imaging work and follow-up and adjudication. The EGC will be involved in the various sessions e.g. as panel members, rather than having a specific session at one point in the day.

### *Health outcome linkage and adjudication report*

Following sign-off of a contract with the English primary care data system supplier TPP, progress has been made towards the extraction of data on around 200,000 participants. UK Biobank expects to receive these data during Q2 2016 and will only know at that stage how much data there is and how much work will be required to make it 'research ready'. A joint letter from the Royal College of GPs, TPP and UK Biobank was sent to GPs offering the practices an opt-out. Queries have been raised by only a handful of practices and are being dealt with through the provision of further information or copies of participant consent forms.

Quarterly updates of death and cancer data from England and Wales were re-established in Q4 2015 after prolonged discussions with the Health and Social Care Information Centre (HSCIC). Issues still remain, however, including the need for UK Biobank to re-negotiate its contract, which currently only allows data usage up to May. Members agreed that the Council would like to show support for UK Biobank in its negotiations with HSCIC, as appropriate. Professor Collins offered that Mr Jonathan Sellors could provide an update at the October EGC meeting on where UK Biobank is up to in terms of the approvals.

### *IT and data security report*

Given the scale and complexity of data now held by UK Biobank, the decision was made to appoint a new Chief Information Officer (CIO), Dr Mark Effingham. Dr Effingham will take responsibility for writing the biannual IT and data security updates in future.

UK Biobank has started to provide the genotyping data as an institutional data set. This means the data can be made available to multiple researchers from the institution who have approval from UK Biobank to access the data for a defined research purpose. This system avoids the need for multiple researchers at the same institution to hold a copy of the very large data set. Members asked if any specific restriction or safeguards have been put in place over and above the conditions that apply to data being held for a one-off project. Specifically, once the projects have come to an end could the situation arise whereby the data continue to be held by the institution for many years or are there provisions for destruction of the data that would prevent this?

**Action:** Professor Collins agreed to report back on the requirements for data destruction, as applied to data sets held at the institutional level.

### *Any other developments and outstanding recommendations from EGC45*

In 2016 UK Biobank will go through a core funding renewal process; it is anticipated that the EGC's input on UK Biobank's future plans will be sought by the funders during this process.

6. Follow-up from the discussion under item 5

**Access alerts and the new access systems:** In relation to the missed re-contact alert (see item 5), members discussed whether there might be an opportunity during the access systems re-build to move the alerts from being a manual to an automated process.

**Action:** The Secretary will raise this with Professor Collins and the CIO.

7. Archiving of EGC materials at the Wellcome Library

The Wellcome Library collects material for the study of human health in historical and cultural contexts and has one of the richest and most comprehensive collections in Europe. The Library has approached the EGC with a proposal to permanently preserve and manage its records. Members agreed that the EGC Secretary's papers should be transferred into the Library as an absolute gift on the understanding that the Secretary is involved in the sensitivity review, which is undertaken as part of the cataloguing process.

8. Future work programme and format of meetings

Members discussed future operations, including having an away day.

9. Report on meetings attended and upcoming activities

*UK Biobank participants' meeting, Leeds 01/03/16*

Members noted a report from Dr Wallace on UK Biobank's participants' meeting.

*UK Biobank Board of Directors meeting 31/03/15*

The EGC Chair attended the March Board of Directors meeting.

10. Any other business

No other business was raised.

11. Date of next meetings    AGM, 13 June, QE II Conference Centre, London  
   EGC meeting, 3 October, Wellcome Trust, London