

# UK Biobank Ethics and Governance Council Tenth Meeting

Meeting at Wellcome Trust  
215 Euston Road London NW1 2BE

Tuesday 16 January 2007 at 10.30am

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## **Agenda**

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1. **Apologies**
2. **Introductions**
3. **Minutes** of ninth meeting held on 25 September 2006
4. **Matters arising**
  - (i) Public report of ninth meeting held on 25 September 2006
  - (ii) Tracking of requests to UK Biobank
  - (iii) EGC Memorandum of Understanding
5. **Report on meetings attended**
6. **EGC expenditure 2005-2006 and future funding**
7. **Professional consultancy fees**
  - (i) Ongoing work
  - (ii) Suggestions for further initiatives
8. **Communications activities**
  - (i) Discussion: Meeting in public
  - (ii) Proposal: To hold a public meeting in June 2007
  - (iii) Annual report
9. **Update from UK Biobank** (Professor Rory Collins, Chief Executive Officer, UK Biobank)
  - (i) Progress update: Main phase
  - (ii) UK Biobank's complaints handling SOP
  - (iii) UK Biobank's intellectual property and access policy (23 November 2006)
  - (iv) UK Biobank dealing with ethics and law
  - (v) Internal and external relationships of UK Biobank
10. **Access to UK Biobank**
  - (i) Discussion: UK Biobank's intellectual property and access policy
  - (ii) Future EGC activities in relation to the intellectual property and access policy (including activities of the subgroup)
11. **Any other business**
12. **Date of next meetings**

12 March 2007 - London (tbc)

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

**16 January 2007  
Wellcome Trust, London**

Present: Professor Graeme Laurie (Chair), Ms Sally Smith QC, Professor Chris Wild, Professor Roger Higgs, Professor Ian Hughes, Professor Erica Haines, Ms Andrea Cook, Ms Hilary Newiss, Dr Anneke Lucassen, Dr Roger Moore and Dr Heather Widdows.

In attendance from EGC Secretariat: Ms Adrienne Hunt.

Observers: Miss Ellie Pond and Ms Tara Camm for the whole meeting, Wellcome Trust. Dr Caroline Stone, Medical Research Council for items 9 onwards.

Speakers: Professor Rory Collins (Principal Investigator and Chief Executive, UK Biobank) for agenda item 9 only.

1. Apologies

Apologies were received from Professor Martin Richards for the whole meeting.

2. Introductions

The Chair welcomed the six new members of the Council, thanked them for being part of this endeavour and briefly outlined the main activities of the Council over the coming year. All members briefly introduce themselves to the Council.

3. Minutes of the last meeting held on 25 September 2006

The Council approved the circulated unconfirmed minutes.

4. Matters arising

*Public report of ninth meeting held on held on 25 September 2006*

The Council approved the circulated unconfirmed report.

It has been the practice of the Council to date to produce both a minute of each meeting and a public report. The latter has been more succinct, less formal and excluded confidential items. After discussion, however, the Council agreed that a single document – a minute – should be produced as a more favourable and transparent policy. The Council has always considered it important for the minute to include an account of the deliberation undertaken at the meeting, not simply a summary of the decisions reached, and this practice will continue.

The Council agreed that the minute will be published on the EGC website. The Council reserves the right, however, to withhold items from the published minute where just cause can be shown (e.g. commercial confidentiality). The minute will state when an item has been withheld and the reason for this action. A summary of decisions will be published alongside the minute.

**ACTION:** The Secretary will write a policy on the publication of minutes. It will describe the types of reasons why an item may be excluded. [AH]

#### *Tracking of requests to UK Biobank*

The log of requests for information from UK Biobank had recently been updated with the Council's request to have sight of two of UK Biobank's protocols; the protocol describing the management of incidental finding at enrolment and the protocol describing how capacity to consent will be assessed during the enrolment visit.

The Council noted the importance of having sight of such papers with sufficient time to make comments of use to UK Biobank.

#### *EGC Memorandum of Understanding*

The draft EGC MoU (7 July 2006) was discussed by the Council at its September 2006 meeting. Professor Laurie and Sir Alan Langlands have since signed the MoU, whilst noting the caveats discussed at the last Council meeting.

### 5. Report on meetings attended

#### *Report from the Secretary*

The Secretary has received a number of visitors since the last Council meeting including two delegations representing Taiwan Biobank and Biobank Japan. She also attended and occasionally presented at various conferences, including the Public Population Project in Genomics (P3G) meeting, whose International Working Group on Ethics, Governance and Public Engagement is collecting the intellectual property and access policies currently being used by P3G members. This may be of future value to the Council to exchange ideas on best practice.

The Secretary also attended the final conference of the Property Regulation in European Science, Ethics and Law (PropEur) Project led by new EGC member, Dr Heather Widdows. Dr Widdows commented that UK Biobank's model of governance is well respected by the European community, and that new challenges for biobanks include addressing concerns about commercialisation within trusted models of governance.

#### *Meeting between the EGC Chair and Sir Alan Langlands (21/11/06)*

The Chair of the EGC and the Chair of the Board of Directors, Sir Alan Langlands, met on the 21/11/06 to discuss a number of matters relating to the relationship between UK Biobank and the EGC.

**ACTION:** The Council agreed to invite Sir Alan Langlands to attend part of its March meeting. [AH]

While acknowledging that UK Biobank's policies are now in an advanced state of development (e.g. in relation to questions of feedback of health information and duty of care), the Council considered whether or not it should advise UK Biobank to seek a legal review of the entire protocol (and associated policies and procedures). Such a review could provide advice to the Board as to how best to manage the risks of such a cutting-edge project.

The Council agreed to return to this issue in the afternoon session after the EGC has discussed the matter with, and sought clarification from, Professor Collins.

*Meeting between the EGC Chair and Ms Clare Matterson (Head of Medicine, Society and History, Wellcome Trust) (21/12/06)*

The Chair has recently had a telephone call with Ms Clare Matterson. Ms Matterson has responsibility for dealing with matters relating to the EGC. The Chair and Ms Matterson discussed issues relating to EGC members' honorarium payment and the process by which members are appointed to the EGC. The Funders are currently in discussion on these points.

#### 6. EGC expenditure 2005-2006 and future funding

The Council's expenditure for the September 2005 - September 2006 period was £95,102 equating to 79% of the budget. The main under-spend relates to the Consultancy Fees. The Chair noted that the Consultancy Fees will be one of the main expenditures in the future along with the costs associated with communications activities (e.g. public events, annual reports etc).

The Council's initial funding period ends in September 2007. Given the recent change in membership the Funders have agreed to provide the EGC with an additional year of funding, after which time the Council's activities will be reviewed.

#### 7. Professional consultancy fees

##### *Procurement guidelines*

The Council agreed at its September 2006 meeting that it should have guidelines for the procurement of consultancy services. Given that the EGC Financial Process states that the Wellcome Trust will generally procure services and enter into the relevant contract on the EGC's behalf, the Council agreed to adopt the Wellcome Trust guidelines.

In light of recent experiences in commissioning a research paper, the Council considered how to develop robust and transparent procedures for the future. The Council considered that, as standard, a Review Panel should be convened (including

two EGC members and at least one external member) to consider proposals. There may be exceptions to this standard practice where flexibility regarding peer review will be required. An audit trail should be created regarding how and on what basis decisions relating to competing proposals are made.

**ACTION:** The Council agreed that a policy should be drafted, describing how proposals to provide consultancy services will be judged. The policy should describe: the constitution of the Review Panel; that feedback will be provided to the applicants; that proposals will be judged against certain transparent criteria; that an audit trail of the decisions will be maintained. [AH and GTL]

#### *Recent and ongoing work*

- The Council was asked to note the outline proposal for an academic paper on *Conceptual analysis of the public good and the public interest* and it was agreed that comment from one member on the need to distinguish clearly between the two concepts should be fed back to the researchers.
- The Council recently commissioned a scoping study on current literature regarding publics' attitudes to UK Biobank-related issues. The final report of this study was brought to the Council's attention to inform its debate on further initiatives (see below).
- Professor Erica Haimes summarised the findings of her recent report 'Review of Research on Human Biological Sample Collections'. This also informed the Council's subsequent discussion.

Strong support was expressed for conducting a project to investigate aspects of intellectual property and access. The scoping study concluded that the Council may wish to consider how public preferences for some form of profit return or benefit sharing can be realised in practice. The Chair suggested that a project could include questions regarding intellectual property, the commercialisation of research findings and questions regarding models of benefit sharing.

Further projects were suggested which would be complementary to this suggestion:

- A project to examine the practicalities surrounding commercialisation and exploitation of research results, for example acquiring and exercising intellectual property rights, negotiating licences and problems of access.
- A project to investigate how different model of benefit sharing do and/or could work in practice (i.e. considering the specifics of different models rather than commissioning a theoretical discussion paper).
- A project to open-up the language around 'publics'.

The Council could use methods other than commissioning academic papers in order to ascertain the views of certain sectors of the public. For example, the Human Genetic Commission (HGC) has a consultation panel made up of over 100 people with experience of living with genetics disorders. This panel acts as a sounding board for the HGC's reports and recommendations. The YouGov market research agency was also suggested as means by which the Council might elicit the opinion of certain sectors of the public.

**ACTION:** After further discussion during the day, the Council agreed to develop an Invitation to Tender (ITT) for a research study to survey opinions regarding access, intellectual property, benefit sharing and commercialisation. The study will focus on the opinions of two groups, a 40 - 69 age group and an 18 - 28 age group. Members were invited to send research questions to the Secretary, who will develop the ITT. [AH]

**ACTION:** The Secretary will write a list of the other suggested research areas for future reference of the Council. [AH]

## 8. Communications activities

### *Discussion: Meeting in public*

The Council, which currently meets in private, discussed the possibility of changing this policy and permitting observers to attend its normal committee meetings. A paper was presented to the Council describing the activities of a number of other (predominantly public) bodies in this regard.

Strong support was expressed for the principle behind allowing observers to attend meetings (as a means of promoting transparency and trust). However, some members questioned whether allowing observers to attend its meetings is the most effective means of public engagement given other methods that might be available (and given that the EGC has a finite budget for these activities). It was also noted that there was no true comparator body with the same remit as the EGC and questions were raised about whether this approach might inhibit full and frank exchange of views.

**ACTION:** In light of the support for the principle of allowing observers to attend Council meetings, a specific proposal will be presented to the Council at its next meeting. [GTL]

Members were of the opinion that the Council should reserve the right to meet in closed session if required (e.g. if items/documents to be discussed are confidential). In the event that the EGC does change its policy and open its meetings up to observers, the Secretary will write a policy describing what types of issues would be discussed in an open session and which might be reserved for a closed session.

**ACTION:** Permitting observers to attend its normal committee meeting represents one element of a broader communications strategy which the Council needs to develop. Ms Cook agreed to take forward the development of this strategy. [AC]

### *Proposal: To hold a public meeting in June 2007*

The Council agreed to hold a public event in Manchester (where recruitment will begin in April 2007) on 11 June 2007 in the early evening. Members were asked to keep 12 June 2007 free for a normal committee meeting.

**ACTION:** The Secretary will organise the public event.

### *Annual report*

The Council discussed the purpose, design and content of the EGC annual report. The Council agreed that the report should be targeted towards the semi-knowledgeable participant, highlighting, concisely, the main achievements and challenges of the EGC. The Council agreed that the 2006 annual report should be less text heavy and include more images than the 2004/2005 report (which was felt to be too academic in style).

**ACTION:** Members were asked to send their ideas regarding the annual report to Ms Cook and the Secretary. [All]

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

### *Progress update: Main phase*

Professor Collins provided the Council with an update on UK Biobank's recent and future activities as it moves towards the main phase of recruitment.

### *MREC approval*

The main study protocol was submitted to the North West Multi-Centre Research Ethics Committee (MREC) in September 2006. The MREC provided a provisional favourable ethical opinion in October 2006, and subject to a few additional minor changes, further ethical approval was provided in December 2006. Subsequently, some small changes requested following the PIAG review (see below) were submitted for MREC approval in January 2007.

### *PIAG and CHI approval*

At the Council's last meeting Professor Collins informed members that UK Biobank had been in discussions with the Department of Health regarding release of contact details for potential participants in England and Wales from a few central NHS sources for the main study.

In light of the fact that GP details and NHS number were being requested, UK Biobank was advised by the Patient Information Advisory Group (PIAG) to submit an application to that body to use patient identifiable data for research purposes (under section 60 of the Health and Social Care Act 2001). UK Biobank's application was considered by PIAG in December 2006 when PIAG was supportive of the approach that UK Biobank had taken during the integrated pilot phase and which would continue in the main study. PIAG approved UK Biobank's application for 5 years on a number of minor conditions which had since been met.

The Community Health Index Number (CHI) Advisory Group considered and approved UK Biobank's application for a similar approach in Scotland in December 2006.

UK Biobank has not yet been given an indication as to when the contact details will be available from central sources. Given this uncertainty, UK Biobank has requested contact details from Manchester and Oxford Primary Care Trusts (PCTs). Both PCTs have responded positively to the request. UK Biobank anticipates that the main phase of recruitment can begin in mid April, utilising these PCT contact details, while it awaits confirmation of the timing of release for the data from central sources.

#### *Appointment of the Head of Communications*

Mr Andrew Trehearne has recently been appointed as Head of Communications, UK Biobank. One of Mr Trehearne's first tasks is to re-design UK Biobank's website so that it is more user friendly and informative. The site may host a virtual tour of an assessment centre and of the laboratory. It will also have a description of UK Biobank's complaints procedure.

It is the aim that a revised Intellectual Property and Access Policy will be on the website before launch so that information regarding the approach to access is available to (potential) participants.

#### *Facilities and Assessment Centre operations*

A number of refinements have been made to the assessment centre procedures following the pilot, including the combination of certain stations and the addition of heel ultrasound (which gives an indication of bone density). The Standard Operating Procedures (SOPs) are being revised to reflect these changes. In addition, these SOPs will include guidance on assessment of mental capacity, dealing with incidental findings and handling of complaints.

#### *Future work: Enhancement of the protocol and follow-up*

UK Biobank will hold a meeting between members of the Regional Collaborating Centres (RCC) and non-RCC academics to discuss possibilities for enhancing the core UK Biobank protocol. Professor Collins invited members of the EGC to attend this meeting, which will be held on 21 February 2007 in Oxford with a view to recommendations for enhancement of the protocol.

#### *Discussion*

Professor Collins explained that the SOPs describing the management of incidental findings at enrolment and describing how capacity to consent will be assessed during the enrolment visit would be developed shortly and in time for the launch of the project in mid-April. The Council would also be provided with a copy of the current timetable.

Two questions were put to Professor Collins regarding the MREC approval: Does the approval relate to a specific time period? Was class approval provided to UK Biobank as a Research Tissue Bank (under the new system introduced by the Central Office of Research Ethics Committees in October 2006)? Professor Collins commented that UK Biobank is required to send annual reviews to the MREC, but

did not have information to answer these two questions fully. He agreed to address both of these points for the EGC in due course.

Under the current plans the first 6 assessment centres (out of a final total of 35) will be located in the regions of the RCC leads (Manchester, Oxford, Glasgow, Cardiff, Birmingham/Leicester and London). UK Biobank will monitor responses to invitations and assess how far people are willing to travel to participate; the location of subsequent recruitment centres will be decided accordingly.

#### *UK Biobank's complaints handling SOP*

The Council reviewed UK Biobank's Standard Operating Procedures (SOPs) for enquiries and complaints handling (in the assessment centre, call centre and in general). These SOPs are intended as a guide for staff working on UK Biobank. Professor Collins made the point that there was only one document for dealing with both matters because in the first instance it is not always possible to know if an approach is a matter of enquiry or complaint, from the perspective of a staff member. Professor Collins commented that UK Biobank has developed a series of 'Question and Answers' which will be used by the call centre staff to address standard enquiries. For non-standard enquiries or complaints there was a process of escalation to more senior staff (as outlined in the SOPs and used successfully in the integrated pilot). The Council suggested that UK Biobank might write a script for its employees to use when responding to complaints in order to manage and promote consistency in the handling of complaints.

In addition to the draft SOPs intended as a staff guide, the Council considered there to be a clear need for UK Biobank to develop a complaints policy to be published on the UK Biobank website, and to separate out procedures for handling complaints from those for dealing with enquiries.

A complaints policy should describe, in a clear and transparent way, the procedure by which a complaint will be handled. The Council recommended that the policy should include a statement of intent (e.g. regarding the seriousness with which UK Biobank will deal with complaints) and should describe standards regarding response times (e.g. including an initial response to acknowledge receipt of the complaint and the time within which a full response should be expected). The Council suggested to UK Biobank that the websites of various public bodies could be used as a point of reference for such policies.

The SOPs state that the EGC will receive six-monthly reports from UK Biobank regarding the types of enquiries and complaints received and that 'serious issues will be drawn to the attention of the EGC'. The Council endorsed the six monthly reporting and the strategy by which UK Biobank will flag any serious issues on a case-by-case basis.

A number of new members asked for clarification regarding the Council's role with regards to arbitration of individual cases between UK Biobank and a complainant. The Chair re-iterated comments made at the last meeting that the EGC is a guardian of the policy (not the process) and that, as an arms-length committee, it should

monitor the reason for, and trends in, complaints received but not have a role to play as arbiter for specific cases.

**ACTION:** After further discussion in the course of the day, the Council recognised that it should also have a policy which describes to interested parties how complaints about the EGC's activities will be managed. This policy will be developed by the Secretary. [AH]

*UK Biobank's intellectual property and access policy (23 November 2006)*

The UK Biobank intellectual property and access policy (23 November 2006) (IPA2) was brought to the Council's attention. Professor Collins, who drafted IPA2 with comments from the Steering Committee and Board, indicated that the initial draft policy (January 2005) (IPA1) did not describe why the resource was being set up as it is, which is relevant to policies related to its access and use.

The Council commented that IPA2 sets out helpful principles regarding how the resource will be used and contains both elements of policy and strategy, the latter being an important issue from a scientific perspective when dealing with depletable elements of the resource (such as samples), and when it is difficult to assess currently how long these might last. The Council noted that from a sensitivity perspective, in terms of participants' interests, different aspects of the resource might raise different issues and so merit different treatment, and that it might be helpful for the policy also to consider the issues surrounding different types of data.

It was generally accepted that not all elements of an access policy need be in place before launch, but the view was also expressed that requests for access may come quickly and a clear timetable would be useful.

In response to queries about the likely uses of the resource, Professor Collins responded that the value of all research requests would be judged in terms of the purposes of UK Biobank. The need for an independent Access Committee was briefly discussed. Professor Collins envisages that this committee will be responsible for balancing the different competing 'claims' on the resource (i.e. the different uses in term of different diseases) and the depletable nature of the resource.

**ACTION:** In light of further discussion among Council members later in the day, it was agreed that it would be valuable to establish an EGC sub-group on Access and IP to assist UK Biobank. A subgroup, comprising Graeme Laurie, Hilary Newiss, Chris Wild and Heather Widdows will take forward this aspect of the Council's work.

It was suggested that UK Biobank's policy should:

- elucidate the different types of data that might be available to researchers (e.g. questionnaire data, physical samples, information from health records)
- indicate when the different types of data will be 'mature' for use (e.g. for particular conditions).

Further issues might include:

- the process by which applications for access will be managed

- the remit and constitution of the access committee
- the criteria against which applications will be assessed
- the process by which access decision-making will be audited
- the provisions to be made for researchers who wish to challenge a decision of the access committee not to permit access
- a policy on the commercialisation of research findings.

#### *UK Biobank dealing with ethics and law*

Drawing on the morning's discussion, and mindful that it is not the Council's role to provide ethics and legal input to UK Biobank at the operational level, the Chair initiated a discussion with Professor Collins about the range of legal and ethical input available to UK Biobank. Professor Collins confirmed that all requisite ethical approvals had been sought and received, and that UK Biobank has legal support from the Company Secretary primarily on governance, corporate and contractual issues. UK Biobank has also obtained legal input in the development of the participant materials, consent procedures and feedback policy (as well as the revised Ethics and Governance Framework) from the Wellcome Trust legal team, who have the relevant expertise and knowledge of the project.

In closed session, the Council reflected on the discussion and considered that UK Biobank presents an opportunity to set a gold standard in terms of how it addresses ethical and social dilemmas in dynamic and imaginative ways. The Council agreed to recommend that an internal mechanism could be developed by UK Biobank to seek input from legal and ethics experts who can respond directly to developments in the project and help UK Biobank in the formulation of its responses or, for example, the development of SOPs or policies. This may include legal review of various aspects of the project design as a whole (which is not to suggest that certain aspects have not already been subject to such review).

**ACTION:** The Chair, on behalf of the Council, agreed to write to Sir Alan Langlands and Professor Rory Collins to offer this recommendation. [GTL]

#### *Internal and external relationships of UK Biobank*

UK Biobank will hold its first meeting with the International Scientific Advisory Board on 28/29 June 2007. The contracts for the Regional Collaborating Centres (RCCs) are currently being finalised. Professor Collins confirmed that, through the contract, the RCCs will agree to act in accordance with the Ethics and Governance Framework.

#### 10. Any other business

##### *Council papers*

Members were asked to confirm with the Secretary whether they would prefer to receive papers in electronic and/or hard copy.

*Relationship with the Funders and UK Biobank*

The Council's Secretary and the Company Secretary of UK Biobank are both hosted by the Wellcome Trust. One member commented that the Council should always be mindful of, and be comfortable with, this proximity for the possible perceptions that it may generate, however unfounded.

11. Date of next meeting

12 March 2007 - London (tbc)