

# UK Biobank Ethics and Governance Council Thirty-sixth Meeting

Meeting at Royal York Hotel  
Station Parade, York, YO24 1AA

Tuesday 10 September 2013 at 9.30am

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## Agenda

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1. **Apologies**
2. **Minutes** of thirty-fifth meeting held on 20 May 2013
3. **Matters arising**
  - (i) Tracking of requests to UK Biobank
  - (ii) Subgroup reporting: Access
  - (iii) Subgroup reporting: Feedback – draft feedback report
  - (iv) Funders' response to the EGC work plan
  - (v) Effectiveness of the EGC
4. **Imaging pilot**
5. **Closed discussion on topics to discuss under item 6**
6. **Update from UK Biobank** (Ms Tara Camm, Access Sub-Committee Chair, Mr Jonathan Sellors, Company Secretary and Mrs Lorraine Gillions, Research Access Administration Manager)
  - (i) Report on access process and applications
  - (ii) Data linkage between cohort studies
  - (iii) Draft re-contact procedures
  - (iv) Genotyping
  - (v) Imaging pilot
  - (vi) Any other developments and outstanding recommendations from EGC35
7. **Closed discussion of matters arising under item 6**
8. **Changes in EGC membership**
9. **Risk register**
10. **Communications activities**
11. **Report on meetings attended**
  - (i) Board of Directors meeting 28/06/13
  - (ii) National University of Singapore workshop 'Pathogen Diversity in South East Asia' 07/08/13
12. **Any other business**
13. **Date of next meeting** 9 December 2013 - MRC, Level 13, 1 Kemble Street, London

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

**20 May 2013  
Royal York Hotel, York**

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.

In attendance from EGC Secretariat: Ms Adrienne Hunt.

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

Speakers: Ms Tara Camm, Access Sub-Committee Chair, Mr Jonathan Sellors, Company Secretary and Mrs Lorraine Gillions, Research Access Administration Manager for item 6 only.

1. Apologies

Apologies were received from Professor Kate Hunt, Professor Heather Widdows and Professor Rory Collins.

In November Professor Widdows will step down from the Council, having reached the end of her second term of office. The Chair recorded and highlighted Professor Widdows's invaluable contribution to the Council over the years, in particular her clear focus on the public good.

2. Minutes of thirty-fifth meeting held on 20 May 2013

The Council approved the circulated minutes.

3. Matters arising

As the UK Biobank cohort ages, an increasing number of participants may not have the capacity to consent to new data/sample collections. At its last meeting the EGC briefly discussed this in the context of UK Biobank's cognitive function web questionnaire, which will be rolled out to participants shortly. While not an item on the current agenda, members agreed not to lose sight of the issue of the cognitive decline of the cohort over time (and the implications for future participant re-contacts).

*Tracking of requests to UK Biobank*

Members noted the outstanding requests to UK Biobank.

### *Subgroup reporting: Access*

The EGC access subgroup reported back from its July meeting, including discussion of the EGC's oversight responsibilities. The access database and the EGC's level of access to information were also discussed.

### *Subgroup reporting: Feedback – draft feedback report*

The Council discussed the latest draft of its report on feedback with a view to the EGC Chair and Vice Chair discussing the report with Professor Rory Collins, Ms Tara Camm and Mr Jonathan Sellors later in September.

### *Funders' response to the EGC work plan*

The funders have approved the EGC work plan 2013 – 2015 and the two-year pro-rata extension of the existing funding envelope, subject to the Council considering different models for the proposed conference in order to bring down the costs.

In response to the funders' directive, members agreed to explore the possibility of holding the conference at the Wellcome Trust and agreed that a registration fee should be charged. Ideally the conference will be held in cabaret style to promote small group discussion.

### *Effectiveness of the EGC*

The Chair advised that this item will be taken at the December Council meeting, when members will be asked to reflect on the EGC's activities and effectiveness and to think about the key topics for its quinquennial review submission. The funders' quinquennial review is expected to take place from Spring 2014 – Summer 2015 and will include consideration of, amongst other things, the nature and scope of the EGC's advisory and oversight role.

## 4. Imaging pilot

Members discussed the first draft imaging materials with a view to feeding these comments into the upcoming series of meetings with UK Biobank and funder colleagues.

The Council will provide comments on the finalised materials as part of the funders' formal imaging review process.

## 5. Closed discussion on topics to discuss under item 6

No further matters were raised.

6. Update from UK Biobank (Ms Tara Camm, Access Sub-Committee Chair, Mr Jonathan Sellors, Company Secretary and Mrs Lorraine Gillions, Research Access Administration Manager)

### *Report on access process and applications*

Ms Tara Camm and Mrs Lorraine Gillions provided a thorough account of the end-to-end access process. The presentation and subsequent discussion touched on aspects such as how applications are prioritised for the attention of the Access Sub-Committee (ASC); criteria for evaluating applications which use depletable samples or involve re-contact; adjudication of phased applications and reasons for which an application might be declined. It was very valuable to hear directly from the ASC Chair about the Sub-Committee's current thinking on these issues and how experience is – and will continue to – inform the ASC's deliberations.

Six ASC meetings have taken place to date, meaning it is still very much early days. A manageable and steady number of applications have been received by UK Biobank, which has allowed the ASC to take a measured approach during this early stage. The ASC has reviewed the applications at the granular level but over time will reduce the information it processes on individual applications (in particular for data only requests). In time the ASC's focus will move to applications that involve the use of depletable samples or where there are precedent setting or other issues.

The ASC uses broad criteria to adjudicate applications that involve depletable samples. To date, only one such application has been declined – it being judged that the value of the proposed research did not outweigh the significant burden on the resource.

UK Biobank requires researchers to submit an annual report on the progress of their research projects; the initial tranche of reports are due shortly. The UK Biobank Access Procedures also state that researchers should do their best to publish their findings in an academic journal or in an open source publication. The initial outcomes of research are beginning to be reported publicly, for example, a paper is soon to be published in a journal and other research results were reported recently at a conference. While approval from UK Biobank is not required, researchers must provide copies of all such reports to UK Biobank at least two weeks before their expected presentation or publication date. A dedicated space on UK Biobank's website will provide details and links to published papers.

The access process was recently streamlined and the systems changes are now coming into effect (for example there is no longer a requirement for the researcher to select variables for a Preliminary Application but broad variables are selected as part of a Main Application submission). Mindful that the funders require UK Biobank to undertake a further review of the access process, UK Biobank colleagues advised that the recent changes and technical issues should have bedded down by the end of the year. As such the next review might be more substantive if undertaken mid-2014.

### *EGC oversight*

At its May meeting the EGC discussed the possibility of moving towards an 'audit' (or 'scrutiny') model where the emphasis of the EGC's access oversight would be largely of an *ex post* nature. Ms Tara Camm's attendance at this meeting was a valuable step for the EGC in terms of gaining a better understanding of the full access process. 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 ASC sees them. This is a further means by which the EGC might better understand the access systems, before it moves to consider a future 'audit' role.

One of the key 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. Examples here might be UK Biobank's policy on handling re-contact applications or dealing with linkage requests.

### *Data linkage between cohort studies*

This item was held in closed session.

### *Draft re-contact procedures*

UK Biobank shared with the EGC its draft re-contact procedures, the aim of which is to outline the circumstances in which UK Biobank may re-contact its participants and the criteria that it uses (will use) to determine for each category of re-contact whether such re-contacts are appropriate. The procedures identify three main categories of re-contact: for the purpose of communication by UK Biobank; for the purpose of additional phenotyping by UK Biobank; and for the purpose of third party research, where re-contact may involve additional phenotyping by the researcher. Members agreed to provide UK Biobank with written comments.

### *Genotyping*

The Council received a comprehensive update on UK Biobank's plans for the genotyping analysis work, including the proposed sample and data flow.

### *Imaging pilot*

UK Biobank proposes to adopt a limited feedback loop during the imaging pilot whereby any potentially serious findings that happen to be noticed by the radiographer, and that are subsequently verified by a radiologist, will be fed back to participants and their GP. Reviewing the circulated imaging materials, the EGC and UK Biobank colleagues discussed the proposed evaluation of the feedback process, the proposal to provide no option to opt-out of feedback and the need for both quantitative and qualitative assessments of the participants' experience of receiving feedback.

### *Any other developments and outstanding recommendations from EGC35*

The Council re-iterated a request (and query) from its previous meeting, namely, who has responsibility for the data security provisions of the Cardiff University systems that deal with UK Biobank data (e.g. relating to the Participant Resource Centre) and do their systems fall within the scope of UK Biobank's ISO 27001:2009 Certification? This query should be addressed at the next Council meeting under UK Biobank's biannual IT and data security report.

#### 7. Closed discussion of matters arising under items 6

It was recognized that the formal quarterly Council meetings are not the most constructive forum for unfettered and in depth discussion with UK Biobank colleagues and that other methods of working could be more effective. For example, small roundtable group discussion – as happened during the development of the access procedures – might facilitate more open debate between the EGC and UK Biobank. Candidates for such discussion might be UK Biobank's draft re-contact procedures and any future policy decisions in relation to access and use of the resource. The EGC will contact UK Biobank and offer to participate in small group discussion on these and such future issues.

#### 8. Changes in EGC membership

EGC membership was discussed in the context of the EGC's funding cycle and the upcoming quinquennial review (which will consider the constitution of the EGC, including size and expertise). It was agreed that two new members should be recruited for Spring 2014 and that two current members – who would otherwise step down at the end of 2013 – should be offered a 6 month extension.

#### 9. Risk register

Mixed views were expressed on the need for the EGC to develop and maintain a risk register. Members agreed to discuss this further at the next meeting.

#### 10. Communications activities

Members were informed about a number of upcoming meetings and conferences, namely: Later this week the EGC Vice Chair and Secretary will meet with colleagues from the Taiwanese Ministry of Health and Welfare; the EGC Vice Chair will attend the Genomics England's first 'Town Hall' engagement event in October and the EGC Chair will attend the HandsOn: Biobanks 2013 conference in November.

## 11. Report on meetings attended

*Board of Directors meeting 28/06/13*

The EGC Chair attended the June Board of Directors meeting.

*National University of Singapore workshop 'Pathogen Diversity in South East Asia'  
07/08/13*

The EGC Chair presented a paper entitled 'UK Biobank and the Ethics and Governance Council: A Work in Progress' at a workshop of the National University of Singapore.

## 12. Any other business

At its last meeting the EGC agreed that it should learn more about informatics and the risks and benefits of cloud computing and agreed to invite speakers to its December meeting to provide an overview of these topics. It was agreed that the presentations should be postponed until the March meeting and that, in the meantime, the EGC should keep abreast of the work of the Nuffield Council on Bioethics Working Party on Biodata (which is chaired by the EGC Vice Chair). The Working Party is in the process of arranging a number of events with a similar theme (informatics and '-omics').

## 13. Date of next meeting

9 December 2013 - MRC, Level 13, 1 Kemble Street, London