

**Summary of decisions and recommendations from
the Twenty Second Meeting of the UK Biobank Ethics and Governance Council
(22 March 2010)**

1. The Council approved the circulated minutes and summary of decisions and recommendations of its twenty first meeting.
2. Members discussed and agreed revisions to a draft report of its 8 December 2009 workshop 'Involving publics in biobank research and governance'. The draft report will be revised and published in due course. [AH]
3. The EGC's Modus Operandi details that 'the Council may, in due course, choose to include up to two UK Biobank participants in its membership'. The Council will return, at a future date, to the question of whether future recruitment processes should specifically target participants. [All]
4. EGC funding review:
 - a. People Science and Policy (PSP) Ltd has been commissioned by the EGC's funders to carry out a stakeholder survey and a literature review of the EGC's activities to date. The EGC will be given the opportunity to respond to PSP's findings. [AH]
 - b. The funders plan to commission PSP to undertake focus group consultation work with a selection of UK Biobank participants. Section I.B.5 of the Ethics and Governance Framework (EGF) states that 'decisions on whether re-contact is appropriate for particular proposals will be made by UK Biobank with advice from the EGC and will be subject to Research Ethics Committee approval'. At the funders request the Council discussed:
 - i. the appropriateness of their draft re-contact proposal, in light of the provisions of the EGF and the expectations and consent of UK Biobank participants;
 - ii. how UK Biobank and the funders should address issues around re-contact for the purpose of reviews of this nature in the future;
 - iii. the draft proposal overview (including objectives, methodology and associated invite materials) and whether the review should be considered audit or research.

A list of conclusions and recommendations will be circulated to the funders and UK Biobank. [AH] (see Annex A).
5. A number of EGC members have written a paper that draws together the Council's analysis and discussion regarding the ethical implications of MRI imaging in a biobanking context. Members agreed that:
 - a. The paper should address the main ethical considerations which are likely to arise for any biobank project that includes MRI, rather than focus on UK Biobank's proposal (the details of which are under development).
 - b. The paper should most likely be submitted for publication on behalf of the Council, rather than by the members acting in their individual capacity. The final draft will be circulated to the Council shortly for endorsement.
 - c. The paper offers the EGC an opportunity to share its deliberations with a wider audience and to contribute to broader debates through its work.
6. A member proposed that the Council might write a paper on the topic of representativeness and population biobanks. The Council agreed to return to this proposal at its next meeting. The Secretary will compile and circulate previous

Council discussions regarding the representativeness / generalisability of the UK Biobank cohort. [AH]

Recommendations and requests to UK Biobank

7. Recommendation and request – UK Biobank information systems

At its December meeting the Council was reassured to learn that an audit of the IT systems and procedures within CTSU that relate to UK Biobank would be commissioned and would report in early 2010. The Council understands – and agrees – that the initial audit quote was prohibitively expensive and that the scope of the review has now been revised, and the cost decreased accordingly. Despite the decreased cost, members were informed that UK Biobank cannot commission the audit in the short term due to budgetary constraints. While assured that UK Biobank remains committed to the CTSU audit, members were disappointed that the audit is being postponed at this stage. The Council recommends that the audit be progressed as soon as feasible in order to provide an assurance to UK Biobank and its stakeholders about CTSU's security provisions.

Mr Sellors proposed that UK Biobank prepare a short presentation for the Council's 7 June meeting, outlining the project's plans and progress in relation to the IT systems development. Members were grateful for this suggestion.

Dr Sprosen offered to provide further information after the meeting regarding the outcomes of the ISO 27001 stage 1 assessment and an update on UK Biobank's progress through the accreditation process.

8. Request – Access and IP (AIP)

Mr Sellors provided a verbal update and a meeting between UK Biobank and the EGC AIP subgroup was proposed for mid/late May 2010 prior to the next EGC meeting in early June. It is hoped that it would be possible to discuss the draft procedures at this time.

9. Request – Imaging visit and incidental findings protocol

UK Biobank intends to submit the application for the imaging re-assessment visit for initial review by the International Scientific Advisory Board in October and then for funder review by the end of 2010, with initial funding for a pilot study involving approximately 4,000 participants and thereafter for the full 100,000 participant study. UK Biobank will revisit and review the imaging incidental findings protocol and will circulate this, and the detailed MRI proposal, to the Council for its review and input in advance of the funding application.

Dr Sprosen offered to provide details of the Google Docs page which is being used as a portal for expert MRI discussion of UK Biobank's proposal.

10. Recommendation – *Equity report*

The Council was pleased to have sight of the Equity Report regarding participation in UK Biobank. While understanding that UK Biobank's scientific objective is to collect generalisable and not representative data and samples, the Council considers it important from a prudential and political viewpoint that UK Biobank aims to be as inclusive as possible. Therefore, it is recommended that UK Biobank demonstrates further serious attempts to overcome barriers to participation for those individuals identified by the audit report as having been under-recruited, or for which no data was available but under-recruitment is likely (e.g. Asian and black people and those with disabilities). Further, it is recommended that the project make every effort to address the outcomes of the audit. UK Biobank might find it useful to contact local organisations and individuals for advice on how to reach particular groups e.g. the Local Authority Adult Services, Equality and Diversity officers etc.

11. Request – *Biocentre*

Mr Sellors offered to provide further background and information, at the Council's 7 June meeting, regarding UK Biobank's plans to establish a Biocentre to act as a storage and retrieval service for other research initiatives venture.

Annex A Funder proposal for participant re-contact

Broad aspects of re-contact

Conclusions

- Re-contact for this type of work – being a form of participant engagement for audit of governance – is appropriate in view of the consent and expectations of UK Biobank participants and in terms of the EGF. While participants consent for their data and samples to be used for 'health-related research', they provide consent to be re-contacted by UK Biobank for a wider variety of reasons, including the possibility of being asked to consent to research that falls outside of their original consent.
- It is a reasonable interpretation of EGF Section I.B.5 (as it stands) that UK Biobank is the principal decision-maker on the appropriateness of re-contact, with advice from the EGC and subject to REC approval.
- The Council is hopeful that it will not be necessary to go back to the REC in every single circumstance of research for audit (either by the funders or UK Biobank). UK Biobank is advised to seek clarification from the REC regarding its duties to report and seek approval for re-contacts of this nature (see recommendations below).

Recommendations

- The Council recommends that the EGF section I.B.5 be revised to incorporate provision for quality control, audit and regulatory inspection. In particular the re-wording should clarify:
 - whether or not all proposals for research for audit require REC approval.

A literal interpretation of section I.B.5 of the EGF would suggest that every individual proposal for re-contact requires separate REC approval. Under a less literal interpretation the phrase 'particular proposals' might encompass a category of proposals (e.g. research for audit purposes).

The Council recommends that UK Biobank seek the REC's view on whether the current proposal should be considered as research or audit. Further, UK Biobank should seek clarification regarding whether or not REC approval is necessary for every case of this type of work (conducted by the funders or UK Biobank).

- that the provisions in the EGF should not present a barrier to legitimate audit by the funders.

The Council recommends that the following text be added as a second sentence to the final paragraph of section I.B.5 'These provisions will not preclude the project's funders from carrying out legitimate audit of UK Biobank or its governance structures'.

- The Council recommends that UK Biobank address the issues of quality control, audit and regulatory inspection in the draft Access and IP procedures and policy.

The draft proposal for re-contact

Conclusions

- It is appropriate and right for UK Biobank to approach this proposal with care given that this is the first time that participants are being re-contacted and invited by UK Biobank to take part in face-to-face sessions. This needs to be done correctly and be seen to be done correctly applying appropriate standards. As part of those appropriate standards the participants need to be reassured that their data are being handled confidentially and told why they were selected by UK Biobank.
- It is appropriate that REC approval is sought for the current proposal.
- On the audit and research distinction, *audit* was understood to be a means of assessing standards and processes while *research* was considered to encompass the creation of generalisable knowledge and to address a hypothesis. Given that the proposal involves ascertaining opinions on the governance of UK Biobank and the current and possible future roles of the

EGC, members considered the proposal to be more akin to research, albeit for audit purposes. Further, if the funders plan to publish the focus group findings this moves the proposal closer to research. The REC should be consulted for its view on this distinction in relation to the current proposal.

Recommendations

- The focus groups will investigate the EGC in the context of UK Biobank's governance more broadly. It is entirely appropriate that the EGC is not represented during the focus group work. Further, in order not to inhibit or potentially bias the discussion the Council recommends that the provision of accurate written material and an independent observer (with background in social research and who is knowledgeable about UK Biobank) would be preferable to having an observer from UK Biobank. The presence of a funder representative at the focus group meeting was considered appropriate and unproblematic.

The draft proposal materials¹

Conclusions

- The current materials produced by PSP are not sufficient for the EGC to provide a proper review of the proposal. More information is required on how the focus groups will be conducted. PSP's tightly-timed agenda and written note regarding UK Biobank and the EGC should be sent to both UK Biobank and the (Chair of) EGC as soon as possible. It is noted that such materials will be needed for an application to the REC.
- The Council is ready to comment, and provide feedback, on the detailed proposal as soon as required.

¹ The Council's detailed recommendations regarding the revision of the draft materials are described in the full minute (available at www.egcukbiobank.org.uk/meetingsandreports).