

**Report: Public meeting of the UK Biobank Ethics and Governance Council  
12th February 2009  
The Royal Hotel, Cardiff**

The independent Chair of the meeting, Dr Mairi Levitt (Senior Lecturer in the Department of Philosophy, Lancaster University), opened the session by welcoming everyone. Dr Levitt explained that the meeting is hosted by the UK Biobank Ethics and Governance Council (EGC), an independent advisory committee that was established in November 2004 to oversee the UK Biobank project.

The EGC is charged with advising UK Biobank on the interests of participants and the public and holds public meetings as a means of gauging what interests people have in relation to the project. The Cardiff meeting is the Council's first meeting in Wales and the fifth meeting in the series. Earlier meetings were held in London, Manchester, Edinburgh and Oxford. The Council chose to meet in Cardiff because UK Biobank recruited in the city in 2008 with nearly 18,000 people from the region agreeing to participate in the project. Nationally, as of 30 January 2009, a total of 250,000 people have agreed to participate. The project expects to reach its target of half a million participants in Summer 2010.

The purpose of the meeting was:

- To raise awareness and encourage debate among attendees about biobanking broadly, and more specifically regarding UK Biobank and the role of the EGC.
- To invite comments and questions in relation to the ethics and governance aspects of UK Biobank. These comments and questions will be used to inform the EGC's advice to UK Biobank.

The format of the meeting was different to the previous public meetings, demonstrating the Council's desire to find more engaging ways of communicating with the public. First, there were three presentations<sup>1</sup> which addressed the following subjects:

- An introduction to biobanking (Mairi Levitt);
- Background and progress regarding the UK Biobank project (Rory Collins, Chief Executive Officer and Principal Investigator of UK Biobank and Professor of Medicine and Epidemiology at the University of Oxford);
- An overview of the EGC and its work (Graeme Laurie, EGC Chair and Professor of Medical Jurisprudence at the University of Edinburgh).

The presentations were followed by a brief Question and Answer session from the floor after which attendees were invited to discuss their thoughts and questions in relation to the presentations in small groups. Graeme Laurie posed a number of ethical questions at the end of his talk as a prompt for discussion. However,

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<sup>1</sup> The presentations were broadly similar to previous public meetings and so have not been reported here. Please refer to the December 2007 public meeting report for a description of the presentations (available at: [www.egcukbiobank.org.uk/meetingsandreports](http://www.egcukbiobank.org.uk/meetingsandreports))

attendees were encouraged not to be confined by these areas and to instead raise any matter of interest to them. In order to facilitate the discussion, the small groups were convened at round tables with two Council representatives at each table to answer questions. This meeting style led to a number of lively and involved discussions. The section below reports on these discussions (as reported by EGC members to the Secretary after the meeting).

### Question and answer session

**Q1 Have the proposed enhancements been approved by an ethics committee?**

A1 (RC) The pilot and main study protocol for the UK Biobank project were approved previously by the NHS North West multi-centre research ethics committee (REC). The first set of proposed enhancements, which should be introduced into the baseline assessment centre visit from April 2009, are about to be submitted to the REC. These enhancements include extra cognitive and psychological measures, a hearing test, pulse wave velocity using a non-invasive finger clip, heel ultrasound on both heels (currently done on one heel) and web-based dietary questions. They are similar in style to the current baseline measures; for example, UK Biobank already carries out some cognitive measures at baseline. The hearing test is a new technique for UK Biobank, but it has been validated in other contexts with more than 100,000 people having undertaken the test already.

The second set of enhancements (including visual and eye measures, saliva collection, blood collection for RNA, fitness assessment with limb ECG and activity monitoring) have not yet been funded. If the enhancements are funded the proposal will then go forward for REC approval.

(GL) It should be noted that UK Biobank is subject to all ethical and regulatory standards required of such a research project. Indeed the project has gone beyond the necessary regulatory requirements by stating its commitments to participants in its public Ethics and Governance Framework and by the fact that an Ethics and Governance Council has been established to oversee the project's conformance with this Framework. I refer to this as a 'governance +' approach.

**Q2 I am concerned that you are collecting biometric data (e.g. eye measurements) which has been the subject of much public discussion in terms of government's plan to introduce identity cards. There is no public consensus on this issue. Also, the psychological tests open up a broad field of study which goes beyond the current baseline measures.**

A2 (RC) UK Biobank has spoken to the North West REC about the first set of enhancements and it has indicated that an amendment to the original protocol will be required for these new measures, rather than a new full submission. The proposed measures are similar in concept to those already undertaken in the baseline visit (e.g. we already conduct cognitive function tests at baseline), for which participants provide consent. We have not yet spoken to

the REC about collecting additional blood for RNA, but this proposal is similar to our current approved practice of collecting DNA and metabolites.

**Q3 What is your concept of informed consent? How can people be informed if the future uses of the resource are unknown?**

A3 (RC) UK Biobank uses a model of broad consent and, based on advice from the EGC, deliberately does not use the language 'informed consent' to describe its consent procedures. This topic has been discussed with the EGC and the REC in great detail with all parties agreeing that this model is appropriate for UK Biobank.

(GL) Researchers have an obligation not only to obtain consent but also to keep participants informed about how the UK Biobank resource is being used. The concept of broad consent is linked to a participant's right to information and their right to withdraw should they become unhappy with how the resource is being used. Participants can withdraw at any time for any or no stated reason and without consequence.

**Q4 What information is given to participants and how long are they given to consider it?**

A4 (RC) An invitation letter and information leaflet are sent to potential participants about 6-10 weeks before their suggested assessment visit dates. Potential participants are invited to call a free-phone Participant Resource Centre (based at Cardiff University) if they have any questions about the project. We have trained staff at this dedicated centre available to answer calls six days a week from 8am–7pm. These staff can address the majority of standard questions about the project. There is also an escalation procedure in place should these staff be unable to address a particular enquiry. Answers to frequently asked questions are also available on the project's website.

During the assessment visit, a summary of the key aspect of consent are displayed on a touch-screen computer before an individual moves on to view the consent form. UK Biobank staff are available during this process to answer any questions that the potential participant has and the staff actively inform potential participants that they are there to address their questions. The consent form contains explicit questions about, for example, the fact that there will be no feedback of health information beyond the assessment centre visit and the fact that commercial entities might apply to use the resource.

**Q5 Is it ethical not to provide feedback of health information to participants?**

A5 (RC) The Ethics and Governance Framework describes in detail the rationale for not providing feedback of health information beyond the assessment centre visit. Considerations include the fact that samples will only be analysed 5, 10 or 20 years in the future. (Once some people have already developed a particular condition their samples will be compared with the samples of people who have not developed the condition.) In a different model, where feedback is provided, difficulties arise if participants do not receive any feedback and interpret this as an indication that they have no health problems (whereas it might only indicate that their samples have not yet been analysed). Difficulties

may also arise over the interpretation of genetic data and how this is feedback to participants. For example, a risk factor for heart disease may only be associated with a small percentage increase in risk meaning that the feedback would not be 'you will get disease x' but instead 'you are at a slightly higher risk of developing disease x'. For these reasons, UK Biobank has a policy of no feedback beyond the assessment visit. It is made explicit to participants that they will not receive feedback and that they should only agree to participate if they are comfortable with this condition.

(GL) The question of whether or not – and when – to provide feedback continues to beleaguer researchers. Indeed, UK Biobank and the EGC may need to review the project's policy in light of the proposed enhancements in order to see if the current 'no feedback' policy is appropriate in terms of some aspects of the new measurements.

(RC) A second set of proposed enhancements includes Magnetic Resonance Imaging (MRI). We have considered the feedback issue in relation to this technique and know from researchers in the field that, for example, a whole body MRI on young individuals will show an abnormality of some kind on 25% of the scans. But, a substantial proportion of such abnormalities is not likely to be materially relevant to disease (i.e. would be a 'false positive'). UK Biobank is currently considering the question of whether or not you should cause alarm to participants by telling them that their scan shows an abnormality when the significance of the finding is unknown, while also bearing in mind that some of the scans will identify serious abnormalities.

## **Small group discussions**

### **Consent**

The issue of mental capacity, literacy and language was raised in relation to consent. While a study nurse can refuse participants entry into the study if they felt that the person did not have capacity or did not understand what they were signing up to, there is no formal testing of mental capacity or language skills.

### **Assessment centre questionnaire**

A number of attendees sought clarification regarding how UK Biobank can be sure that the information given by participants during the assessment visit (e.g. on diet and lifestyle) can be trusted. UK Biobank can employ a number of methods to take account of potential misreporting, including repeat contacts using different tools (such as food-frequency questionnaires vs diaries or 24-hour recall tools).

### **Follow-up of participants through their 'health-related' records**

Attendees expressed varied opinions regarding the acceptable breadth of interpretation of the phrase 'health-related'. One participant was happy with a broad definition (e.g. to include occupational health records). Another attendee expressed surprise that UK Biobank might seek access to participants' occupational records (as stated explicitly in the information materials) and considered that some participants might not realise that they had provided consent for this linkage (although she herself might not mind such linkage).

## **Security of data**

Several attendees sought further information regarding UK Biobank's provisions for securely holding participants' data. Participants' data are encrypted and reversibly anonymised and firewalls are used for protection. Key-coding is used to link data and samples to identifying details. This affords high security while allowing re-linking (e.g. for linkage of subsequent disease development and in the event that a participant wishes to withdraw from the project). Access to the key-codes within UK Biobank is very restricted. The project works with external companies to ensure that its systems are robust and are in conformance with international standards. UK Biobank is also working towards International Organization for Standardization (ISO) accreditation that evaluates how an organisation securely manages its information and data (ISO 27001). The EGC recently established an Information Security subgroup to investigate this area in more detail, including site visits to UK Biobank's co-ordinating centre to meet with the project's Systems Architect and Security Officer.

## **Feedback of MRI**

A number of views were expressed in relation to whether or not feedback ought to be provided in relation to the MRI scans. Professor Collins explained to one group that the MRI scans will not be read systematically, but only on a case-control basis after the identification of a sufficient number of cases of a given disease.

A number of attendees considered that if a serious abnormality is seen then the participant and/or their GP should be informed. However, within this policy there should be an option for participants to express their right 'not to know' any feedback from the scans. A number of attendees acknowledged that there is a lack of clarity and information about what can be detected through MR imaging, what represents a 'serious' abnormality and what abnormalities might be related to health issue that might or might not be treatable. Even in light of these uncertainties some attendees asserted that they would still prefer to receive feedback.

One delegate commented that they understand the financial reasons why UK Biobank might not provide feedback (i.e. costs associated with employing a radiologist to interpret the scans and the costs of managing the feedback process). However, they did not support the idea that no feedback should be provided simply because 25% of each type of scan may show a 'false positive' abnormality. In this situation that attendee would prefer to receive the information and deal with any concern that arises.

## **Access to UK Biobank**

Attendees raised a number of issues around the subject of access:

- One attendee commented that all researchers should have ethics approval for their research before they are allowed to access data held by UK Biobank.
- Some attendees asked if UK Biobank would charge researchers for access to the resource and Rory Collins responded that he does not envisage that there will be cost recovery through the access process and that UK Biobank will not be run as a business.
- Concern was expressed that researchers who have access to data that has been stripped of a participant's identifiers should not be able to re-identify people (for example, by matching data from UK Biobank with other

information). Rory Collins advised that the agreement to use the data will include this requirement.

- Rory Collins explained to some attendees the value of comparing data across biobanks and across different ethnic groups and stressed that any data that are provided to researchers will be key-code anonymised to protect privacy. While some attendees initially seemed surprised that the data may be shared across borders (which is stated explicitly in the information materials), they were not opposed to the idea of such data sharing.
- Concern was expressed that insurance companies, perhaps working with academics, might want to use UK Biobank information to stigmatise certain genetic conditions or that government might overturn privacy promises if it was considered "in the national interest" to do so. The Ethics and Governance Framework states that the purpose of UK Biobank is 'to support a diverse range of research intended to improve the prevention, diagnosis, and treatment of illness and the promotion of health throughout society'. Access proposals will be considered for only those projects that meet this purpose. All such proposals will be reviewed by UK Biobank to ensure they are consistent with the participants' consent and the Ethics and Governance Framework, and that they have relevant ethics approval.
- The fact that UK Biobank will vigorously resist access by law enforcement agencies was endorsed by attendees, but it was understood that access could be required under a court order.

### **Re-contact**

Attendees expressed very different views about what might be an acceptable frequency of re-contact; some regarded 2 per year to be too frequent while another regarded 5 per year as acceptable. One attendee suggested that re-contact on an annual basis would be reasonable and that he would be happy to be re-contacted more frequently than not because the extra information generated through the re-contact will make the resource more valuable.

### **Withdrawal**

The policy of having three different options for withdrawing from the project was endorsed by some attendees as reasonable. The right of relatives to withdraw a participant after the participant's death was discussed with some attendees, especially with regard to information which would be 'personal' to the relative as a family members rather than just personal to the deceased participant.

### **EGC operational issues**

Some attendees asked for details regarding how members are recruited to the EGC. All members are appointed following public advertisement, through an open appointments process in keeping with the Nolan Principles of Public Life.

Dr Levitt concluded the session by thanking the participants for attending and thanking Zena O'Connor and Adrienne Hunt for organising the event. Dr Levitt invited everyone to continue the discussion over a post-meeting drink in the bar. Most attendees remained seated and continued with their discussions for a further hour and so drinks were brought to the tables.