

UK Biobank Ethics and Governance Council Eleventh Meeting

Meeting at Wellcome Trust
215 Euston Road London NW1 2BE

Monday 12 March 2007 at 10.30am

Agenda

1. **Apologies**
2. **Introduction to Sir Alan Langlands** (Chair, Board of Directors, UK Biobank)
3. **Update from UK Biobank** (Professor Rory Collins, Chief Executive Officer, UK Biobank)
 - (i) General update from UK Biobank
 - (ii) Update regarding recommendations from EGC10 (including complaints policy for publication on UK Biobank's website)
 - (iii) Protocol describing the management of incidental findings (at the assessment centre)
 - (iv) Protocol describing the assessment of capacity (at the assessment centre)
4. **UK Biobank's intellectual property and access policy: subgroup work**
5. **Minutes** of tenth meeting held on 16 January 2007 (format for discussion)
6. **Matters arising**
 - (i) Summary of decisions and recommendations from tenth meeting held on 16 January 2007
 - (ii) Tracking of requests to UK Biobank
 - (iii) Update: Public event (11 June 2007)
 - (iv) Update: EGC policy on the publication of Council meeting minutes
 - (v) EGC policy on complaints handling
 - (vi) EGC policy on judging proposals to provide consultancy services
7. **Proposal to hold EGC committee meetings in public**
8. **Report on meetings attended**
 - (i) Meeting between the Secretary, Andrew Trehearne and Barry Taylor (02/02/07)
 - (ii) Board of Directors meeting (23/02/07)
 - (iii) Joint RCC meeting (21/02/07)
9. **Consultations**
 - (i) Proposal: An exploratory project to study opinions regarding the terms of 'third party' access to UK Biobank
 - (ii) Access to the UK Biobank resource: Concepts of the public interest and the public good
10. **EGC business plan: future work packages**
11. **Any other business**
12. **Date of next meetings**

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

**12 March 2007
Wellcome Trust, London**

Present: Professor Graeme Laurie (Chair), Professor Chris Wild, Professor Roger Higgs, Professor Ian Hughes, Professor Erica Haines, Ms Andrea Cook, Ms Hilary Newiss, Dr Roger Moore and Professor Martin Richards.

In attendance from EGC Secretariat: Ms Adrienne Hunt.

Observers: Dr Alan Doyle for items 1 - 4 inclusive and Miss Ellie Pond for item 5 onwards, Wellcome Trust.

Speakers: Sir Alan Langlands (Chair, Board of Directors, UK Biobank) for agenda items 1 - 4 inclusive. Professor Rory Collins (Principal Investigator and Chief Executive, UK Biobank) for agenda items 1 - 4 inclusive.

1. Apologies

Apologies were received from Dr Heather Widdows, Dr Anneke Luccasen, Ms Sally Smith QC for the whole meeting.

2. Introduction to Sir Alan Langlands (Chair, Board of Directors, UK Biobank)

The EGC Chair welcomed Sir Alan Langlands to the meeting. Sir Alan outlined the role of the Board of Directors as charity trustees, company directors and as providing management oversight of UK Biobank. Each role is undertaken in the interests of the public and participants and in the spirit of, and where possible, to the letter of the Ethics and Governance Framework. The Board views UK Biobank as a public good resource and a science-led project. While the context of UK Biobank will change over time, the recruitment of members to the Board is staggered to maintain organisational memory. Sir Alan stressed the importance of keeping a good relationship with the EGC through clear lines of communication. In replying to questions about the future challenges for UK Biobank, Sir Alan suggested that areas requiring ongoing scrutiny are the recruitment process, participant confidentiality and access policies.

The term 'public interest' can apply to many different publics, for example, the participants of UK Biobank, the entire UK population or parts of it, or indeed future generations. When considering the question of publics one might also look to an 'international public'. If biobanks work together internationally the heterogeneity of the dataset will be increased (i.e. a greater diversity of conditions will be represented in the dataset). Sir Alan commented that this could provide opportunities for rarer conditions to be investigated more rapidly than would be possible if researchers use just one biobank in isolation. Professor Collins informed the Council that infrastructures are currently being put in place to assist sharing of anonymised data

by biobanks internationally. For example, the Public Population Project on Genomics (P3G) is an ongoing initiative which aims to promote collaboration between researchers in the field of population genomics. UK Biobank is a member of P3G. New initiatives are also being established, for example, the European Commission's Framework 7 Programme includes a call for proposals for the topic 'Networking biobanking initiatives across Europe: developing standards and norms for human sample biobanks'.

Sir Alan was asked to comment on the extent to which UK Biobank had so far engaged with the commercial world. Sir Alan noted that the commercial world was watching developments in UK Biobank with interest but that to date UK Biobank had had very few direct dealings with the sector. It is anticipated that more direct involvement will be with medical charities, such as the British Heart Foundation.

UK Biobank will determine priorities for access by referring to the project's aim to eliminate the causes of common diseases. It is envisaged that there will be a 'gateway point' for access to biological samples whereby applications from groups looking at similar areas may be bundled together. Complex relationships and processes may be developed because of this, but it is a model that is likely to foster cooperation. Access strategies are being developed through which UK Biobank wishes to encourage open applications for consideration rather than attempt to steer any particular research agenda.

3. Update from UK Biobank (Professor Rory Collins, Principal Investigator and Chief Executive, UK Biobank)

General update from UK Biobank

Professor Collins provided the Council with an update on UK Biobank's activities:

- *IT systems.* The assessment centre IT system has been developed and formally tested and will be tested by UK Biobank staff shortly. The web-based assessment centre management system allows staff at the Cheadle co-ordinating centre to assess the numbers and categories of people who have been invited to participate and to request further contact details as appropriate. Contact details are centrally processed by a mailing house in Oxford and are not accessible to co-ordinating centre staff.
- *Launch of the assessment centres.* The first invites will be distributed in Manchester in the week of 12 March 2007. The first visits will take place on the 16 April. Fifty people per day are expected at the start of recruitment, increasing to an attendance rate of 110 people per day. This target is dependant on the project receiving sufficient contact details from the local Primary Care Trusts. A second assessment centre will open in Oxford at the beginning of May 2007.
- *Recruitment strategy in Scotland.* UK Biobank recently met with the Community Health Index Number Advisory Group to discuss UK Biobank's recruitment strategy in Scotland. In addition, representatives from UK Biobank

and Generation Scotland will shortly meet with colleagues at the Scottish Executive to discuss the overlap between the two projects.

- *Sample stores.* Samples will be divided and stored in two locations. While the automated sample store is being built, samples will be stored in liquid nitrogen tanks in Cheadle along with a site in Wythenshaw. The automated sample store should be complete in Spring 2008 when the samples held in Cheadle will be transferred.
- *Future work: Enhancement of the protocol and follow-up.* UK Biobank aims to develop a co-ordinated proposal for enhancement of the protocol and follow-up to submit to its Funders in a year's time. UK Biobank recently held a meeting to inform the development of this proposal and to increase communication between the Regional Collaborating Centres (RCC) and non-RCC researchers. Attendees were invited to present their ideas regarding possible enhancement opportunities, which included dietary assessment, physical assessment, vessel wall reactivity, cognition and mental status. Professor Collins found this to be a very productive meeting and hoped it would give rise to wider involvement in UK Biobank by the research community in the future. A working group has been established to coordinate the development of protocols for enhancements.
- *Communications.* Andrew Trehearne (Head of Communications, UK Biobank) is re-developing UK Biobank's website to be more accessible to participants and the broader public. Awareness-raising for the Manchester assessment centre launch will have a predominantly local focus. Communication methods, such as radio interviews and local paper coverage, will be piloted to determine strategies to be used in future locations.
- *Duration of MREC approval + Tissue Bank approval status.* Professor Collins provided answers to two questions which were raised at the Council's last meeting. First, MREC approval has been provided for the duration of recruitment. The MREC will be supplied with an annual report after the International Scientific Advisory Board meeting in June 2007. Secondly, UK Biobank is seeking clarification from the MREC as to whether case-by-case ethical approval is required for research conducted on the resource (or whether, providing future use is consistent with the purpose of the project, no further approval is required).

Professor Collins invited EGC members to visit the co-ordinating centre in Cheadle and the Manchester assessment centre.

ACTION: The Secretary will liaise with EGC members and co-ordinate the visits to UK Biobank. [AH]

Update regarding recommendations from EGC10 (including complaints policy for publication on UK Biobank's website)

The Council previously recommended that UK Biobank should develop a complaints policy to be published on the project's website. This policy has since been developed and was presented to the Council at this meeting. The policy includes definitions (e.g. what is a complaint?) and commits UK Biobank to act within certain timescales. The Council considered the policy to be a very welcome addition, and complement to, UK Biobank's previous work in this area (which has focussed on standard operating procedures instructing UK Biobank staff regarding how to handle complaints).

UK Biobank staff will collect and log comments made by participants during their visit. In addition, 10% of participants will receive a follow-up questionnaire that asks for feedback on their experience. The Council suggested that feedback from participants could be prompted by having a 'suggestions box' at the assessment centre. Professor Collins considered this to be a useful idea.

At its last meeting, the Council advised UK Biobank to develop its procedures for enquiries and complaints handling in separate standard operating procedures. Professor Collins explained that these procedures have not been separated out because the escalation process for enquiries and for complaints follow the same procedure and, though the latter may require greater sensitivity in handling, both are priorities for UK Biobank. Further, it may also be difficult to categorise the exact nature of a call; an enquiry may become a complaint, whereas an apparent complaint may reflect a misunderstanding that can be successfully resolved in the same way as other enquiries. The Council supported this reasoning and was satisfied to learn that complaints and enquiries would be un-bundled for reporting to the Council on a six-monthly basis.

Protocol describing the management of incidental findings (at the assessment centre)

The following principles underpin UK Biobank's standard operating procedure (SOP) describing the management of incidental findings:

- UK Biobank staff are trained to understand that it is not their role to provide interpretation of findings to participants during the recruitment process. This is in keeping with the UK Biobank Ethics and Governance Framework.
- There may, however, be occasions when it is appropriate to draw attention to results of measurements taken at the assessment centre (e.g. very high blood pressure) or incidental findings (e.g. suspected melanoma) that may be potentially serious (i.e. life-threatening).
- Potentially serious results will be drawn to the participant's attention and they will be directed towards relevant advice (e.g. to leaflets available at the assessment centre and to contact details for NHS Direct). Where appropriate, they will also be advised to discuss their results with their GP at the earliest opportunity.

- Two categories of potentially serious incidental findings (i.e. unexpected findings which are not part of the research assessment and may have clinical significance) are identified: *Observational findings* that range from physical evidence (e.g. skin discolouration suggestive of melanoma) through to comments made by participants (e.g. threatened suicide); and *disclosed findings* where participants may voluntarily raise health concerns with staff during the course of the assessment visit (e.g. severe chest pain on exercise). All potentially serious incidental findings will be reported to a senior member of staff who will exercise their professional judgement to decide what action to take (including, for example, discussing the finding with the participants in a neutral manner and advising them to discuss it with their GP at the earliest opportunity).

Council members endorsed the SOP, recognising that it is in the spirit of the EGF (specifically that it is premised on the fact that UK Biobank is operating in a research rather than healthcare context). The provision for escalating the management of incidental research findings to a senior nurse was noted by the Council with some reservation. The nature of duty of care may shift if expectations are raised by this provision. Members were informed, however, that some measurements may be taken by staff who do not have nursing experience. Thus UK Biobank considers it appropriate to escalate potentially serious incidental findings to a senior nurse who will have the relevant training and experience required to manage the situation. Having received this explanation, the Council supported the provision for escalation.

The SOP states that ‘potentially serious’ equates to ‘life-threatening’. The Council considered the implications of this phrase. It could be taken to be a very high bar to meet and that few findings will fall within this category. However, the phrase might incorporate a large number of disclosed findings where, given that the nurse may not be able to say whether the finding is life-threatening, it should be treated as such in the absence of certainty (e.g. if a participant complains of having dizzy spells).

It was suggested that UK Biobank might consider preparing a script for staff to use when discussing incidental findings with participants. The script could be revised in light of the experience of the staff in the future. However, the Council recognised that such a conversation would have its own dynamic and so a script may not be of practical benefit.

The Council noted that no incidental findings had been brought to Professor Collins’ attention during the pilot phase and were reassured to learn that such findings will be logged and monitored during the main study¹.

Protocol describing the assessment of capacity (at the assessment centre)

The following principles underpin UK Biobank’s standard operating procedure (SOP) describing the assessment of capacity:

¹ Post-meeting note: Following the meeting, Professor Collins advised the Secretariat that a few incidental findings (e.g. participants expressing feelings of depression or anxiety) were observed during the pilot.

- There is an assumption that individuals do have the required capacity unless there are clear signs that raise reasonable doubt.
- The assessment of capacity is “decision specific”; that is, a person may have adequate capacity to make relatively simple decisions (e.g. the need to use the toilet), but lack the required capacity to make more complex decisions (e.g. taking part in UK Biobank).
- Where uncertainty exists, staff should determine whether the person has read the information leaflet, and aim to provide a full understanding of what participation involves. If it is thought that there is a lack of mental capacity then the assessment centre manager (or their deputy) should be involved and should attempt to determine the person’s capacity to provide consent to participate. This is to be done in a sensitive manner that preserves their dignity (for example by asking questions about the individual’s reasons for wanting to take part and their understanding of what participation involves).
- Where doubt persists about a person’s ability to give consent, assessment centre staff are advised to err on the side of caution. The person should be advised in a sensitive and respectful manner that they will not be able to participate and they should be thanked for their attendance.

The Council considered the SOP to express well the dilemma between the need to protect people who lack capacity, while not wishing to create harm by excluding people unnecessarily. Participants whose capacity is in doubt will be assessed for their understanding of what participation means for them (e.g. ongoing access to their medical records, use of their data by researchers) rather than an understanding of the research process. Proxy consent for adults lacking capacity was discussed and, as per the EGF, was considered inappropriate in this research context.

The Council suggested that the SOP should be revised to reflect the fact that there is different legislation in England and Wales (the Mental Capacity Act 2005) and Scotland (the Adults with Incapacity (Scotland) Act 2000). The Council also recommended that the SOP should follow the legal test for incapacity which refers to a person’s ability to understand, retain and believe the information (as described, inter alia, in the Mental Capacity Act 2005).

Professor Collins noted that the number of people refused the possibility of participation due to a finding of incapacity would be monitored during the main study.

ACTION: The Council will provide UK Biobank with a proposed wording for the legal test for incapacity. [GTL and AH]

4. UK Biobank’s intellectual property and access policy: subgroup work

An EGC subgroup has reviewed UK Biobank’s draft intellectual property and access policy (November 2006) and submitted comments to Professor Collins. The

comments were brought to the Council's attention and the Chair thanked the subgroup, in particular Ms Hilary Newiss, for reviewing the policy.

Professor Collins will revise the policy in light of the subgroup's and Funders' comments and then bring the policy back to the Council.

5. Minutes of the last meeting held on 16 January 2007

The Council approved the new style of minutes (re-iterating that both the decision, and the reason for the Council's decisions, should be recorded so that there is a 'memory' that will outlast any given constitution of the Council).

The Council approved the circulated minutes.

6. Matters arising

Summary of decisions and recommendations from tenth meeting held on 16 January 2007

The Council agreed that the current text-based summary document should be re-formatted to a bullet point list, to compliment the fuller minute.

ACTION: The Secretary will re-format the summary document. [AH]

Tracking of requests to UK Biobank

The following documents have been brought to the current meeting and will therefore be removed from the tracking of requests document:

- SOP for describing the assessment of capacity (at the assessment centre)
- SOP for describing the management of incidental findings (at the assessment centre)
- Complaints handling policy (for UK Biobank's website)

Update: Public event (11 June 2007)

The public event will take place on Monday the 11 June 2007 between 16.30 and 19.00. There will be a few short presentations, a question and answer session and a drinks reception. The Secretary will shortly be conducting a site visit in Manchester to four potential locations for the event.

A full Council meeting will take place on 12 June 2007, also in Manchester. The Council agreed to invite Andrew Trehearne, UK Biobank's new Head of Communications, to attend and present at this meeting.

ACTION: The Secretary will contact Andrew Trehearne. [AH]

Update: EGC policy on the publication of Council meeting minutes

The Secretary postponed the writing of this policy given:

- the inter-relationship between the policy and the Council's current discussion regarding whether or not to hold its meetings in public
- that the Council is being asked to approve a new format for the minutes at this meeting.

The policy will be brought to the Council's attention in due course.

EGC policy on complaints handling

The policy was approved with minor changes. In particular the following statement was added: 'If a complaint relates directly to either the Secretary, the Chair, or the/a Vice-Chair, an ad hoc subgroup of Council members will be convened, not involving the said colleague, to consider the complaint '.

ACTION: The Secretary will revise and publish the policy on the EGC's website.
[AH]

EGC policy on judging proposals to provide consultancy services

The policy was approved with minor changes.

ACTION: The Secretary will revise and publish the policy on the EGC's website.
[AH]

7. Proposal to hold EGC committee meetings in public

As a result of discussions at the two previous Council meetings, the Chair had agreed to put forward an explicit proposal for meeting in public. The following points were raised in relation to the proposal:

- The effectiveness of the EGC is dependant on its relationship with UK Biobank. The Council does not operate at an abstract, high policy level but has a specific remit to monitor and advise UK Biobank, a company limited by guarantee and which may often deal with confidential information. A survey conducted by the EGC Secretary of policy and advisory bodies, such as the Human Genetics Commission, the Human Fertilisation and Embryology Authority and the Agriculture and Environment Biotechnology Commission revealed that there is no exact parallel body to the EGC. Much information reviewed by the EGC is owned by UK Biobank (e.g. policies and protocols which are under development). Only information generated by the EGC could be made public without prior approval from UK Biobank. The situation may change in time, for example once UK Biobank's policies and protocols have been developed and when the Council's monitoring role becomes established. It may be more appropriate to meet in public at this future time.

- Meetings could be held in two sessions; one closed session for confidential items and one open session for non-confidential items. However, from its own experience the Council noted that it is often difficult to anticipate the full breadth of a discussion in advance of it taking place. The question was raised as to whether part reserving a meeting would undermine the intended transparency of the process. Members agreed that this should not be the case providing that the Council is upfront about the fact that some business will be in closed session.
- There are many 'publics' with whom the EGC could engage (e.g. participants, community groups, the scientific community, the general public). The Council considered its key public to be the participants of UK Biobank.
- The question of meeting in public should be considered in the context of a broader communications strategy and the ways in which the EGC can best meet its public reporting role. There are many possible strands to such a strategy, of which meeting in public can only be a part. An open, transparent practice of inviting observers to attend meetings could help promote trust. The Council should be clear, however, of the intention behind adopting this practice. It should not be viewed as a 'ticking boxes' exercise (as meeting in public is not an end in itself). There is a further level of detail that should be considered before the policy can be decided upon (e.g. the role and involvement of attendees).
- The Council has already established a subgroup to consider its communications strategy and it was agreed that this particular issue must be reviewed in light of that strategy as it is developed.
- It was agreed that this question of meeting in public is an important one which should remain on the Council's agenda for future consideration. It was not appropriate, however, to adopt the practice at the present time.

ACTION: The communications subgroup will consider the proposal to hold EGC meetings in public alongside the broader communications strategy. [AC, RM, MR, HN, AH]

8. Report on meetings attended

Meeting between the Secretary, Andrew Trehearne and Barry Taylor (02/02/07)

The Secretary, Barry Taylor (the EGC's communication consultant) and Andrew Trehearne (the new UK Biobank Head of Communications) recently met to discuss their respective roles and the communications strategies that UK Biobank may use during the Manchester assessment centre launch.

UK Biobank's joint RCC meeting (21/02/07)

The Secretary attended UK Biobank's meeting which explored opportunities for enhancing the protocol (see agenda item 3 '*General update from UK Biobank*'). She found the meeting to be an open and positive forum for discussion.

The Council noted that the meeting attendees seemed to be predominantly from a scientific background. Inviting input on enhancement more broadly (e.g. from social scientists on the inclusion of more detailed social data) might be advantageous and increase the public good potential of the project. The Council encourages a strategy of broad engagement with researchers.

ACTION: The Secretary will ask UK Biobank whether attendance at the enhancement meeting was by invite only or if the meeting was advertised to a broad research community. [AH]

The Council recalled that, as a means of maintaining a broad scope of potential future uses, UK Biobank's participant materials were revised to state that future uses will be for 'health-related' rather than 'medical' research. The Council noted that while it may have its own view on the interpretation of the term 'health-related', it would be useful to ascertain how other members of the public interpret this term (including participants of UK Biobank). An investigation of the meaning of this term is proposed in the exploratory project to be considered under agenda item 9 (i).

Board of Directors meeting (23/02/07)

The Chair attended the Board of Directors meeting on 23/02/07. He and the Board discussed the nature of the EGC, as an arms-length advisory and monitoring committee, and the provisions available to UK Biobank for seeking ethics and legal input and review of its protocols and procedures.

9. Consultations

Proposal: An exploratory project to study opinions regarding the terms of 'third party' access to UK Biobank.

The Council was presented with a draft specification of requirements and invitation to tender (ITT) for: 'Access, commercialisation, intellectual property and benefit sharing: An exploratory project to study opinions regarding the terms of 'third party' access to UK Biobank'.

The ITT was approved with minor changes. The Council agreed:

- that Sarah Cunningham-Burley (University of Edinburgh) should be asked to provide comment on the draft ITT (given her recent published work in this area)
- that respondents will have to demonstrate how their proposals will add value to this field of research and show a clear understanding of the issues being addressed

- that the Council will only commission work which the Review Panel considers to suitably address the various elements described in the ITT.

ACTIONS: The Secretary will contact Sarah Cunningham-Burley and ask her to provide comment on the ITT. [AH]

The Secretary will revise the ITT accordingly, finalise the timetable for the tender process and disseminate the final ITT. [AH]

Access to the UK Biobank resource: Concepts of the public interest and the public good

A draft of the recently commissioned paper on the concepts of the public interest and the public good was brought to the Council's attention for comment. This was a helpful opportunity to consider how this paper might better help the Council in its decision-making process and suggestions were made in this regard.

ACTIONS: The Chair will provide the researcher with the Council's feedback. [GTL]

10. EGC business plan: future work packages

Members were asked to consider work packages which the EGC might address in the coming years (recognising that its work will respond to UK Biobank's progression from the set-up to recruitment phase). The constitution of the Council was raised as one area that might be considered. (For example, while certain disciplines are represented on the current Council, will these disciplines be the most effective for the Council in the future?)

ACTIONS: Council members should send their ideas for future work packages to the Secretary. [All]

11. Any other business

No business raised.

12. Date of next meeting

11 June 2007 - Public event, Manchester

12 June 2007 - EGC meeting, Manchester