

**Summary of decisions and recommendations from
the Twenty First Meeting of the UK Biobank Ethics and Governance Council
(7 December 2009)**

1. The Council approved the circulated minutes and summary of decisions and recommendations of its twentieth meeting.
2. The EGC information security subgroup recently visited the Clinical Trial Service Unit (CTSU) to meet with colleagues from UK Biobank and CTSU (including those responsible for the security of UK Biobank's data). The purpose of the visit was for the subgroup to arrive at the level of reassurance about data security that it and participants might expect. The subgroup reported that the meeting was both open and constructive with a number of topics having been discussed (see full meeting report for details).
3. The Council discussed the March 2010 public meeting format and the possibility of holding an engagement exercise focused on UK Biobank's Access and IP (AIP) procedures. The following was agreed:
 - The EGC will hold a public meeting in March 2010 using the traditional meeting format. While issues of AIP might be raised and discussed, the purpose of the meeting is not to consult specifically on the AIP procedures.
 - The Council should be clear as to the respective role and responsibilities of the EGC and UK Biobank in relation to the duty to consult the public in relation to the AIP procedures (see point 11).
 - In 2008 the Council commissioned a public attitude survey, involving telephone interviews and focus groups, to consider issues of access to UK Biobank. It is likely that any further consultation by the EGC at this stage would not add to the findings of this or other public attitude studies which have investigated this topic. The next step for the Council is to see how UK Biobank responds to these findings during the development of its procedures.
 - Further consideration will be given to the idea of an AIP consultation event, in light of both the outcomes of the EGC's 8 December workshop on public involvement and UK Biobank's public consultation plans. [Communications subgroup, AH]
4. The March 2010 public and Council meeting dates were changed from 15 and 16 March to 22 March.
5. The three completed equality and diversity assessments - on the Council's published material, its public meetings and the process by which members are recruited - will be posted on the EGC website and the outcomes further considered (e.g. improving the accessibility of the website). [AH] The method of systematically considering the Council's activities in relation to equality and diversity issues should henceforth be a routine aspect of how it does business. [All]
6. Professor Martin Richards and Professor Ian Hughes were voted to serve as joint Vice Chairs of the EGC.
7. The EGC will be reviewed by its funders in 2010 in parallel with a review of the UK Biobank project. The draft EGC review submission will be revised in light of members' comments and an indicative budget for 2010 - 2015 drawn-up based on the identified activities. [AH]
8. Members noted that the total spend on EGC operations in 2008/2009 was approximately £95,936 (81% of the budget). £145,786 has been allocated for the

2009/2010 budget year (including costs associated with the workshop on public involvement).

9. Professor Erica Haines has resigned from the Council with effect from January 2010 having recently been invited to join the Ethics and Public Policy Committee of the International Society of Stem Cell Research and, as a co-opted member, the Ethics and Law Advisory Committee of the Human Fertilisation and Embryology Authority. On behalf of the Council the Chair wished her well for the future and her new appointments.

Recommendations and requests to UK Biobank

10. Request and recommendation – UK Biobank information systems

In light of the inter-relationship between the two organisations, UK Biobank is commissioning an audit of the IT systems and procedures within CTSU that relate to UK Biobank. The EGC information security subgroup reiterated its request for sight of the Terms of Reference of the audit.

The Council recommended that UK Biobank publish up-to-date information about the project's data management and security processes for participants e.g. through revision of the 'Confidentiality' section of the Ethics and Governance Framework and/or through publication of a separate lay summary of the processes and actors involved, to be published on UK Biobank's website. This last option is highly desirable given evidence that privacy concerns remain high on the agenda and a source of quick reassurance on a dedicated page might help to allay any fears.

11. Request and recommendation – Access and IP (AIP)

The Council received UK Biobank's draft skeleton procedures in November and has provided initial feedback to the project's Board of Directors (see Annex A). Members discussed a version of the procedures which the Secretary had annotated with individual EGC members' comments. Further, these comments have been synthesised into a list of core issues, which served as a framework for the discussion with UK Biobank.

The Council agreed to send to UK Biobank:

- a. the EGC annotated skeleton procedures including the list of core issues.
- b. the EGC's list of questions which has been revised in light of the skeleton procedures.

The Council was keen to know how addressing the EGC's questions fits in with UK Biobank's timetable for developing its procedures. For example, does UK Biobank aim to address all of the questions in the first draft procedures or will some questions only be addressed in later drafts? An answer to this question would be welcome as soon as possible and before the March 2010 Council meeting. The Council has, for example, tried to make it clear to UK Biobank which questions it considers should be addressed as a matter of priority.

UK Biobank's timetable indicates a public review of the procedures towards the end of 2010 – the Council would welcome further information regarding what form this

will take. (An answer to this question in the short term would assist the Council as it considers what public consultation, if any, it might itself undertake in 2010).

UK Biobank is advised to consider whether or not there are any equality and diversity issues to be considered in relation to the access and IP procedures. This is part of the Council's general position on equality and diversity, viz, that assessments should become a matter of course for all policies and procedures adopted by UK Biobank.

12. Request – *Post-visit survey*

The Council welcomed the update on UK Biobank's revision of its post-visit survey and looks forward to the revised survey being circulated to EGC members for further comment.

Annex A Recommendations: Access and intellectual property procedures

The Ethics and Governance Council, particularly through its sub-group on Access and Intellectual Property (AIP), welcomes sight of these draft skeleton procedures. It considers these to be a useful start in the process towards the development of a robust access mechanism that is fit for purpose for the model on which UK Biobank is founded.

The Council has a number of questions and queries about specific aspects of the draft procedures and is happy to share these with UK Biobank. We consider, however, that there are certain fundamental matters which require clarification before attention is turned to any further level of detail.

UK Biobank is founded on a model of trust and broad consent and with the primary objective of building a resource to be managed in the public interest. We believe that continued and on-going consideration must therefore be given to the interests of participants and to the use of the resource in the public interest and that this ought to be adequately reflected in any access mechanism adopted by UK Biobank.

Public interests - It is clear that there is a strong public interest in scientifically sound health-related research, but the UK Biobank access policy and procedures cannot proceed on this basis alone. Other public interests may be at stake with any given proposal, such as (lack of) public support for the uses to which the resource will be put or public concern about the ways in which research results are commercialised. A robust access mechanism must be able to identify and respond appropriately to the potential range of public interests at stake, and it must be clear about how conflicts between public interests will be resolved.

Privacy and other private interests - The protection of privacy is central to the interests of participants which are at stake in the maintenance and operation of UK Biobank. Even if a request for access to data (or samples) appears straightforward and valuable in scientific terms, the likely impact on privacy must be considered. A robust access mechanism must be able to assess and weigh in the balance any privacy risks and must do so at the earliest possible juncture within access

procedures. Furthermore, other interests of participants might be at risk with different kinds of request for access, for example, those involving re-contact.

Decision-makers - The unique governance model of UK Biobank, the range of public and private interests at stake and the broader ethical and social issues involved must all be reflected in the UK Biobank access mechanism. The draft skeleton procedures identify key decision-makers as (a) UK Biobank itself (and its Board), (b) an Access Committee, (c) the Ethics and Governance Council and (d) Ethics Committee. However, there is no information on how access applications will be classified in order to receive appropriate scrutiny (including how public interest will be judged). Clarity regarding the roles, training and responsibilities of key decision-makers is required in addition to clarity regarding their relationships to each other.

We understand that the full details will emerge over time and for this reason we have recommended that UK Biobank should be working towards the production of Pilot Procedures by December 2010, to be tested thereafter. Furthermore, it is recommended that in the first instance the Access Committee should be involved in all decisions until greater clarity emerges. Its composition should include individuals drawn from ethics, law and social science as well as from the scientific community.