

UK Biobank Ethics and Governance Council: Workplan 2009 – 2010

The Funders have requested an EGC workplan for the period January 2009 – September 2010 as one outcome of the 2008 EGC review. This paper responds to this request.

Two main categories of activity are identified in this paper– those in which the EGC takes a proactive role (for example its own public engagement work or commissioning of research) and those where it has a reactive role (for example to developments of UK Biobank). We have indicated below how the EGC's own proactive initiatives will be taken forward in 2009 - 2010. For the reactive category we have highlighted the areas which the EGC hopes UK Biobank will bring to it for advice in the specified period.

1. Proactive

1.1. Communications

- 1 *EGC public meetings and public engagement activities*
Timing: February and September 2009 and one meeting in 2010. The Council is actively experimenting with different public engagement techniques to raise its profile and to reach a wider range of members of the public and other interested audiences.
- 2 *Representation at Science Festivals*
Timing: We are making plans to take part in the Manchester Science Festival in October/November 2009. If this is successful we will plan to take part in a different festival in 2010. This is a new initiative in the period 2009-2010.
- 3 *Active participation in the Public Population Project on Genomics*
Timing: 2 meetings/year in Spring and Autumn. This will increase the potential reach and influence of the Council in the governance of biobanks world-wide.
- 4 *Raising the EGC's profile by attending and/or presenting at conferences and meeting with international stakeholders*
Timing: Ongoing as and when opportunities arise e.g. Graeme will be speaking at the National Cancer Research Institute workshop on cancer biobanking (January 2009) and the GeneBanC-project international conference on the ethical, legal and governance aspects of biobanking (May 2009). The Council might consider hosting a conference on governance in 2010.

1.2. Subgroup work

- 1 *Access and Intellectual Property (AIP)*
The Council considers that the AIP policy and procedures ought to be a key priority for UK Biobank and for itself in the coming two years. We have advised UK Biobank on previous drafts of its AIP policy and have recently provided Mr Sellors with a comprehensive list of questions that we recommend should be addressed in future policies and procedures. The subgroup aims to meet with Mr Sellors early in 2009 to discuss this list and the future development of the procedures. The timing of the subgroup's work in this area is to a large extent

dependent upon UK Biobank's progress in developing further draft policies and procedures.

2 *Communications*

This subgroup considers the EGC's communications strategy broadly, including location and timing of public events, involvement and development of topics for Science Festivals, website issues etc. The subgroup meets on average twice a year between Council meetings and maintains email contact throughout the year, as necessary.

3 *IT/Security subgroup: a new initiative for 2009-2010*

The Council has identified IT and data security as one of its priority areas. We had hoped to recruit an information systems security specialist in the 2008 round of recruitment. This was not possible and the Council is now considering other strategies for receiving expert input. At its December 2008 meeting the EGC agreed to establish a new subgroup to examine this area in more detail on behalf of the full Council. The subgroup will develop the EGC's work in this area in the period 2009 - 2010 and, in particular, it is expected to develop a series of questions which will form the basis of an EGC commission of an IT/security expert to review UK Biobank's IT and data management strategy (i.e. reporting on UK Biobank's activities in an expert testimony to the Council). If useful, this testimony might be commissioned on an annual basis.

1.3. External speakers

The Council will continue the practice of inviting guest speakers to address particular topics pertinent to its work.

1.4. Consultations

A proportion of the Council's budget is set aside for commissioning research. The Council has received anecdotal evidence that its ability to commission research is considered as a very real indicator of its independence. At least two commissions are currently being considered:

1 *IT/security testimony* (see section 1.2)

- 2 *A workshop on how to achieve participant representation in biobanking activities*
The question of how participants' interests can be represented in biobanking activities has often been raised with the EGC, both at academic conferences and by members of the public at the Council's public meetings. The Council is interested in drawing on the academic work in this area and in exploring possible models for participant representation and the feasibility of applying these models to UK Biobank. In light of this we are considering organising a workshop to bring together the main actors in this area. We welcome a discussion with the funders on this proposal.

1.5. Foresight

- 1 *Expansion and evolution assessment* (March 2010 – September 2010).
Further to a discussion with our Funders on 5 December 2008, the Council would

be willing to conduct an expansion and evolution assessment, including a consideration of the scope of the Council's remit with respect to projects other than UK Biobank. This would directly inform the next EGC review.

2. Reactive

It must be re-iterated that much of the work of the EGC is necessarily driven by initiatives and developments within UK Biobank itself. In this respect, we see our work distilling into the following categories.

2.1 Monitoring of UK Biobank's conformance with the EGF

The Ethics and Governance Framework (EGF) describes UK Biobank's high-level policy commitments to participants, research users and the public. A key feature of the Council's remit is to monitor UK Biobank's conformance with these commitments, in particular as the high-level policies are implemented through detailed procedures. For example, during the development of UK Biobank the Council spent a great deal of time reviewing the project's participants materials and consent form in order to monitor that their content conformed with the elements described in the EGF (Section I.B.1).

The Council undertakes to check the project's compliance with the EGF primarily through its interactions with UK Biobank at Council and subgroup meetings. The Council receives a number of biannual reports from UK Biobank which assist in this monitoring aspect of its remit. These reports provide both information on UK Biobank activities and a platform for detailed discussions on those activities. For example, UK Biobank's plans for follow up through a participant's health record and other 'health-related' records are likely to give rise to discussions on how broadly 'health-related' might be interpreted. The Council is currently engaged in an interactive process with UK Biobank and how this crucial term might, and will be, interpreted.

The Council currently receives the following biannual reports from UK Biobank:

- 1 IT and data security (to the June and December meetings)
- 2 Complaints and enquiries (to the June and December meetings)
- 3 Follow up of participants through medical and health-related records (to the March and September meetings)

Monitoring UK Biobank's conformance with the EGF will continue to be a key objective of the Council in the period 2009 – 2010. For example, the Council will monitor how the policy commitments regarding access, intellectual property and on the sharing of data and research findings are reflected in UK Biobank's detailed procedures.

2.2 Reviewing and advising

1 Enhanced phenotyping of participants

This topic has been discussed at recent meetings, focussing in particular on the question of whether or not feedback should be provided for the category 3 enhancements. The full proposal should be considered by the Council at its March 2009 meeting with the discussion potentially continuing through to the June meeting. If UK Biobank receives funding for the category 3 enhancements the Council would hope to review and advise

on the participant materials and review the outcomes of the pilot phase. In particular the Council would hope to review any participant attitude survey that might be conducted as part of the pilot. This work would likely be late 2009 through to 2010, depending on when UK Biobank develops its materials and conducts the pilot.

2 Access and Intellectual Property (AIP)

The Council has strongly encouraged UK Biobank to further develop its AIP policy and procedures in the short rather than longer term. This will be a major area of work for UK Biobank and in turn for the EGC as the project moves from the recruitment to access phase. This shift in phases corresponds with the end of the current funding period of the Council and represents an ideal opportunity to revisit the work of the Council in tandem with a shift in focus for UK Biobank. Given this, the Council hopes that UK Biobank will provide a draft version of its AIP procedures for at the latest, the June 2009 Council meeting. It is likely that the subsequent developments and refinements of the procedures and policy will be considered at most EGC meetings in the period 2009 – 2010. In addition, as already mentioned above, the EGC's AIP subgroup will – and has – offered to provide advice to UK Biobank between Council meetings.

3. Operational

Of note, 5 members' terms of office end in November 2010 in addition to the Chair's term of office ending in August 2010. The agreed recruitment process involves a 12-week timetable such that the members' and Chair's appointment processes would ideally begin in August 2010 and in May 2010, respectively. While the EGC will continue to be responsible for appointing new members, the Funders continue to be responsible for managing the process of recruiting a new Chair. We mention this here because the Funders might wish to time the next review of the Council (prior to confirming funding after September 2010) to coincide with this timetable. For example, recommendations from the review regarding the expertise that should be represented on the Council from 2010 and beyond could be taken into consideration when seeking new members.

Success/impact indicators

The success of a body like the EGC is difficult to measure for many reasons; much feedback to date is very positive but anecdotal. Notwithstanding, potential indicators include:

- A continued positive and productive working relationship with UK Biobank
- An increased public profile for the Council in positive terms
- An increase in public participation at EGC public events
- An increase in traffic on the EGC website (which could be subject to a Google Analytics survey)
- Evidence of EGC good practice being adopted in other biobanks
- The absence of adverse feedback from the public or negative reports in the media with respect to ethical aspects of the UK Biobank