

# UK Biobank Ethics and Governance Council Forty-third Meeting

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

Monday 1 June 2015 at 10.30am

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## Agenda

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1. **Apologies**
2. **Minutes** of forty-second meeting held on 9 March 2015
3. **Matters arising**
  - (i) Tracking of requests to UK Biobank
  - (ii) Subgroup reporting: Access meeting 27/04/15 and escalated application
  - (iii) Subgroup reporting: Imaging pilot update meeting 23/03/15
4. **Funders' review of the EGC**
5. **Closed discussion on topics to discuss under item 6 and 7**
6. **Imaging update from UK Biobank** (Professor Cathie Sudlow, Chief Scientist, Dr Naomi Allen, Senior Epidemiologist, Mr Jonathan Sellors, Company Secretary)
7. **General update from UK Biobank**
  - (i) Report on access applications
  - (ii) Review of the access process
  - (iii) Revision of the EGF
  - (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 EGC42
8. **Closed discussion of matters arising under item 6 and 7 (including escalated application)**
9. **Funders' review of the EGC (continued)**
10. **Communications activities**
11. **Report on meetings attended**
  - (i) Board of Directors meeting 27/03/15
  - (ii) Conference 'Biobanking for Research', Masaryk University, Brno 25-26/05/15
12. **Any other business**
13. **Date of next meeting** Dinner 7 September and meeting 8 September 2015, Oxford

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

**1 June 2015  
Wellcome Trust, London**

Present: Professor Roger Brownsword (Chair), Mr Andrew Russell, Dr Sheelagh McGuinness, Ms Tracey Phillips, Mrs Margaret Shotter, Professor Nils Hoppe, Professor Søren Holm, 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 from UK Biobank: Professor Cathie Sudlow (Chief Scientist) by phone for item 6. Dr Naomi Allen (Senior Epidemiologist) and Mr Jonathan Sellors (Company Secretary) for items 6 and 7.

1. Apologies

Apologies were received from Dr Jonathan Hewitt and Professor Rory Collins.

2. Minutes of forty-second meeting held on 9 March 2015

The Council approved the circulated minutes.

3. Matters arising

*Tracking of requests to UK Biobank*

Members noted the outstanding requests to UK Biobank.

*Subgroup reporting: Access meeting 27/04/15 and escalated application*

A subgroup of the EGC met with UK Biobank and funder colleagues on 27 April to discuss the proposed review of the access process. The subgroup left the meeting feeling reassured by what had been discussed, including UK Biobank's plans for streamlining the access process.

UK Biobank has received an application that requests re-contact with participants in order to invite them into another study; this application has been escalated by UK Biobank for EGC advice. A provisional discussion took place and continued under item 7 with UK Biobank colleagues.

*Subgroup reporting: Imaging pilot update meeting 23/03/15*

A subgroup of the EGC met with UK Biobank and funder colleagues on 23 March to discuss the interim findings of an evaluation of the incidental findings imaging protocol. Under the terms of this protocol, potentially serious incidental findings (PSIFs) are fed back when they are observed initially by radiographers during the imaging visit and subsequently confirmed by radiologists (or other appropriate specialists). The incidental findings protocol is running in parallel to a separate process whereby the first 1,000 scans have been systematically reviewed by a Panel of radiologists. The purpose of this process is to evaluate the standard protocol by assessing the number of false positives and false negatives. This evaluation will inform the development of the imaging protocol for the main phase, which is expected to involve 100,000 participants.

The Chair highlighted two main points arising from the interim findings: (i) that there will be a significant number of false positives if UK Biobank continues with full radiologist review of scans during the main phase (UK Biobank has predicted that there will be around 18,000 PSIF notifications under this scheme); and (ii) if UK Biobank continues with the piloted incidental findings imaging protocol (involving escalation by radiographers) approximately 2,000 PSIFs would be reported and a number of true positives would be missed. On assessing the number of true positives identified to date, UK Biobank colleagues had advised that in the majority of cases it is not clear that there is net benefit in identifying PSIFs early before the condition presents clinically.

Members returned to this discussion with UK Biobank colleagues under item 6.

The EGC Chair has redrafted the EGC feedback report to take account of recent legal developments, including the *Montgomery* decision (see item 6). During the discussion it was proposed that the report should also highlight the recent decision in *ABC v St George's Healthcare NHS Trust*, where the High Court—underlining the reluctance of English law to recognise positive duties or to impose liability for omissions—struck out a claim alleging that the defendants were in breach of duty in failing to disclose (confidential) health care information that was relevant to the claimant's pregnancy.

The feedback report will be revised and circulated to Council for comment. Members agreed to send the report to the funders and UK Biobank as soon as possible, so that, if they so wish, they can take it into account in relation to the imaging main phase application.

#### 4. Funders' review of the EGC

The funders have convened a Review Panel to assist during the EGC's quinquennial funding review. The Panel will make recommendations regarding the future remit and activities of the EGC. While the Panel's recommendations have not yet been finalised, the funders provided only a high-level verbal summary of the main recommendations.

5. Closed discussion on topics to discuss under item 6 and 7

Members agreed on a number of matters to raise with UK Biobank colleagues.

6. Imaging update from UK Biobank (Professor Cathie Sudlow, Chief Scientist, Dr Naomi Allen, Senior Epidemiologist, Mr Jonathan Sellors, Company Secretary)

Professor Cathie Sudlow and Dr Naomi Allen presented the interim findings of an evaluation of the incidental findings imaging protocol (with data up to mid-March 2015). In light of the findings, UK Biobank proposes to adopt the piloted incidental findings imaging protocol for the main phase (whereby PSIFs that happen to be noticed by a radiographer are escalated for radiological review).

Both quantitative and qualitative research is being undertaken during the pilot. An understanding of consent questionnaire has been sent to all participants 2 days after the imaging visit. This questionnaire has demonstrated a high level of understanding of the invitation materials; 96% of the consent questionnaire respondents 'knew what to expect and the aim of the study'. However, data from the questionnaire also showed that only 64% understood that there was no opt-out policy for feedback while 25% thought they had a choice and the remainder were unsure. UK Biobank colleagues and the Council agreed that more work is required to enhance the participants' understanding of this aspect of the feedback policy. It was suggested that the no opt-out policy could be re-iterated to participants as part of the eligibility check phone call.

During the qualitative research, only one of the 20 focus group participants indicated that they wanted an opt-out option (although they participated in the imaging pilot anyway). While 50% of participants informed about a PSIF felt that other participants should be given a choice to opt out, the data seem to suggest that if there was an opt-out policy participants would probably still choose feedback. The vast majority of notified participants were glad to have had the feedback despite the anxiety that was generated.

The social science research group have prepared a comprehensive report of their findings to date. This ongoing work will be published later in the year.

The Wellcome Trust has funded a research fellow to take a further and more detailed look at the impact of receiving PSIFs, including the long-term implications (e.g. by following participants' health via their NHS records). This researcher will be based with Professor Sudlow.

During the discussion the EGC Chair highlighted the recent UK Supreme Court's decision in *Montgomery v Lanarkshire Health Board* which looks like a ground-breaking decision that prioritises the right of persons to make informed health care choices. Although the context for this case is clinical rather than research, it was suggested that UK Biobank may want to consider whether the case has implications for the framing of its feedback protocol and the principles that guide its practice.

The EGC expects to receive the imaging main phase application on July 7. Members' comments will be compiled in an EGC response; the final response should be sent to the funders by August 17. The EGC Chair will attend the funders' review panel meeting in early September.

## 7. General update from UK Biobank

### *Report on access applications*

Members discussed the re-contact application with UK Biobank colleagues. Dr Allen clarified that the applicant has requested re-contact only i.e. no data and samples are required. UK Biobank will identify potential participants, send out emails containing introductory information and then it will be up to the participants to choose whether or not to consent to the new research (via the other study's website). Both UK Biobank and the other study will require Research Ethics Committee approval for this work.

It was reported that, earlier in the day, the Access Sub-Committee (ASC) had decided to approve the application on the understanding that: (i) the project will need to fit in with UK Biobank's own timetable of re-contacts; (ii) the study will serve as a pilot (the cost and resource implications for UK Biobank will be monitored and assessed, in addition to participant take-up); and (iii) the EGC does not raise any further concerns. The findings for this pilot will be used to draw up a framework for how to manage this kind of request in the future (i.e. use of UK Biobank as a recruitment platform for other studies).

It is likely that a proportion of UK Biobank participants may want to participate in other studies. So, while there is a risk of participant fatigue from multiple re-contacts, taking an overly precautionary approach creates a risk of not letting participants have the choice to be involved in other research. Two options were discussed:

- The creation of a dedicated page on UK Biobank's website to host information about third party studies; this could provide a neutral way of letting participants know about other studies. The options for third party research could also be mentioned in UK Biobank's newsletter (either highlighting specific research or simply alerting participants to the relevant webpage).
- Providing participants with the option to opt out of this type of re-contact i.e. introducing a further category of withdrawal that allows participants to opt out of receiving email invitations to participate in third party research while continuing to receive updates and invitations to participate in further UK Biobank schemes.

It was agreed that, where participants are re-contacted for this purpose, it is imperative that the introductory information from UK Biobank is absolutely clear; and, in particular, it needs to be made clear that UK Biobank and the third party study are different entities operating under different rules.

### *Review of the access process*

Due to time constraints this item was not discussed.

### *Revision of the EGF*

Due to time constraints this item was not discussed.

### *Health outcome linkage and adjudication report*

Due to the introduction of new, complex data sharing agreements and assessment procedures at the Health and Social Care Information Centre (HSCIC), the delivery of linked data for research has been delayed. One consequence is that UK Biobank has not received quarterly death and cancer event updates since around spring 2014. Everyone agreed that this is problematic as UK Biobank could potentially re-contact deceased participants. UK Biobank is currently awaiting a new data sharing agreement and hopes that regular updates will resume in a month's time.

No further primary care data has been received by UK Biobank since the last EGC meeting. UK Biobank is making progress with plans to obtain primary care data for England through the three major UK GP systems suppliers. It is hoped that linkage to primary care data from one supplier, covering approximately 120,000 participants, will occur by autumn 2015.

### *Participant and public involvement biannual report*

Members received the communications report noting that: (i) UK Biobank has hosted four participant meetings (two in Edinburgh, one in Bury and one in Cheadle); and (ii) EGC members have a standing invitation to attend future participant events. The Secretary will ask Mr Andrew Trehearne for the dates of the upcoming meetings.

### *IT and data security biannual report*

Members received the biannual report, and were reassured to see that no non-conformances were raised in the recent ISO 27001:2013 Coordinating Centre visit. Members noted that the requested schematic of data flows between the various organisations that process and/or store UK Biobank data had been omitted from the report.

At the last meeting, members sought confirmation as to whether UK Biobank might commission an external audit of the Cardiff University systems that deal with UK Biobank data. Mr Jonathan Sellors confirmed that such an audit will take place.

### *Any other developments and outstanding recommendations from EGC42*

The first tranche of genotyping data for 150,000 participants is now available to the research community, comprising 100 million variants per participant. UK Biobank will host a media briefing when the genotype data for all 500,000 participants are released later this year. This approach will allow UK Biobank to release data for the

existing main applications in the first instance as a means of testing and refining its processes before advertising the availability of the data more broadly. It is anticipated that there will be considerable interest in these data.

At the end of last year, the UK Biobank, EGC and funder discussions on feedback resulted in a proposal from UK Biobank 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 (including the imaging). Mr Sellors confirmed that the note would be prepared in the next few months.

The Council asked for an update on UK Biobank's plans to prepare a re-contact monitoring report, based on the central log of participant re-contacts. Mr Sellors confirmed that the re-contact monitoring report will be included in Mr Trehearne's communications reports.

#### 8. Closed discussion of matters arising under item 6 and 7 (including the escalated application)

With a view to formulating its advice, members discussed the re-contact application and the general principle of UK Biobank acting as a recruitment platform for other studies.

The re-contact application is clearly significant in that it will set a precedent for use of UK Biobank as a recruitment platform. By offering such a mechanism for participant recruitment, UK Biobank could provide a great benefit and service to the research community. However, facilitating this kind of request is not a neutral activity for UK Biobank. It will take time and resources that could arguably be used elsewhere. This raises two questions: (i) in what circumstances would it be acceptable for UK Biobank to divert resources to this type of application and (ii) in what circumstances would it be prudent to refuse?

The Council agreed with the ASC's conclusion that such applications will need to be balanced against UK Biobank's own email and web-based enhancement activities. UK Biobank clearly goes to great lengths to make the enhancements as valuable as possible, taking advice from the scientific community and making strategic decisions. With its own schedule of web-related enhancements, how should ad hoc third party re-contacts be accommodated? Members discussed whether there would be an advantage in putting out calls for proposals – so the most competitive can be selected – as a method of prioritising participant exposure to third party re-contact. (The Council understands that the intention is that the current re-contact application will serve as a 'pilot' and that the impact on both UK Biobank and participants will be monitored closely before any decisions are made about advertising future calls.)

The key points of the advice were agreed.

With regard to matters of process, the EGC noted that this alert took place a few months after the preliminary application had been submitted to UK Biobank. Unless there are special circumstances, the EGC takes it that the spirit of the new access

oversight model is that the EGC should be alerted at the earliest opportunity and that, along with the alert, full details of the application should be provided—this enabling the EGC to offer a carefully considered and timely opinion on the issues raised by the application.

#### 9. Funders' review of the EGC (continued)

No further issues were raised.

#### 10. Communications activities

On June 3 the EGC Chair and Secretary will meet a colleague from the South Korean Science and Technology Policy Institute.

The conference videos have been made available on both YouTube and on a new page on the EGC's website. There have been over 300 views on the YouTube channel.

#### 11. Report on meetings attended

##### *Board of Directors meeting 27/03/15*

The EGC Chair attended the March Board meeting, which took place at the Coordinating Centre in Cheadle and involved a visit to the imaging facility.

##### *'Biobanking for Research', Masaryk University, Brno 25-26/05/15*

Dr Susan Wallace spoke at a conference at Masaryk University on behalf of the EGC. The conference involved staff and students from the university and representatives from the Czech Republic biobanking community, including the national BBMRI node.

#### 12. Any other business

There was no other business.

#### 13. Date of next meeting

Dinner 7 September and meeting 8 September 2015, Oxford