

UK Biobank Ethics and Governance Council Thirty-seventh Meeting

Meeting at Medical Research Council
Room 2, Level 13, One Kemble Street, London, WC2B 4AN

Monday 9 December 2013 at 10.30am

Agenda

1. **Apologies**
2. **Minutes** of thirty-sixth meeting held on 10 September 2013
3. **Matters arising**
 - (i) Tracking of requests to UK Biobank
 - (ii) Subgroup reporting: Feedback – Imaging
 - (iii) Subgroup reporting: Feedback – EGF policy
 - (iv) EGC access oversight role
 - (v) EGC conference
 - (vi) Recruitment of new members
4. **Funders 2014/2015 review and the effectiveness of the EGC**
5. **UK Dementias Research Platform**
6. **Closed discussion on topics to discuss under item 7**
7. **Update from UK Biobank** (Dr Naomi Allen, Senior Epidemiologist and Mr Jonathan Sellors, Company Secretary)
 - (i) Imaging
 - (ii) Report on access
 - (iii) Genotyping
 - (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 EGC36
8. **Closed discussion of matters arising under item 7**
9. **Expenditure report 2012/2013 and budget 2013/2014**
10. **Risk register**
11. **Communications activities**
12. **Report on meetings attended**
 - (i) Meeting with colleagues from the Taiwan Ministry of Health and Welfare 17/09/13
 - (ii) Meeting with the funders 19/09/13
 - (iii) UK Biobank's International Scientific Advisory Board meeting 3-4/10/13
 - (iv) UK Biobank Board of Directors meeting 11/10/13
 - (v) HandsOn: Biobanks 2013 20–22/11/13
13. **Any other business**
14. **Date of next meeting** 10 March – Wellcome Trust

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

**9 December 2013
Medical Research Council, London**

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

In attendance from EGC Secretariat: Ms Adrienne Hunt.

Observers: Dr Katherine Giles (MRC) in person and Ms Katherine Littler (Wellcome Trust) by phone for the whole day.

Speakers: Dr Naomi Allen, Senior Epidemiologist and Mr Jonathan Sellors, Company Secretary for item 7 only.

1. Apologies

Apologies were received from Professor Kate Hunt and Professor Rory Collins.

2. Minutes of thirty-sixth meeting held on 10 September 2013

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: Feedback – Imaging

Over the last few months several members of Council have worked with UK Biobank and funder colleagues during the development of the imaging materials. The current meeting presented an opportunity for the remaining Council members to raise any further issues that might have been missed in the earlier discussion. No substantive issues were raised.

Subgroup reporting: Feedback – EGF policy

In September the EGC Chair, Vice Chair and Secretary met with Professor Rory Collins, Ms Tara Camm and Mr Jonathan Sellors to discuss the Ethics and Governance Framework (EGF) policy on feedback and the EGC's draft feedback report. Members were updated on this meeting and its outcome—namely, a

suggestion that UK Biobank, the EGC and the funders should convene a series of joint meetings to further discuss the EGF policy. The first such meeting is scheduled for 30 January.

EGC access oversight role

At its last meeting, on discussing the EGC's oversight responsibilities and access to information, one suggestion was that the EGC might have unrestricted access to applications for a limited period (e.g. 6 months) so that it could see applications as the Access Sub-Committee (ASC) sees them. This was seen as a further means by which the EGC might better understand the access systems, before it moves to consider a future 'audit' role.

In response UK Biobank put forward a proposal that the EGC could 'audit' the entire process and information relating to a number of approved applications (as opposed to having real-time access to applications that are being adjudicated). This proposal would be a trial after which UK Biobank and the EGC would discuss and reach consensus as to how to continue and/or amend the process. Members discussed the proposal and agreed to hold an extraordinary meeting in the New Year to discuss this further (see item 8).

EGC conference

The EGC conference will take place at the Wellcome Trust, with a capacity to seat 140 delegates in cabaret style. A public lecture is planned for the 3 November, followed by the two day conference on the 4 and 5 November.

Recruitment of new members

Up to three new members of Council will be sought in the New Year. An Appointments Committee has been convened comprising:

- Chair – Professor Roger Brownsword (EGC Chair)
- Independent Member and Assessor – Dr Kathy Liddell
- Wellcome Trust Governor – Professor Dame Anne Johnson
- Medical Research Council member – Baroness O'Neill of Bengarve
- Additional EGC member – Dr Jonathan Hewitt

The appointments will be advertised in late January, with the interviews taking place on the 25 March.

4. Funders 2014/2015 review and the effectiveness of the EGC

Agreeing that this item is closely linked to the question of the EGC's oversight role, the Chair proposed that this item should be discussed at the extraordinary Council meeting in the New Year.

5. UK Dementias Research Platform

Dr Kath Giles provided an introduction to the MRC UK Dementias Research Platform which 'aims to bring together many of the UK's best-characterised cohorts to create a unique single research platform for the investigation of dementia'¹. The project is being led by Professor John Gallacher. Because UK Biobank will be a key cohort involved in this new Platform, members agreed to invite Professor Gallacher to attend a future EGC meeting to talk about this work.

6. Closed discussion on topics to discuss under item 7

Members raised a number of matters to discuss with UK Biobank under item 7.

7. Update from UK Biobank (Dr Naomi Allen, Senior Epidemiologist and Mr Jonathan Sellors, Company Secretary)

Imaging

A new version of the imaging materials will be available on Friday 13 December. Mr Jonathan Sellors proposed that he, Professor Rory Collins and the EGC Chair meet that day after the Board of Directors meeting to talk through the changes. The EGC expects to receive the final materials from the funders on 17 December and will provide comments as part of the formal review process by 16 January.

Report on access

Members appreciated receiving the run of access papers and the verbal update on a number of specific applications, not least the further discussions concerning linkage between cohort studies.

UK Biobank colleagues provided a useful clarification regarding the different terms (e.g. legal) involved in UK Biobank commissioned work (e.g. Professor John Gallacher's work on the Healthy Minds Project) versus applications for access. Where a researcher is directly commissioned by UK Biobank to generate information, the researcher will have no preferential access; if they wish to use the data, they will be required to submit an access application.

Noting that a number of research projects have produced results, the EGC requested an update for its next meeting on UK Biobank's procedures and experience of having researchers return results and on these being incorporated into the resource.

Genotyping

The Council was provided with an update on the genotyping work, which is progressing well.

¹ www.mrc.ac.uk/Ourresearch/Resourceservices/UKDementiasResearchPlatform/index.htm

Health outcome linkage and adjudication report

Members discussed a comprehensive report on UK Biobank's progress with receipt, 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. A number of challenges have been faced, not least navigating a range of complex regulatory and permissions processes, the interpretation of complex dataset structures (e.g. the hospital episode data) and presenting complex data to researchers in an understandable way.

UK Biobank has achieved linkage for almost all participants to hospital episode databases covering hospitals in England (Hospital Episode Statistics [HES]), Wales (Patient Episode Data for Wales [PEDW]), and Scotland (Scottish Morbidity Record [SMR]). These data are currently complete to the end of 2010. UK Biobank colleagues advised that the processing, checking and incorporation into the UK Biobank database of the complex data from HES is now complete for 2006-2010. Explanatory documentation and summary information has been prepared to describe the data available to researchers, and a simple system has been established for displaying hospital episode data within Showcase for selection by researchers (focusing on incident outcomes). In due course, the same approach will be applied to the PEDW and SMR datasets, and to the HES, SMR and PEDW retrospective (pre 2006) and outpatient data.

UK Biobank plans to collect data from participants by web questionnaire. Cognitive function, occupational history and mental health questionnaires are currently planned while other potential, future topics will be discussed at a dedicated meeting early in 2014. Members asked whether participants would get a good sense of what is happening if they looked at UK Biobank's website. UK Biobank colleagues advised that the website provides information about what is coming up in the next 12 months on the Data Showcase, including the availability of data from the web questionnaires.

Participant and public involvement biannual report

Members received this report for information.

IT and data security biannual report

Members thanked UK Biobank for producing such a comprehensive report and for addressing in particular the Council's query regarding the data security provisions of the Cardiff University systems that deal with UK Biobank data.

Any other developments and outstanding recommendations from EGC36

The Ethics and Governance Framework (EGF) was last revised in 2007 and as such does not reflect the full gamut of current UK Biobank activities. Members and UK Biobank colleagues exchanged views about how the EGF might be best updated.

8. Closed discussion of matters arising under item 7

EGC access oversight role

On considering UK Biobank's proposal the EGC noted and decided that:

- The proposal does not directly respond to the EGC's request for a 6-month trial view of the database.
- The proposal has been couched in terms of being tentative (i.e. for discussion) and flexible (in terms of which applications the EGC could 'audit' and the timing of the 'audit').
- The Council is seriously contemplating changing to an 'audit'/scrutiny role but is approaching this in a cautious way i.e. if the EGC was to accept the proposal it would be on a 'without prejudice' basis.
- The funders have indicated that it would be useful if the EGC could articulate how it interprets its oversight responsibilities.
- The Council will meet on the 30 January to discuss its oversight role and UK Biobank's proposal, all in the light of the funders' quinquennial review that will commence in 2014.

9. Expenditure report 2012/2013 and budget 2013/2014

Members noted that the total spend on EGC operations in 2012/2013 was £92,098 (76% of the budget). £161,574 has been allocated for the 2013/2014 budget year, including ring-fenced consultation fees of £30,000 (which require prior approval from the funders e.g. before any research is commissioned). No consultation work was commissioned during the 2012/2013 budget year.

The Secretary advised that the increase in budget relates to the recruitment of new members (advertising costs) and the 10-year anniversary conference. When the 2013/2014 budget was approved the EGC anticipated holding the conference at an external venue, but this will now be held at the Wellcome Trust. As such it is anticipated that the budget will be reforecast and revised down early in 2014.

10. Risk register

While a formal risk register was not deemed necessary, members agreed that the Secretary could usefully draw up a list outlining the potential risks that relate to the EGC's work.

11. Communications activities

Professor Michael Tai, a member of the Taiwan Biobank Ethics and Governance Council, has been in contact with the UK Biobank EGC Secretary regarding a potential visit to the UK in Spring 2014.

12. Report on meetings attended

Meeting with colleagues from the Taiwan Ministry of Health and Welfare 17/09/13

The EGC Vice Chair and Secretary met with Dr Chun-Fen Chou and Dr Lily Y.C. Lo from the Taiwanese Ministry of Health and Welfare and discussed the remit and activities of the EGC in addition to the governance of biobanking and tissue regulation.

Meeting with the funders 19/09/13

The EGC Chair and Secretary met with the funders as part of their series of 6-monthly meetings. Discussion included the draft imaging materials, the EGC feedback report and the EGC's oversight responsibilities.

UK Biobank's International Scientific Advisory Board meeting 3-4/10/13

The EGC Chair attended the ISAB meeting at which the main point for discussion was UK Biobank's imaging materials.

UK Biobank Board of Directors meeting 11/10/13

The EGC Vice Chair attended the October Board meeting.

HandsOn: Biobanks 2013 20–22/11/13

The EGC Chair attended the HandsOn: Biobanks conference.

13. Any other business

Members agreed to hold the 2 September 2014 EGC meeting in Manchester.

14. Date of next meeting 10 March – Wellcome Trust