

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

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

Monday 17 March 2008 at 10.30am

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### **Agenda**

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1. **Apologies**
2. **Minutes** of thirteenth meeting held on 1 November 2007
3. **Matters arising**
  - (i) Summary of decisions and recommendations from thirteenth meeting held on 1 November 2007
  - (ii) Tracking of requests to UK Biobank
  - (iii) Update: Appointment of new EGC members
  - (iv) Discussion and decision: Access to the UK Biobank resource: Concepts of the public interest and the public good
4. **Research project: 'UK Biobank: public attitudes to third party access and benefit sharing'** (Professor Andrew Webster and Dr Jane Kaye)
5. **Update from UK Biobank** (Professor Rory Collins, Chief Executive Officer, UK Biobank)
  - (i) General update from UK Biobank
  - (ii) Update regarding recommendations from EGC13
  - (iii) UK Biobank's long term communication strategy
6. **UK Biobank's access and intellectual property policy** (Mr Jonathan Sellors, Company Secretary, UK Biobank)
7. **Research project: 'UK Biobank: public attitudes to third party access and benefit sharing'** (discussion in closed session)
8. **Appointment of EGC Vice Chair**
9. **Communications activities**
  - (i) Update and discussion: Public meetings
  - (ii) Update: EGC annual review 2007
10. **Report on meetings attended**
  - (i) 'Biobanking: A Two-Day Intensive Course' (25 and 26/11/07)
  - (ii) 'Critical Issues for Electronic Health Records' meeting (27 and 28/11/07)
  - (iii) British Computing Society Lecture Series (Edinburgh branch) (20/02/08)
11. **Any other business**
12. **Date of meetings in 2009**

16 March, 8 June, 7 September, 7 December
13. **Date of next meeting**

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

**17 March 2008  
Wellcome Trust, London**

Present: Professor Graeme Laurie (Chair), Professor Ian Hughes, Ms Andrea Cook, Professor Roger Higgs, Dr Roger Moore and Professor Martin Richards.

In attendance from EGC Secretariat: Ms Adrienne Hunt.

Observers: Dr Alan Doyle and Dr Claire Kidgell (Wellcome Trust) for items 1 - 7.

Speakers: Professor Rory Collins (Principal Investigator and Chief Executive, UK Biobank) and Mr Jonathan Sellors (Company Secretary, UK Biobank) for items 4, 5 and 6 only. Professor Andrew Webster and Dr Jane Kaye for item 4 only.

1. Apologies

Apologies were received from Professor Chris Wild, Professor Anneke Lucassen, Professor Erica Haines and Dr Heather Widdows.

2. Minutes of the last meeting held on 1 November 2007

The Council approved the circulated minutes.

3. Matters arising

*Summary of decisions and recommendations from the thirteenth meeting held on 1 November 2007*

Independent statements regarding the change in wording to the 'No further use' option of withdrawal have now been posted on UK Biobank and the EGC's website.

The Council agreed to produce a statement regarding the process of this revision to be published on its website. (A joint statement with UK Biobank was considered but rejected as unnecessary and because it might be perceived to compromise the independence of the Council and/or cause confusion about its relationship with UK Biobank.) UK Biobank will have sight of the statement before it is posted on the web.

**ACTION:** The Secretary will draft and post a statement on the EGC website. [AH]

The summary document states that it would be beneficial to have an information technology expert on the EGC. It was clarified that the Council should seek an expert in information security, rather than information technology.

The Council approved the circulated summary of decisions and recommendations.

### *Tracking of requests to UK Biobank*

At its last meeting the Council requested sight of the British Heart Foundation (BHF) leaflet which is being distributed to potential UK Biobank participants. The leaflet offers participants a free consultation with a BHF nurse at the conclusion of their assessment centre visit. The Council had been concerned about the potential confusion that may occur regarding the relationship between UK Biobank and the BHF nurse (i.e. the consultation might be considered part of participating in UK Biobank). Having had sight of the BHF leaflet the EGC was assured that the leaflets design was sufficiently different from the project's participant materials to convey the 'separateness' of the BHF from UK Biobank.

The three other requests for further information will be addressed during agenda items 5 and 6.

### *Update: Appointment of new EGC members*

A recruitment process will take place in Autumn 2008 with the aim of recruiting at least two new members. An Appointment Panel will be convened comprising the EGC Chair, EGC member Dr Roger Moore, Ms Hilary Newiss as the independent assessor and one Wellcome Trust Governor and one Medical Research Council member.

The importance of regular attendance by members of the Council was discussed and agreed. The Chair, whose responsibility it is for monitoring attendance and addressing undue absence with individual members, will keep alert to the situation and remind members of this obligation.

**ACTION:** Professor Laurie will write to all Council members about this matter and explain the low attendance rate to Professor Collins.

### *Discussion and decision: Access to the UK Biobank resource: Concepts of the public interest and the public good*

The authors of the report have confirmed that the Chair's summary, discussed at the last EGC meeting, is an accurate reflection of their findings. The summary is a living document and will be revised over time to take account of new thinking by the Council on its interpretations of 'public interest' and 'public good' (e.g. in response to other commissioned work or future experiences).

**ACTION:** The summary will be modified and published on the EGC website along with a link to the original, prefaced report. It will be made clear that the report is not an instrument of the Council but rather a piece of independent commissioned work. The website will invite comments on the report's findings to be submitted to the EGC. [GTL and AH]

4. Research project: 'UK Biobank: public attitudes to third party access and benefit sharing'

Professor Andrew Webster and Dr Jane Kaye presented the findings of their report. The Council, together with Professor Rory Collins and Mr Jonathan Sellors, discussed the report with its authors. The Council and Professor Collins found that there were some valuable findings in the report, but also noted that there were a number of matters that required attention. A process for providing detailed feedback to Professor Webster was agreed. The feedback will stress the need for the report to be re-structured and re-written to reflect the current policies and practice of UK Biobank. The report should also be explicit with regards to policies and practices which are established and those which are under development.

The study surveyed the attitudes of members of the public from the age range of UK Biobank participants (40 – 69). However, a number of questions in the study are not restricted to an exploration of the opinions of those in this age range. To reflect the fact that these are much wider questions which raise issues of the wider general public's awareness, perceptions and opinions towards biobanks and their use, a young person's group, 18 – 30 years, was also surveyed to explore opinions amongst young people, especially as these will be amongst the expected beneficiaries (in later life) of UK Biobank research.

Professor Webster's tender states that 150 participants from the 18 – 30 age group will be recruited. In the event only 50 participants from this age group were recruited. This number does not allow for statistically significant conclusions to be drawn and only allows speculative comments about the attitudes of the groups. It also affects the ability of researchers to effectively compare the attitudes of the younger and older age groups.

**ACTION:** Professor Laurie will contact Professor Webster to discuss these matters and to suggest that the research team might go back and survey more participants from the younger age group.

The Council agreed on the importance of closely monitoring achievements against set milestones within respect to future research briefs.

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

*Recruitment - invitation and assessment centre operations*

1.7 million invites to participate have been distributed (as of 8 March 2008). The project has received 265 000 reply cards, 9 000 responses via its website and 134 000 calls to the Participant Resource Centre. More generally there have been tens of thousands of hits to the project's website.

As of 17 March 2008 84 000 participants have been recruited with an attendance rate of 10% of those invited. A good age and gender mix is being achieved within the participant group: less younger than older people have been recruited but the numbers are very close; more female than males have been recruited but again the

numbers are similar (and this is true of all age groups).

Invitations are initially sent out to potential participants living within a 10 kilometre radius of the assessment centres. This distance is then increased up to the point where a drop-off in the uptake rate is observed. UK Biobank has seen no detrimental effect on the response rate when inviting potential participants up to 20 km from the assessment centres.

Recruitment is taking place at 5 - 7 centres at any one time with approximately 100 people being recruited at each centre per day, for 6 days a week. To date a maximum of 700 participants have been recruited on a single day. Some inconsistent recruitment patterns have been experienced resulting in spikes of very busy periods at the centres. Modification of the IT appointment system and weekly meeting between Clinical Trial Service Unit (the processors of the potential participants' contact details) and UK Biobank has rectified this situation. Recruitment has been working smoothly for the last few months.

Having recruited approximately 14 000 participants at each, the Manchester and Oxford assessment centres have now closed. The following assessment centres are currently open:

<b>Assessment centre</b>	<b>Number of participants recruited</b>	<b>Closing date (2008)</b>
Glasgow	16 000	19 April
Cardiff	12 000	end of May
Edinburgh	9 000	12 July
Stoke	7 000	mid June
Bury (Manchester)	5 000	end of November
Newcastle	3 000	end of December
Leeds	1 000	end of December

Four new centres are being planning:

<b>Assessment centre</b>	<b>Opening date (2008)</b>
Reading	14 May
Bristol	2 July
Nottingham	30 July
London (UK Biobank plans to operate several centres in London. The first will be based at Professor Mark Caulfield's laboratory at St Bartholomew's and will run as a 'half' assessment centre.)	27 August

There are a number of advantages and disadvantages between the 'small town' versus 'big city' approach to recruitment. While a town may have a comparatively small population it is possible to extend recruitment out further from the assessment centre. This provides a greater mix of participants including, for example, rural and urban areas. This mix increases the heterogeneity and generalisability of the cohort. The 'big city' recruitment approach could be the easiest given the greater number of people who live in a city. However, travelling in a city is different to that in a town and people may not be prepared to travel the 10 - 20 km to the assessment centre. UK

Biobank has adopted a mixed approach and will be recruiting in both cities and towns. For smaller populations, half assessment centres will be employed. In addition, UK Biobank is actively exploring a proposal from the Welsh Assembly to provide a mobile assessment centre to be used to recruit in rural areas.

#### *UK Biobank's plans for enhancement of the protocol*

UK Biobank is developing a proposal for enhancement of its protocol to be submitted to the Funders for approval later in the year.

A web based diet assessment is being developed by Professor Valerie Beral. Initial data from an ongoing validation looks very good with the web based data correlating 75-80% with diet diaries (as compared to normal diet questionnaires which correlate to diet diaries by only 30%). The web based assessment is being developed to maximise the ease of usability and, once piloted, may be used by a subset of UK Biobank participants.

The Enhancement Working Group, Chaired by Professor Paul Elliott, is investigating proposals for enhancement including the use of more questions and the collection of more samples and measurements. Two main avenues are being investigated:

#### 1. Aspects that could be added to the current assessment centre visit

UK Biobank has found that some people are prepared to spend an additional 20 minutes at the centre to undertake a consultation with a British Heart Foundation nurse. This suggests that once at the assessment centre, participants might be prepared to stay beyond the current 90 minute assessment period, if the visit is of interest to them.

Additional assessment centre measures might included a hearing test on a touch screen, a range of eye measurements, information about vascular state, additional questions around exposures and on past employment. Participants may also be asked to wear a pedometer for a week after their visits after which time it is returned to UK Biobank for an assessment of their activity. The main costs associated with these new measure will be the costs of the extra time required for the assessment centre staff.

#### 2. Aspects that could be investigated in a subset of participants (separate to the initial assessment centre visit)

The Working Group is currently investigating the merit of re-contacting participants and inviting them to undertake detailed magnetic resonance imaging. This might include investigation of the brain, heart, blood vessels, joints and skeletal muscles. The results could be strongly predictive of future disease and susceptibility. For example, blood vessels and heart may provide an indication of cardiovascular disease whereas joint condition is predictive of disability in the long term.

Invites to participate in the imaging will not be based on suspicion of disease and the decision to participate in the imaging will be entirely voluntary. The Council asked if the imaging brings UK Biobank closer to diagnosis and asked what implications this

has for the project's current policy on providing limited feedback of health information to participants. Professor Collins confirmed that the images will be analysed in the future on a nested case-control basis and that no detailed analysis will take place in the short term. However, UK Biobank could potentially make an incidental finding as a result of the imaging that requires feedback to the participant. Given this the current policy will need to be re-visited (but any new policy should be consistent with the current policy). UK Biobank intends to contact other studies which have undertaken imaging (e.g. ALSPAC) in order to establish how they dealt with the feedback issues.

The proposal for enhancement will be developed over the coming months through discussions with the Regional Collaborating Centres and UK Biobank's Funders. The detailed proposal will be taken to the International Scientific Advisory Board and the EGC in summer before being submitted to the Funders for approval in September 2008.

The Council recognises that some of the proposed enhancements, in particular the imaging, might raise new ethical issues (e.g. if the proposed new measurements provide a clear indication of the current or future health status of a participant).

**ACTION:** Professor Collins and the EGC agreed that the Council's advice should be sought in plenty of time for it to provide effective input into UK Biobank's proposals. [RC and AH]

#### *Update regarding recommendations from EGC13*

##### *British Heart Foundation presence at the Manchester assessment centre*

The option of a 20 minute consultation with a British Heart Foundation (BHF) nurse has now been extended to additional assessment centres. Take-up has been approximately 75%, with participants being informed of this option through a flyer included in the initial invite to participate in the project. UK Biobank has entered into a formal agreement with the BHF in order to guarantee sufficient numbers of nurses to cope with the demand for the service. Through the contract UK Biobank and the BHF aim to provide the same level of service to participants.

At its last meeting the Council asked to have sight of the BHF information leaflet and asked UK Biobank whether any participants had gone back to UK Biobank staff to ask questions after their BHF consultation. Having had sight of the BHF leaflet the Council was satisfied that it is sufficiently different from UK Biobank's participant materials to demonstrate the separateness of the UK Biobank project and the BHF consultation. Professor Collins informed the Council that there had been very few cases of a participant going back to a UK Biobank nurse after their BHF consultation and that UK Biobank staff are trained not to provide health advice.

### *UK Biobank's long term communication strategy*

A paper prepared by Mr Andrew Trehearne, UK Biobank's Head of Communication, describing the provisional elements of the project's long term communication strategy was discussed. The strategy favours electronic means of communication including the project's website, text and email. News media and advertising are also included in the strategy and a participants' panel remains to be an area for possible further discussion.

The Council has previously suggested that UK Biobank might produce a hard copy newsletter for distribution. However, given the logistical difficulties involved, the project team is instead considering posting a newsletter on its website. While not underestimating the difficulty of the task, given the size of the cohort and the likely attrition over time, the Council cautioned that a strategy focused on electronic communications may disenfranchise older and lower economic groups. Other outlets could be used to supplement these communications e.g. posting information in GP and hospital waiting rooms and libraries. Local council free newspapers and intermediary organisations might also be used to communicate messages about UK Biobank.

A participants' panel was briefly discussed including the history of the now disbanded public panel which was convened by UK Biobank's funders in the early stages of the project's development. It was agreed that it is hard to make any such Panel representative of its constituency. The Council envisaged that such a Panel would initially deal with issues regarding the assessment centre based on direct practical experience of the assessment centre visit (i.e. issues of a lower strategic order than those dealt with by the EGC).

Participants are able to submit their comments to the project team via UK Biobank's website and it was suggested that the website might be used to even greater effect in future. The website has recently been updated with a 'New developments' page and the site might be developed further to include more information about the project's progress.

The long term communication strategy continues to be developed with reference to communication methods adopted by other similar studies.

**ACTION:** At Professor Collins' request, Ms Cook agreed to liaise with Mr Andrew Trehearne over these issues. [AC]

### *Participants' comments on the EGC*

At its last meeting the Council requested that UK Biobank might pass on any enquires or complaints that it receives in relation to the Council. Professor Collins confirmed that UK Biobank would be willing to pass these on, providing the enquirer/complainant agrees. He commented that participants are generally positive about the EGC, seeing it as an additional safeguard to the standard process of research ethics committee approval.

### *Translators at assessment centres*

UK Biobank has investigated the Council's suggestion that a telephone translation service might be used at the assessment centres but has subsequently decided not to pursue this option at this time. Translation capacity has not been problematic as visits are scheduled for when a translator is present and when the assessment centre is quieter. When recruiting in certain ethnic group areas UK Biobank aims to recruit assessment centre staff from these communities. The Council recommended that UK Biobank could draw on established local housing agencies, tenants associations and law and advice centres who already have good local links into the community and also often possess language and translation skills which they would be prepared to offer on a sessional or peripatetic basis.

### *Biannual complaints and enquiries report*

At its last meeting the EGC reviewed a report from UK Biobank outlining the enquiries and complaints that it had received in the first 6 months of operation. The Council subsequently requested additional information to be included in future reports regarding complaints and enquiries of an ethical nature (e.g. relating to commercialisation or feedback of health information). Professor Collins commented that UK Biobank does receive a number of enquiries about commercial access to the resource. The rationale of commercial use is explained to the enquirer along with the difficulty of separating out commercial from purely academic research. If the enquirer has residual concerns they are advised not to participate in the project.

### *Data Security*

At its last meeting the Council recommended that UK Biobank provide more information on its website regarding its data security measures. Professor Collins confirmed that a lay summary is available on the project's website. While UK Biobank is open to doing more in this regard, providing too much information on the web might have the counteractive effect of compromising the security of the project's systems.

## 6. UK Biobank's access and intellectual property policy (Mr Jonathan Sellors, Company Secretary, UK Biobank)

UK Biobank's access and intellectual property policy is set out within the Ethics and Governance Framework. The Council discussed a paper prepared by Mr Jonathan Sellors describing UK Biobank's current thinking with regards to the process of developing the detailed guidelines, protocols and procedure for access and separately for intellectual property (although the two policies will still be interlinked). As part of this process UK Biobank is reviewing the access guidelines, protocols and procedures of other resources (including those of other biobanks) but their preliminary impression is that this research will prove to be advisory and UK Biobank will ultimately have to develop its own access guidelines, protocols and procedures. UK Biobank's access policy will necessarily be distinct from other (non biobank)

research resources as it is set up to study the prevention, diagnosis and treatment of multiple diseases.

When the guidelines, protocols and procedures for access have been developed - which will be done in consultation with a number of parties (including the Ethics and Governance Council) - these will be tested internally against a number of different scenarios. The Council recommended that it might be beneficial for UK Biobank to provide participants with case studies of different access scenarios e.g. to demonstrate when UK Biobank might and might not seek to share some profits resulting from research conducted on the resource. This could be extended/used as a deliberative exercise by posting the case studies on UK Biobank's website and inviting comments from participants and the public.

UK Biobank is considering whether assays on samples should be performed by UK Biobank (whether by UK Biobank itself or outsourced to a third party). This would have certain advantages in relation to the intellectual property considerations.

Mr Sellors' paper raised the question of how 'health' should be interpreted in terms of access for 'health-related research'. The Council recommended maintaining a broad definition of 'health' when considering access requests.

A number of the surveyed participants in Professor Webster's study favoured a hybrid fee-paying and profit-sharing model for access. It was reported that UK Biobank is investigating the possibility of charging fees for access. UK Biobank has not formally considered the profit sharing model: however, this would not be a straightforward model and moreover, UK Biobank is keen not to negotiate each licence to use the resource on a case by case basis. The Council highlighted the value of flexibility, however. The access policy could state that 'UK Biobank will not normally benefit financially from research conducted on the resource'. This leaves open the possibility that in rare, exceptional circumstances UK Biobank may negotiate some form of profit sharing.

UK Biobank will not in principle make a claim on intellectual property rights developed independently by third parties but it may seek a licence-back of certain rights for research or experimental use. UK Biobank recognises that a balance needs to be struck between enabling researchers to benefit from the results of their work and at the same time not preventing or impairing further research.

Professor Webster's study was premised on the fact that UK Biobank will not seek a share of profits made as a result of research conducted on the resource. The responses should be read in this context. The Council discussed how UK Biobank might be perceived if it was to seek a profit routinely. It was suggested that such a policy might change the 'public good' nature of the resource and might give the appearance of the project being a commercial venture. Such a shift might, in turn, discourage the altruistic participation of some people. By the same token, UK Biobank will have to develop a practical approach to access and intellectual property rights that addresses the issues identified and discussed and find an acceptable balance between the 'public good' nature of the resource and the possibility of return of some benefits from research conducted on the resource, where appropriate.

The Council was informed that the finalising of guidelines and procedures is a task for the 'medium term' and that the Board of UK Biobank will set an outline timetable in due course. Clarification was sought regarding the meaning of the phrase 'medium term' and the Council stressed the importance of developing a clear timetable for the development of the policy in the near future.

The EGC access and intellectual property (A&IP) subgroup has previously commented on earlier drafts of the policy (including comments in relation to the Access Committee and more articulation of principle than found in the EGF).

**ACTION:** The EGC Secretary will send the EGC A&IP subgroup's comments to Mr Sellors for re-consideration during the further development of the policy. The comments will also be sent to Council members. [AH]

## 7. Appointment of EGC Vice Chair

Members agreed to support the appointment of Professor Martin Richards as EGC Vice Chair. It was agreed that another Vice Chair may be appointed in due course if this was thought to be necessary and appropriate.

**ACTION:** The Secretary will inform Professor Richards and the EGC's funders of the outcome and arrange the relevant paperwork. The Chair will inform the unsuccessful candidate of the outcome. [AH and GTL]

## 8. Communications activities

### *Update and discussion: Public meetings*

A public meeting will be held on 1 July 2008 at the Hub in Edinburgh from 18.30 - 20.00.

The Council agreed to hold a further public meeting in Wales in either Cardiff - where recruitment is ongoing but will cease at the end of May 2008 - or a future recruitment location.

**ACTION:** The Secretary will ask UK Biobank for its plans to open new assessment centres in Wales. [AH]

**ACTION:** The Council agreed to explore opportunities for raising awareness about its activities, for example through presentations at Science Festivals and other external events. [AH]

### *Update: EGC annual review 2007*

The EGC Annual Review 2007 was brought to the Council's attention. The Review will be distributed to UK Biobank's assessment centres and to the EGC contacts list.

**ACTION:** Members were invited to submit to the Secretary the names of individuals or organisation who might be interested in receiving a copy of the Review. [Members]

#### 9. Report on meetings attended

##### *'Biobanking: A Two-Day Intensive Course' (25 and 26/11/07)*

By invitation, Dr Roger Moore attended a two-day intensive course on biobanking on 25 and 26/11/07 to present a talk entitled 'UK Biobank Ethics and Governance'. Representatives from other biobanks expressed considerable interest in the EGC, highlighting the need for the Council to report its work publicly through its minutes, in order that other biobanks may be informed by the Council's decisions.

##### *'Critical Issues for Electronic Health Records' meeting (27 and 28/11/07)*

The Secretary attended a meeting organised by the Nuffield Trust and the Wellcome Trust. The meeting aimed to identify the main issues, opportunities and challenges of Electronic Health Records.

##### *British Computing Society Lecture Series (Edinburgh branch) (20/02/08)*

The Chair recently presented a talk outlining the Council's role in UK Biobank's Access and Intellectual Property Policy as part of the British Computing Society Lecture Series (Edinburgh branch). When the EGC recruits later in the year the advert might usefully be sent to the Society for distribution to its members.

#### 10. Any other business

One member proposed that the EGC website could contain more educational material related to its field of work. The member will consider the proposal more fully before bringing it to Council for consideration.

#### 11. Date of meetings in 2009

16 March, 8 June, 7 September<sup>1</sup>, 7 December

#### 12. Date of next meeting

The next Council meeting will take place on 9 June 2008. A public meeting will be held on 1 July 2008.

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<sup>1</sup> Subsequent to this meeting it was decided that the 7 September 2009 would be reserved for a public meeting and the 8 September 2009 would be reserved for a Council meeting.