

## **UK Biobank Ethics and Governance Council Sixteenth Meeting**

Meeting at Wellcome Trust  
215 Euston Road, London, NW1 2BE

Monday 15 September 2008 at 10.30am

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### **Agenda**

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1. **Apologies**
2. **Minutes** of fifteenth meeting held on 9 June 2008
3. **Matters arising**
  - (i) Summary of decisions and recommendations from fifteenth meeting held on 9 June 2008
  - (ii) Tracking of requests to UK Biobank
  - (iii) Update: EGC recruitment
  - (iv) Report 'Public attitudes to third party access and benefit sharing: their application to UK Biobank'
4. **Council closed discussion: Proposal for enhanced phenotyping of participants**
5. **Update from UK Biobank** (Professor Rory Collins, Chief Executive Officer, UK Biobank)
  - (i) General update from UK Biobank
  - (ii) Update regarding recommendations from EGC15
  - (iii) Development of UK Biobank's access and intellectual property procedures
  - (iv) UK Biobank post-visit participant questionnaire
  - (v) UK Biobank touch-screen and interviewer questionnaires
6. **UK Biobank's proposal for enhanced phenotyping of participants** (Professor Rory Collins, Chief Executive Officer, UK Biobank)
7. **UK Biobank's proposals for longitudinal follow up of participants** (Professor Rory Collins, Chief Executive Officer, UK Biobank)
8. **EGC review**
9. **Communications activities**
  - (i) External speaking opportunities
  - (ii) External enquiries to the EGC
10. **Report on meetings attended**
  - (i) Governing genetic databases conference (24-26/06/08)
  - (ii) Board meetings (04/07/08)
  - (iii) 'Genome-Wide Association Studies and Ethics Meeting' (24/07/08)
11. **Any other business**
12. **Date of next meetings**

**UK Biobank Ethics and Governance Council  
Sixteenth Meeting**

**15 September 2008  
Wellcome Trust, London**

Present: Professor Graeme Laurie (Chair), Professor Ian Hughes, Professor Anneke Lucassen, Dr Heather Widdows, Professor Erica Haines, Professor Chris Wild, Dr Roger Moore, Ms Andrea Cook and Professor Martin Richards.

In attendance from EGC Secretariat: Ms Adrienne Hunt.

Observers: Dr Alan Doyle (Wellcome Trust) for items 4 – 9 only. Dr Catherine Moody (Medical Research Council) for the whole day.

Speakers: Professor Rory Collins (Principal Investigator and Chief Executive, UK Biobank) and Mr Jonathan Sellors (Company Secretary, UK Biobank) for items 5, 6 and 7 only.

1. Apologies

Apologies were received from Professor Roger Higgs.

2. Minutes of the last meeting held on 19 June 2008

The Council approved the circulated minutes.

3. Matters arising

*Summary of decisions and recommendations from fifteenth meeting held on 9 June 2008*

The Council approved the circulated summary of decisions and recommendations.

*Tracking of requests to UK Biobank*

At its last meeting the Council proposed that UK Biobank should develop a paper on the legal and ethical implications of its enhancement proposal on the project's feedback policy. The Chair is in the process of commenting on a first draft of a paper from UK Biobank which will be brought to the full Council in due course. This topic was discussed further under item 6.

*Update: EGC recruitment*

The EGC vacancies have been publicly advertised with a closing date of 24 September. Interviews will take place on the 5 and 6 November.

The Chair asked the Council whether or not an application from someone from his own academic institution would be acceptable. The Council decided that an application from the Chair's colleague is not problematic given that there is no power relationship between the two and given that the applicant, while from the same University, is not from the same department. The Chair should declare this interest to members of the Appointment Panel as part of the interview process.

**ACTION:** Members were asked to distribute the EGC advert to their contacts. [All]

*Report 'Public attitudes to third party access and benefit sharing: their application to UK Biobank'*

The Council:

- Discussed the report's recommendations and identified the key implications for the work of the EGC.
- Agreed to publish the final report on the EGC website, accompanied by a preface describing why the report was commissioned and a summary of the key implications for the EGC's work.
- Agreed to update the Council's living document, 'Advising on the public interest and the public good', based on the key implications.
- Agreed a policy that there is an expectation that all EGC commissioned research will result in a public document, except in exceptional circumstances.
- Re-iterated the importance of continuing to manage the process by which the work is prepared for publication, including providing feedback to the authors on the development of the final report.

**ACTION:** The Secretary will draft a preface for the final report including an introduction, an explanation regarding why the report was commissioned and a statement that the report does not express the Council's views but is a stand-alone document. The Secretary will update the Council's living document, 'Advising on the public interest and the public good'. [AH]

The following aspects of the report were discussed:

- Support for UK Biobank policies

The Council was reassured to learn of this overarching support for UK Biobank and its current policies on access and intellectual property.<sup>1</sup>

- Security of information and associated concerns

The report highlights that respondents had more concerns over security of information held by UK Biobank rather than matters of anonymity and consent. The report suggests that security is likely to be a key decisive consideration for potential participants.

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<sup>1</sup> The study was conducted with reference to UK Biobank's draft access and intellectual property policy (January 2005). This policy is currently under revision and the latest version is not available on the UK Biobank website at the time of writing.

The Council agreed that the preface of the report should highlight the ways in which the EGC has already responded to these concerns. First, the EGC is specifically looking for an individual with expertise in information systems security in its 2008 round of recruitment in order to enhance its ability to advise on and monitor this area of the project's activity. Second, UK Biobank provides regular biannual reports to the Council describing recent activities in relation to its data management and security systems strategy.

- Differences between age groups

The Council noted that in the majority of circumstances there was no clear statistical significance found between the opinions of the two age groups. On the whole no firm conclusions can therefore be drawn about any differences in opinion that might exist between the two groups.

- Benefit sharing

The report found that a fees-for-access arrangement was seen as reasonable by the majority of the respondents within the Focus Groups once the practical implications of sliding scales of profit sharing arrangements or similar schemes had been discussed. There was however support for profit sharing where UK Biobank has made a material contribution to the intellectual property behind the new products or processes.

The Council agreed to be mindful of this outcome in its discussions with UK Biobank regarding its access and intellectual property policy and procedures. The Council could look in more detail at the practicalities of the profit sharing model (e.g. How is a 'material contribution' defined? What issues are at stake in determining a definition of a 'material contribution'? Would this model involve UK Biobank asserting reach-through rights on down-stream research, albeit in exceptional circumstances, or by some other model? Should this policy be adopted?). The Council also agreed to be mindful of UK Biobank's commitments to broader benefit sharing models.

- Understandings and expectations of participants

The report's findings suggest that there may be a misperception among some of the respondents regarding the purpose of UK Biobank. Specifically, there appears to be a bias towards the clinical potential of research conducted on the resource rather than the potential public health outcomes. The Council noted that the respondents to the public attitudes study were not selected from UK Biobank's cohort of participants and they had not necessarily received the project's information materials nor been through UK Biobank's consent procedures. Nonetheless, the Council questioned whether or not the potential misperception amongst the respondents may exist amongst UK Biobank participants. The report points to the possibility of UK Biobank being viewed as a clinical experience for some when it notes a potential slippage for a minority of respondents from 'participant' to 'participant-patient' (where some form of individual clinical benefit might be expected). The Council recommended that UK Biobank should continue to be clear in its message in all literature that the resource will support not only medical but also health-related research.

#### 4. Council closed discussion: Proposal for enhanced phenotyping of participants

At its previous meeting the Council considered UK Biobank's proposal for enhanced phenotyping of participants and in particular considered the implications of the proposal for UK Biobank's policy on providing feedback of health information to participants. The Council had recommended that UK Biobank should develop a paper on the legal and ethical implications of its enhancement proposals on the feedback policy. The following six point structure was derived in order to provide a framework within which to consider the implications:

- 1) Re-affirm the basis of the original advice to UK Biobank regarding feedback.
- 2) From what is being proposed, what falls within the existing policy?
- 3) What, if anything, is ethically or legally different about what is proposed?
- 4) What is being done elsewhere (in other biobanks) and what is comparable to UK Biobank?
- 5) What, if anything, has changed?
- 6) What, if anything, should change?

UK Biobank's proposal contains three categories of enhancement. At its last meeting the Council agreed that the third category (including such measures as magnetic resonance imaging (MRI) of brain and heart and electrocardiogram (ECG) scans) could be considered different to measurements taken during the current assessment centre visit due to their more intrusive nature. Therefore the category 3 proposal was considered to require further consideration in terms of acceptability and the feedback policy.

Academic literature was distributed to Council and to UK Biobank since the last meeting which address the topic of feedback of incidental findings made during general research involving MRI – bearing in mind that UK Biobank is distinct in that it is developing a research resource and is not conducting research itself. The Council noted that the literature identified that the approach of research projects towards incidental feedback highlighted the pros and cons of both approaches, namely offering incidental feedback to participants or offering no feedback at all.

One member spoke from their experience of having recently been recruited into UK Biobank. The member is a firm supporter of UK Biobank's policy to provide limited feedback of certain measurements taken during the assessment centre visit only. However, in undertaking the assessment visit the member was struck by how important the feedback issue can be for participants. The member questioned to what extent providing more routine feedback might encourage and motivate individuals to participate in the project. Further, the proposed enhancements have the potential to raise participants' expectations as to the level of feedback they will receive.

The Council noted that UK Biobank is likely to have already raised participants' expectations of receiving feedback given that some participants have access to a free consultation with a British Heart Foundation (BHF) nurse at the end of their visit. While the BHF consultation is distinct from the UK Biobank assessment this

distinction may not be clear to participants, who may view the consultation as part of their involvement with the project.

The Council identified a number of questions that are pertinent to the issue of providing feedback of the results of MRI research: Will the circumstances ever be such that UK Biobank will become aware of an abnormal MRI image? Will participants ask for feedback during procedures? Will images be analysed or simply stored? Will the imaging staff also be clinically trained to provide an analysis? Will images meet a clinical standard? Is it possible to set up the MRI scanner such that the images are not visible to those taking the scan i.e. making feedback impossible? In any event the Council agreed that UK Biobank will need to be very clear in its communications regarding what feedback a participant can and cannot expect to receive regarding the enhanced measures. For example, if the images are not going to be analysed by a qualified clinician during the assessment centre visit, this will need to be clearly communicated to participants so that they know not to expect feedback of routine or incidental findings.

The Council reaffirmed that its role is to advise UK Biobank on policy, rather than to create policy for UK Biobank. In providing its advice the Council needs to be clear on UK Biobank's intended course of action. The Council foresees that the project's policy on feedback will be challenged as the enhancements increase and as the proposed measures become more invasive. It was seen as key that UK Biobank should seek to understand and effectively manage participants' expectations.

5. Update from UK Biobank (Professor Rory Collins, Chief Executive Officer, UK Biobank)

*General update from UK Biobank*

180 000 participants have been recruited to date. UK Biobank continues to operate 6 assessment centres each of which aims to recruit 110 individuals per day over 6 days per week. The cumulative average recruitment rate has been 93 people per day but in the last few months this figure has been 98 people per day. The project's budget is based on a recruitment rate of 100 people per day. Given the current rate of recruitment UK Biobank expects to reach its target of 500 000 participants by the middle of 2010, on budget.

UK Biobank is testing a new assessment centre model in its recently-opened London centre. Given the limited footprint of space available at St Bartholomew's Hospital, the normal assessment stations have been compressed to only the touch-screen area and a station in which all measurements are taken. The centre operates at half the rate of a normal assessment centre, recruiting around 40 people per day. The centre could provide a model for smaller centres including: a mobile centre (which has been offered by the Welsh Assembly but has not yet been accepted by UK Biobank); a smaller centre that could operate in areas of hard to reach groups and as a model for UK Biobank when it undertakes re-assessment of a subset of its participants.

UK Biobank is currently recruiting in a number of major cities where the centres are expected to continue operating for several months. In light of this no new centres will be opened in the next 4 months. During this break UK Biobank is reviewing and refining its recruitment processes. For example, UK Biobank recently met with the Training and Monitoring team to discuss ways in which the setting up of assessment centres can be improved (e.g. by allowing more setting up time and by allowing for a more gradual build up of participants attending the assessment centre in its first week of operation in order to help newly trained staff cope better).

### *Discussion*

Professor Collins was asked how successful the project has been in recruiting participants from towns which neighbour towns in which an assessment centre is based (for example the centre in Newcastle also serves Sunderland and the centre in Leeds also serves Bradford). UK Biobank is monitoring uptake of participation and has so far not seen a markedly different response rate between such towns. UK Biobank is keeping an open mind regarding whether or not the assessment centres will need to be relocated e.g. the Newcastle centre being moved to Sunderland in future. On the subject of recruitment rates, UK Biobank has seen a very different response rate than usual in Bristol where the attendance rate is 20%.

UK Biobank has recently undertaken a revised version of the post-visit survey that was conducted during its pilot phase (the interim results of the survey are reported in a paper submitted to the Council under agenda item 5 (iv)). The survey aimed to explore participants' opinions on the assessment centre visit, the information leaflet and consent process and to test their understandings of the elements of their consent.

The Council noted that the interim results of UK Biobank's post-visit survey point to possible misunderstandings amongst participants regarding the nature of their future involvement in the project. Professor Collins pointed out, however, that it was incorrect to infer from a 76% positive response for a post-assessment recall that the remainder had not understood some particular aspect of the study (e.g. agreement to be re-contacted) when they had given explicit consent to such aspects (e.g. had indicated "I agree" in response to "I understand that I may be re-contacted..."). He indicated that UK Biobank does not intend to repeat the current post-visit survey on a wider set of participants but instead intends to focus on other aspects, including participants' understandings and expectations regarding the project. This could be achieved through a more detailed, systematic survey. Other complementary tools are also available, for example UK Biobank is analysing participant comment cards from all assessment centre, the details of which will be included in the EGC's biannual report on complaints and enquiries.

UK Biobank already has MREC approval in principle for conducting a systematic post-visit survey during the main phase of recruitment and UK Biobank might be in a position to consider a post-visit survey in more detail in the coming months. Professor Collins invited the EGC's input as to which questions such a survey might address.

The Council recommended that UK Biobank pursues its proposal to conduct a further post-visit survey to investigate in more detail the participants' assessment experience, their understandings and expectations of future involvement and the reasons they hold these understandings and expectations. The need for such a survey is supported by the results of the EGC commissioned study (discussed during agenda item 3 (iv)). This study, albeit not conducted specifically on UK Biobank participants nor necessarily involving persons who had been through UK Biobank's consent procedures, highlighted potential misperceptions amongst respondents which it would be useful to test within UK Biobank's cohort of participants. A more detailed survey may help UK Biobank to ascertain whether or not there are uncertainties in the expectations of participants and the cause of these uncertainties. This information could in turn be used as a way of changing the information that the project provides to its participants to improve the clarity of its messages.

**ACTION:** The Council will develop a series of questions that may be addressed in UK Biobank's post-visit survey. The Council will also provide a recommendation on the type of research methodology that might be used. [AH]

#### *UK Biobank post-visit participant questionnaire*

This item was taken early given its relevance to the previous discussion.

The Council considered a report of the interim results of UK Biobank's post-visit survey. The interim report relates to 75 participants who were surveyed at the conclusion of their assessment centre visit. The full analysis of around 200 participants should be completed by the end of September.

76% of the post-visit survey respondents recalled that they had agreed to be re-contacted. The Council found this figure to be encouraging as it shows that there is some clarity about a participant's ongoing involvement in the project. 52% of respondents recalled that they had consented to having their health followed through their medical records and the Council flagged this as a potential issue for UK Biobank to monitor closely since all participants will be followed up through their medical records. If there is a lack of clarity about medical records being followed up, there is a question as to other 'health-related' records.<sup>2</sup>

The post-visit survey also asked participants why they agreed to participate. Although UK Biobank's participant materials are clear that the assessment does not constitute a health check 16% of participants chose this as their reason for participation. This result may suggest that some participants do not make a distinction between their UK Biobank visit (where limited information is provided without interpretation) and the British Heart Foundation (BHF) consultation (where personal advice on cardiovascular risk is provided). The idea of UK Biobank as a health-check may be a cause for concern if people interpret the results of their assessment centre measures as an indication of good health more broadly (when

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<sup>2</sup> In interpreting these retrospective survey data, it should be noted that every participant has to indicate "I agree" in response to the following statement on UK Biobank's consent form "I give permission for access to my medical and other health-related records, and for long-term storage and use of this and other information about me, for health-related research purposes (even after my incapacity or death), and then has to sign the consent form to confirm their understanding of these and other aspects of the project (including, for example, agreeing to be re-contacted).

UK Biobank can not give any such guarantee). The information from the current post-visit survey does not shed light on how participants interpret the feedback they receive and their understanding of the assessment visit and BHF consultation. This result could be an issue in the context of UK Biobank's proposed, new enhancement measures. For example, if a decision is made to provide no feedback will participants fully understand that feedback of these more invasive measurements will not be provided and that a lack of feedback is not an indication of good health? The Council proposed that when conducting a further post-visit survey UK Biobank could work in particular with people who thought they were going to receive a health-check in order to investigate the reasons underlying this belief.

The Council did not consider that the participants' responses indicate a deficiency in UK Biobank's participant information materials. The responses may simply highlight a distinction between participant understandings, which could be quite clear, and their expectations or recollections. For example, the survey showed some contradictory results whereby 75% of those surveyed thought they could skip some questions in the touch-screen questionnaire whereas 53% indicated that they thought they had to answer all questions. This shows a marked inconsistency which, to some extent, may reflect human nature, but may also in part be a result of the methodology where what appear to be contradictory findings can be rationale.

#### *Update regarding recommendations from EGC15*

At its last meeting the Council sought confirmation of whether or not any of the proponents of the specific new technologies proposed to be included in UK Biobank's enhanced phenotyping have a commercial interest in those technologies. UK Biobank is preparing a specific proposal to be submitted to the Funders in January 2009. Any issue of conflicts will be made explicit in this final proposal.

Other recommendations and requests from EGC15 were addressed by Professor Collins in his general update and under the items that follow.

#### *Development of UK Biobank's access and intellectual property procedures*

The Council discussed UK Biobank's paper in closed session before Professor Rory Collins and Mr Sellors joined the meeting. The paper was seen to be a useful scoping exercise that sets the scene and pulls together a number of threads but the paper did not as yet elaborate on the detail of the policies stated in the EGF.

The Council agreed to seek clarification from UK Biobank on a number of topics raised in the paper. For example, the Ethics and Governance Framework states that there will be a requirement on all researchers to place the findings from all research based on UK Biobank in the public domain. Mr Sellors provided clarification regarding the wording of his paper which stated that it is 'probable' that researchers will be required to publish the results of their research. Regarding the requirement for researchers to return their findings to UK Biobank, the paper re-iterated the EGF policy that this will certainly be a condition of access, although the paper did not explicitly state that this will include the return of negative findings. Finally, the paper did not make specific reference to possible benefit or profit sharing, topics that the

Council believes should be kept on the table as separate issues even if, for example, profit sharing is seen as being appropriate in exceptional circumstances only.<sup>3</sup>

Mr Sellors introduced his paper stating that the overall framework for the access and intellectual property (IP) policy is available in the EGF and that UK Biobank is now working out the detail of the procedures which underpin this policy. He commented that UK Biobank is the first among biobank resources to develop access and IP procedures and that UK Biobank is therefore mindful that it must produce something that will stand up to scrutiny by a number of audiences. UK Biobank will consult with a number of stakeholders before publishing the procedures.

The Council has advised UK Biobank on a number of iterations of its access and IP policy. The Council noted that UK Biobank has drawn a distinction between the overall policy, which is already available in the EGF, and detailed procedures, which are now being developed. The Council questioned what implications this framing has for the publication of the more detailed policy and procedures, including when these will be made public. UK Biobank responded that a document that sets out the procedures and elaborates on the policy in the EGF should be publicly available in early 2009 and a more complete document should be available later that year. These documents will draw on the previous text that has been considered by the EGC and on its recommendations.

Professor Collins advised that, in prioritising its work, it was time critical for UK Biobank to finalise its proposals for enhancements as these need to be implemented while the assessment centres are still operating (i.e. early during 2009). On the other hand, detailed access and IP procedures do not need to be in place until the end of recruitment (i.e. the middle of 2010) when the resource starts to be used. The Council had sympathy for this position but noted that the time period to 2010 is not substantial.

UK Biobank aims to create procedures which are not cumbersome and which have as few time constraints as possible. Professor Collins suggested that standard requests for use may be considered by UK Biobank, saving the more complex requests to be considered by an Access Committee.

The access procedures present a challenge not least because UK Biobank diverges from the usual resource model in which the Principal Investigator of a resource owns the samples and determines who should have access. UK Biobank recognises the need to be clear in its communications to the user that if they have a good research question which meets all other terms of access they will be permitted use of the resource. The Council and UK Biobank agreed that it would be useful to have procedures in place in time to give potential users sufficient notice regarding the processes by which they can access the resource.

It was also considered important by the Council for the access and IP procedures to be available as soon as possible for participants. For example, UK Biobank's policy regarding profit and benefit sharing may impact on an individual's willingness to participate. Mr Sellors commented that UK Biobank receives on average one query

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<sup>3</sup> Clarification of the last two points was sought through a series of follow up questions sent to UK Biobank after the meeting (see first action point on page 11).

per 6 - 8 months regarding access and IP issues and that mostly the questions have already been well considered and are straightforward to address.

UK Biobank welcomed the Council's proposal to provide a list of questions that it considers important for UK Biobank to address in its policy and procedures. For example, How will the Access Committee (AC) be constituted? What will be the remit of the AC? What will be the basis for the AC's decisions? How will UK Biobank define 'health-related research' in the access decision making process?

**ACTION:** The Council will compile a list of questions which UK Biobank should seek to address during the further development of its access and IP policy and procedures. [AH]

**ACTION:** The Secretary will circulate the National Cancer Research Institute's consultation on the development of a standard 'template' which could be used to guide the development of access policies for cancer sample collections and datasets to members of the EGC and to Jonathan Sellors, for information. [AH]

In closed session later in the day one member reflected on UK Biobank's update and expressed concern that it was suggested that certain decisions regarding access might be devolved to UK Biobank rather than to an Access Committee. This comment reflects concern within the scientific community that some people will be able to gain access to the resource more easily than others. The Access Committee is seen as key to promoting equal opportunity for access to all researchers. Professor Collins had indicated, however, that the intention was to facilitate rapid access for non-contentious uses of the resource and to reserve the Access Committee for review of those requests that raised particular issues (e.g. requirement for depletable sample). In addition, all requests and approvals for access would be recorded in order that these processes could be monitored.

#### *UK Biobank touch-screen and interviewer questionnaires*

The Council was interested to read UK Biobank's paper reporting the % of participants who chose the 'prefer not to answer' or 'do not know' options when completing the touch-screen and interviewer questionnaires. The paper reported on those questions with a greater than 10% missing answer. The Council requested this information in order to ascertain whether certain questions were being routinely omitted by participants, possibly indicating that the question is either too ambiguous or difficult to answer or too intrusive.

The Council learnt that a very small proportion of people decline to answer questions and no single question had a particularly high 'non response' rate. Professor Collins commented that while some of the questions are covered in an aide memoire, which participants are asked to complete ahead of the assessment visit, this strategy has not resolved all problems relating to a participant's recollection. Further, in some instances participant responses have highlighted some misunderstanding about the way in which the questions have been interpreted.

6. UK Biobank's proposal for enhanced phenotyping of participants (Professor Rory Collins, Chief Executive Officer, UK Biobank)

Professor Collins provided a brief update on UK Biobank's proposal for enhanced phenotyping of participants, in which three categories of enhancement are envisaged.<sup>4</sup> The category 2 measures will include an additional assessment centre station for testing a participant's vision. Feedback will be provided on pressure in the eye, a measure which is easy to check and can provide an indication of glaucoma.

The category 3 measures were previously discussed by the Council in terms of UK Biobank's feedback policy. These measures will involve substantial new funding and will be separated out from the initial assessment visit. UK Biobank is currently seeking funding to pilot the category 3 measures which primarily involve imaging of the brain and body in addition to ECG scans. It is anticipated that the imaging could be piloted in 2010/2011 including an assessment of people's views with regards to the feedback issue. Ultimately UK Biobank would hope to invite from among all 500 000 participants for imaging, with the aim of having 100 000 participants agree to this involvement. New participant information materials will be developed for this aspect of the study and will require research ethics committee approval.

7. UK Biobank's proposals for longitudinal follow up of participants (Professor Rory Collins, Chief Executive Officer, UK Biobank)

UK Biobank has recently received approval from the NHS Information Centre for notification to UK Biobank of all deaths (including date and cause of death) and all new cancer registrations for all UK Biobank participants across the entire UK. Now that approval has been provided it should be possible for UK Biobank to also make a successful application to receive information from other NHS routine records e.g. Hospital Episodes Statistics data.

The Council reviewed a paper prepared by UK Biobank which outlined the project's plan to undertake three exemplar follow up pilots for around 10 000 participants from each country, Scotland, Wales and England. The decision to conduct the pilots in the three countries reflects the different pace of migration to the electronic medical record found in these countries and the differences in the design of the national systems being implemented. The pilots will test the types of NHS data that are available through various records found in the three countries.

During the discussion Professor Collins confirmed that it would be possible for UK Biobank, in principle, to access post mortem data through a participant's NHS records. He also confirmed that the types of data available to UK Biobank may be jurisdictional specific depending on what each country allows. Further, UK Biobank is hoping to seek access to a broad range of health-related records, not purely NHS records.

UK Biobank has also been advising the Research Capability Programme of Connecting for Health on ways in which systems might be set up to facilitate linkage

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<sup>4</sup> See EGC15 meeting report for details of the three categories (available at [www.egcukbiobank.org.uk/meetingsandreports](http://www.egcukbiobank.org.uk/meetingsandreports))

with a wide range of health-related records. UK Biobank has also been looking at dental record systems to see what outcomes are available both in past and future records. The Council noted that this information could only be gleaned for participants who have NHS dental records, excluding those who visit a private practice. Professor Collins agreed and noted that UK Biobank is adding questions about whether the participant has NHS or private health care.

Professor Collins confirmed that UK Biobank will publish a list of record systems which it uses as part of the project's strategy for longitudinal follow up of participants. The Council recommended that this list should also include those systems from which UK Biobank has been denied access. This might provide some leverage if, for example, there is reluctance to permit access within one jurisdiction when access has been approved in other jurisdictions. The Council also recommended that UK Biobank should be explicit about which records it has access to so that, if participants do not think it appropriate for certain records to be accessed, they can assert their right to withdraw from the project.

Professor Collins and Mr Sellors left the meeting, after which the subject of record linkage was discussed in closed session.

Participants provide consent for UK Biobank to access their health-related records (and the information materials give occupational or residential information as examples of these records). Members discussed the potential breadth of interpretation of the term 'health-related' and recognised that a linkage that is acceptable in terms of the consent may not be appropriate in terms of the participant's expectations of the consent provided. It was agreed that UK Biobank should be able to justify why a record is health-related and why access is appropriate and needed.

While agreeing that it would be difficult for the EGC to make any firm decisions about what makes certain records acceptable and other not, UK Biobank and the EGC do need to be clear on what types of records they consider to be, and not to be, 'health-related'. Members stressed the need for the EGC to be kept fully up-to-date with regards to UK Biobank's activities in this area. Decisions regarding the appropriateness of the linkage can then be made on a case-by-case basis.

The opinion was expressed that it is not necessarily a matter of which records UK Biobank has access to but how these data are used by researchers. People may be more willing to accept linkages to a broad type of record providing that the research matches the purpose of UK Biobank. The Council also recognised that some information may not be sensitive on its own but sensitivity may come through linkage with information in other records. Further, what one person regards as sensitive may not correlate with what a different person regards as sensitive and indeed an individual's own concept of what is sensitive may change over time and with age. This illustrates the difficulty of defining what are and are not appropriate records to be accessed and suggests that the focus may also be usefully placed on the ways in which the information is used by researchers.

The Council recognised the need for UK Biobank to evolve scientifically and recognised that the ability to make linkages is a rapidly evolving area of science. The

Council also recognised that there may one day be a need, however, to draw a line between scientific progress and what might be perceived to be mission creep (if access to a wider number of only tenuously health-related records is sought). Further, as discussed with UK Biobank, a published list of records used by UK Biobank as part of its follow up strategy would be an appropriate and essential way of keeping participants informed. UK Biobank would also be advised to question whether the proposed linkage fits the participants' consent and that the project will ensure that the evolution of consent will match the evolution of the resource. (For example, where participants have opted for a sealed envelope with the Connecting for Health initiative, will UK Biobank be permitted access to these data regardless of the participant choosing this option and if so ought UK Biobank gain new consent to access this data?)

## 8. EGC review

The Secretary has developed a paper outlining the EGC's work since its creation in November 2004 as part of the EGC's review by the Funders. Members discussed the paper, which will be submitted to the Funders next week, and suggested amendments for inclusion in the final report.

**ACTION:** The Secretary will revise and submit the review document to the Funders. [AH]

Dr Doyle commented that the review will consider the nuances of the way in which the EGC operates and will consider whether or not the body is fulfilling expectations.

## 9. Communications activities

### *External speaking opportunities*

**ACTION:** The EGC communications subgroup will consider the question of the location and number of Science Festivals that the EGC should seek to have a presence at in 2009.

### *External enquiries to the EGC*

The Secretary reported on the recent external enquiries to the EGC.

### *Andrea Cook and Andrew Trehearne meeting*

Ms Andrea Cook and UK Biobank's Head of Communications, Mr Andrew Trehearne, will be meeting shortly to discuss communications-related issues.

## 10. Report on meetings attended

### *Governing genetic databases conference (24-26/06/08)*

The Chair, Vice-Chair and Secretary attended the Governing genetic databases conference in June. The Vice-Chair presented a paper on the EGC's role and the added value the body brings to the governance of UK Biobank. There was a great deal of interest in the EGC, in particular the fine details of its workings. Feedback from attendees suggests that the Council's ability to commission research is seen as enhancing its independence.

*Board meetings (04/07/08)*

The EGC Chair attended the UK Biobank Board of Directors meeting in July at which the main topic of interest to the EGC was the development of the project's access and intellectual property procedures.

*'Genome-Wide Association Studies and Ethics Meeting' (24/07/08)*

The Wellcome Trust recently hosted a meeting on Genome-Wide Association Studies and Ethics which was co-Chaired by the Council Chair and Professor Mike Parker. A report of the meeting is being drafted by the Wellcome Trust.

**ACTION:** The Secretary will investigate whether or not the report can be circulated to the EGC. [AH]

#### 11. Any other business

A third member of the Council was recently recruited to UK Biobank. The Council briefly reflected on the nature of participant involvement on the Council and how the knowledge gained from the recruitment experience might be used in the committee and also in providing feedback to UK Biobank. It was agreed that members who choose to participate in UK Biobank do so in their own individual capacity and that any feedback provided to UK Biobank is given in their individual capacity and not as a representative of the EGC.

The Council suggested that UK Biobank gives further consideration to the possibility of forming a participant panel to provide input into its policy developments (as envisaged in the EGF and akin to the Human Genetics Commission's consultative panel).

It was agreed that members' titles should be removed from future meeting name plates.

The Chair thanked Professor Chris Wild on behalf of the Council for his work and dedication to the EGC over the last four years and gave the Council's best wishes for his new position in Lyon, France. Professor Wild accepted the wishes, commenting that he had learnt a lot and enjoyed his time on the EGC.

#### 12. Date of next meetings

8 December 2008 - Council meeting      12 February 2009 - Public meeting (Cardiff)