

UK Biobank Ethics and Governance Council Twenty First Meeting

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

Monday 7 December 2009 at 10.30am

Agenda

1. **Apologies**
2. **Minutes** of twentieth meeting held on 7 September 2009
3. **Matters arising**
 - (i) Summary of decisions and recommendations from twentieth meeting held on 7 September 2009
 - (ii) Tracking of requests to UK Biobank
 - (iii) Subgroup reporting as necessary
 - (iv) Equality and diversity assessments
4. **Vice Chairs appointment**
5. **EGC review**
6. **Closed discussion: UK Biobank's access and intellectual property procedures**
7. **Update from UK Biobank** (Professor Rory Collins, Chief Executive Officer, UK Biobank)
 - (i) General update from UK Biobank (inc. imaging incidental findings protocol)
 - (ii) Update regarding recommendations from EGC20
 - (iii) Biannual report on enquiries and complaints received by UK Biobank
 - (iv) UK Biobank's post-visit survey
 - (v) UK Biobank's IT and data management strategy biannual report
8. **Update from UK Biobank: Access and intellectual property procedures**
9. **Closed discussion of matters arising under items 7 - 8**
10. **EGC expenditure and budget**
11. **Communications activities**
 - (i) External speaking opportunities
 - (ii) External enquiries to the EGC
 - (iii) Workshop programme
12. **Report on meetings attended**
 - (i) Genome Canada expert meeting 'GPS: Where Genomics, Public Policy and Society Meet'
27/11/09
 - (ii) Board of Directors meeting 04/12/09
13. **Any other business**
14. **Date of next meetings**

**UK Biobank Ethics and Governance Council
Twenty First Meeting**

**7 December 2009
Wellcome Trust, London**

Present: Professor Graeme Laurie (Chair), Professor Martin Richards, Professor Ian Hughes, Professor Paolo Vineis, Professor Erica Haines, Dr Roger Moore, Professor Roger Higgs, Mrs Margaret Shotter, Ms Tracey Phillips, Dr Jonathan Hewitt, Mr Andrew Russell and Professor Heather Widdows.

In attendance from EGC Secretariat: Ms Adrienne Hunt.

Observers: Ms Katherine Littler (Wellcome Trust) for the whole day. Dr Catherine Elliott for the morning only and Dr Catherine Moody for the afternoon only (Medical Research Council).

Speakers: Professor Rory Collins (Principal Investigator and Chief Executive, UK Biobank), Mr Jonathan Sellors (Company Secretary, UK Biobank) and Dr Tim Sprosen (Chief Scientific Officer, UK Biobank) for items 7 and 8 only.

1. Apologies

There were no apologies.

2. Minutes of twentieth meeting held on 7 September 2009

The Council approved the circulated minutes.

3. Matters arising

Summary of decisions and recommendations from twentieth meeting held on 7 September 2009

The Council approved the circulated summary of decisions and recommendations.

Tracking of requests to UK Biobank

The Council noted the requests to UK Biobank which will be addressed during items 7 and 8. The Chair highlighted the Council's recommendation that UK Biobank review the Ethics and Governance Framework (EGF) and make any changes necessary to reflect the new enhancement measures and the development of the access procedures. The Council anticipates that such a review might occur mid-2010.

Subgroup reporting as necessary

Access and IP

This update was deferred to item 6.

Information Security

The EGC information security subgroup recently visited the Clinical Trial Service Unit (CTSU) to meet with Professor Rory Collins, Dr Tim Peakman (Executive Director, UK Biobank) and colleagues from CTSU (including those responsible for the security of UK Biobank's data). The purpose of the visit was for the subgroup to arrive at the level of reassurance about data security that it and participants might expect. The subgroup reported that the meeting was both open and constructive with the following topics having been discussed:

- The governance relationship between CTSU and UK Biobank was illustrated in a paper prepared by Dr Peakman (including the lines of accountability and responsibility).
- The subgroup noted the important role that CTSU plays in relation to the UK Biobank project through the provision of individual expertise and through the application of established CTSU processes to UK Biobank (e.g. the method of inviting people to participate in the project). Specifically, the subgroup was informed that the Patient Information Advisory Group gave approval for the release of potential participant's contact details partly on account of CTSU's involvement with the project and the Unit's established reputation for the safe handling of personal data.

While the UK Biobank – CTSU relationship was clearly effective in terms of the mechanics of processing and storing data, the subgroup considered that it presents potential challenges in terms of governance (given Professor Collins' role as Chief Executive of UK Biobank and co-Director of CTSU). The subgroup reported that this issue had been clearly recognised from the outset by UK Biobank senior management and its Board. There are processes in place to manage the situation. For example, Dr Peakman, rather than Professor Collins, sits on the UK Biobank Audit Committee which oversees all contracts. Further, Professor Collins is not included in any discussions or negotiations between CTSU and UK Biobank that are of a commercial nature.

- UK Biobank is working towards accreditation for the ISO 27001:2005 Information Security Management System standard. This standard specifies requirements for the implementation of security controls customised to the needs of individual organisations and also relates to the security requirements expected of contractors and service organisations. Given this, and because of the inter-relationship between the two organisations, UK Biobank is commissioning an audit of the IT systems and procedures within CTSU that relate to UK Biobank. This will be carried out by appropriate external specialists and is expected to report by early to mid 2010. It was agreed that the subgroup would be provided with the Terms of Reference for the audit

and, in due course, with the report. It has also been suggested by the audit team that penetration testing of the CTSU systems could be done as part of the audit, and this is being considered by UK Biobank.

The subgroup enquired whether CTSU itself might seek ISO 27001:2005 accreditation. Professor Collins confirmed that CTSU will respond to the findings of the UK Biobank commissioned audit, but was not seeking accreditation itself.

- The next phase of the development of the UK Biobank IT infrastructure will require systems that enable use of the resource. UK Biobank recently hosted a meeting with representatives of potential collaborating academic groups with a view to identifying the best way of developing the required systems and to discuss what their involvement could be. As a result of this meeting UK Biobank envisages the need for an initial stage of development to the existing databases, and linkage to medical records, prior to the provision of specialist analytical and data visualisation tools.

The subgroup noted that this is an area of ongoing work on which the Council will be updated in due course.

The subgroup concluded that it was very much reassured by the meeting with CTSU and UK Biobank colleagues.

Members addressed a number of questions to the subgroup and identified questions to raise with Professor Collins later in the day. The Council agreed to re-visit its public assurance statement regarding UK Biobank's data security provisions once it has reviewed the outcomes of the audit.

Communications

At a previous meeting the Council had decided that UK Biobank's Access and IP (AIP) procedures might form the basis of its March 2010 public meeting. The communications subgroup met recently to discuss the type of event that might be held and concluded the following:

- If the Council is to host an engagement exercise on AIP the format of the meeting will necessarily need to be different from that usually employed for public meetings. For example, it is likely to be a longer event to which the EGC invites key individuals to speak for and against a certain policy option (e.g. the conditions for commercial access to the resource) and attendees could be invited to vote for their preferred option. The meeting could be chaired by a public figure in order to promote interest in the event. While this style of event might be desirable the subgroup agreed that it was not feasible to organise such an event for March but that it would have to take place in the near-term so that the results might feed into UK Biobank's policy development during 2010 (e.g. mid/late summer).
- The subgroup recommended that the EGC should proceed to hold its public meeting in March using the traditional meeting format. The purpose of the meeting will be for attendees to have the opportunity to learn more about the

work of UK Biobank and the EGC and to create a forum in which attendees can express their views or raise concerns.

The Council discussed the subgroup's proposals and agreed the following:

- The EGC will hold a public meeting in March 2010 using the traditional meeting format. While issues of AIP might be raised and discussed, the purpose of the meeting is not to consult specifically on the AIP procedures.
- The Council should be clear as to the respective role and responsibilities of the EGC and UK Biobank in relation to the duty to consult the public in relation to the AIP procedures. UK Biobank's timetable for the development of the procedures incorporates stakeholder consultation, including the public. The Council agreed to request details on the nature of UK Biobank's plans to consult the public.
- Likewise, the Council should be clear about the different purposes for which it may hold a meeting or engagement exercise e.g. on topics which the Council considers to require further public input, for example through a consultation event or through commissioned research, or to hear the questions and comments of concern to members of the public, for example through a traditional public meeting.
- In 2008 the Council commissioned a public attitude survey, involving telephone interviews and focus groups, to consider issues of access to UK Biobank. It is likely that any further consultation by the EGC at this stage would not add to the findings of this or other public attitude studies which have investigated this topic. The next step for the Council is to see how UK Biobank responds to these findings during the development of its procedures.
- The Council reiterated its willingness to work with UK Biobank on any public engagement activity which might be organised in the future, e.g., to celebrate the completion of recruitment.

ACTION: The Secretary will request information from UK Biobank regarding its plans for public consultation on its AIP procedures. [AH]

ACTION: The Communications subgroup will give further consideration to the idea of an AIP engagement exercise, in light of both the outcomes of the EGC's 8 December workshop on public involvement and UK Biobank's public consultation plans. [Communications subgroup, AH]

Equality and diversity assessments

Three assessments have been completed on the Council's published material, its public meetings and the process by which members are recruited. Accessibility of the website has been identified as an issue requiring further consideration (e.g. to investigate the possibility of offering a large font version etc). An issue was also identified in relation to the accessibility of EGC membership to certain individuals, notably those self employed or those who would be required to take annual leave from their normal employment to attend Council meetings. At present members are paid a £200 honorarium for attendance at Council meetings while no honorarium is offered for attendance at subgroup meetings. This policy may create a barrier for certain individuals as their involvement with the Council will signify a loss of earning and/or a loss of annual leave from their normal employment. In turn this barrier may

prevent the EGC from being able to attract a full diversity of individuals to act as members (in particular lay members). While noting that payment of members is a matter for the funders, the Council agreed that, as with all assessments, it is important that barriers are identified and discussed even if no action is ultimately taken to remove the barrier. The Council agreed that the method of systematically considering its activities in relation to equality and diversity issues should henceforth be a routine aspect of how it does business.

ACTION: The three completed assessments will be posted on the EGC's website.
[AH]

4. Vice Chairs appointment

Professor Martin Richards and Professor Ian Hughes were voted to serve as joint Vice Chairs of the EGC.

5. EGC review

The EGC will be reviewed by its funders in 2010 in parallel with a review of the UK Biobank project. The funders are in the process of recruiting an EGC Review Panel, the Chair of which will sit on the broader UK Biobank Review Panel. The EGC Review Panel will consider at least the following elements before making recommendations to the funders:

- The results of a consultation with UK Biobank participants in which they will be asked to share their views about the EGC.
- The results of a web-based stakeholder survey.
- The EGC's review submission which details its activities to date, its vision for 2010 - 2015 and its indicative budget for that period.

The Council will have the right to respond to the EGC Review Panel's initial feedback, which is expected to report in April 2010. This feedback will contribute to the deliberations of the broader UK Biobank Review Panel in July 2010 and ultimately to the funders' decision on the future operations of the Council.

Members discussed the draft EGC review submission and suggested a number of additions.

ACTION: The Secretary will revise the submission based on members' comments and draw-up an indicative budget for 2010 – 2015 based on the identified activities.
[AH]

6. Closed discussion: UK Biobank's access and intellectual property procedures

The Council received UK Biobank's draft skeleton procedures in November and has provided initial feedback to the project's Board of Directors (Annex A).

Members considered a version of the procedures which the Secretary had annotated with individual EGC members' comments. Further, these comments have been synthesised into a list of core issues, which members agreed should be provided the framework for the discussion with UK Biobank later in the day.

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

General update from UK Biobank (inc. imaging incidental findings protocol)¹

Enhancements

The majority of baseline enhancements have now been added to the assessment visit of all assessment centres (including a hearing test, a finger clip to test arterial stiffness, additional cognitive function tests, a diet questionnaire, the collection of blood for RNA extraction, the collection of saliva samples and ocular measures). The remaining measures, a fitness assessment and photographs of the eye, will be rolled out to the assessment centres from December 2009.

UK Biobank intends to submit a proposal to its funders in the third or fourth quarter of 2010 for a future imaging assessment visit to include heart, whole body and brain magnetic resonance imaging of 100,000 participants. At a recent expert meeting, designed to inform the development of the protocols, attendees expressed a great deal of enthusiasm for the proposal. That meeting was about MRI generally, and UK Biobank's next step is to convene expert meetings on each of the proposed areas - brain, body and heart - in order to determine the detailed protocol, and to check its practicability, for each imaging modality. Once submitted a funding decision is anticipated by the second quarter of 2011 and, if funded, a pilot could then commence in the second half of 2011. The pilot will be used to refine the scientific protocol and, in parallel, the protocol for providing feedback to participants of incidental findings made during the imaging visit.

UK Biobank review

UK Biobank is required to submit a funding renewal proposal covering the next 5 years of its operation in April 2010 for review by a specially convened Review Panel in July. The recommendations of the Panel will inform a funding decision which is expected in September 2010.

Update regarding recommendations from EGC20

Updates were included in the topic-specific agenda items throughout the day.

¹ Some discussion of UK Biobank's access and IP procedures took place under this item but is reported under item 8.

Biannual report on enquiries and complaints received by UK Biobank

The Council welcomed UK Biobank's fifth biannual report on enquiries and complaints received by the project. Dr Tim Sprosen (Chief Scientific Officer, UK Biobank) reported that 30 – 40% of participants give feedback on comment cards which are available at all assessment centres. In particular, if an individual has any complaints about the visit, they are asked to complete a card as a record of their complaint. The comment cards are reviewed and analysed monthly, and any highlighted issues escalated promptly.

UK Biobank also receives feedback by telephone, reply forms to the Participant Resource Centre, and by email or letter to the co-ordinating centre. The biannual report to Council provided a breakdown of categories of non-routine enquiries and complaints which had been escalated to a senior member of the study team. The Council noted that the most common category related to 'payment of expenses'. Dr Sprosen confirmed that this related to time delays for individual's payments being processed, but that the problem had now been resolved with the average time from receipt of claim to payment being 11 days.

Dr Sprosen reported that, for the period May 2009 – October 2009, 120 people had withdrawn from the project in total (compared to 411 people for the previous period November 2008 – April 2009). Overall, withdrawal rates are approximately 1 in every 450 participants. The average time between people participating and withdrawing is three weeks, although a fair percentage withdraw on the day of their assessment centre visit. The withdrawals have been analysed by age group, gender and assessment centre, but no associations have been found.

UK Biobank's post-visit survey

Dr Sprosen thanked the EGC for its advice on a draft of UK Biobank's post-visit survey. In his verbal update, he confirmed that the new survey is intended to ask fewer questions about the recruitment process (which was a focus of a previous survey) and will instead focus on participants' understandings of follow-up through health-related records and the future use of the resource.

In addition to the postal survey, UK Biobank proposes to invite a number of respondents to undertake a more in-depth telephone interview. Selection for the interview would be based on a respondent demonstrating some misunderstanding regarding their future involvement with the project and the project's purpose. Its purpose would be to investigate and understand the basis of their misunderstandings so that future communications with participants (including via the project's website) can be designed to address areas of apparent uncertainty. In due course, UK Biobank may conduct focus groups with some of the respondents, for example, to ascertain what information they would hope to receive from UK Biobank in the future and how often.

The Council welcomed the update and looks forward to the revised survey being circulated to EGC members for further comment.

UK Biobank's IT and data management strategy biannual report

Professor Collins reported that UK Biobank and CTSU IT colleagues met recently to discuss the further development of the project's information systems, including the identification of those elements to be developed in-house and those that might be put out to tender.

UK Biobank and colleagues identified certain aspects of the IT system that require further development. It was agreed that a modest extension of the systems by CTSU would allow them to be used for future repeat assessment visits and it was agreed that this work will begin in mid-2010. The meeting also identified the need to develop further UK Biobank's laboratory database. It was agreed that this development work can be undertaken by staff at the co-ordinating centre. After further development, the laboratory assay data would be added to the assessment centre database in a relatively simple way. This would provide a database which, with the addition of query tools, should allow cross-sectional data to be made available for researchers.

In addition to identifying the developments that could take place at CTSU and UK Biobank, the scoping meeting also identified the development work which will be required during the next stages of the project and which will require external input. For example, one aspect would focus on the development work required to allow follow-up data (e.g. derived from health records) to be linked into UK Biobank's database. Another aspect requiring development related to the scope of validation that is required for the outcomes that arise during follow-up (e.g. checking of reported health outcomes). Professor Collins reported that UK Biobank was establishing a Working Group to investigate the possible processes and optimum scope of validation.

One further aspect of IT development concerns the application process for potential research users. For example, it might be useful for researchers to have pre-application information about the resource so that they can judge whether or not their scientific question might be answered by UK Biobank data (e.g. if a researcher is interested in diabetes within a certain age group, are there sufficient cases of diabetes to answer their questions?).

UK Biobank is currently developing a timetable which will describe the aspects of the information systems that need to be developed, and by what time. This will allow their systematic development over a period of time and in parallel with the access procedures.

Members asked how UK Biobank will accommodate and link to records outside of a strictly health sphere (i.e. non-NHS). Professor Collins commented that as part of the pilot in Wales, UK Biobank is investigating the possibility of gaining access to non-medical records. For example, Health Solutions Wales operates an honest broker system whereby approved researchers can link to anonymised data without additional consent (e.g. household data, school records, environmental data etc). Such systems also exist in Scotland, but it would be more difficult to link to non-health data in England as the required networks and systems are not yet in place.

Mindful of the increasing amounts of data that UK Biobank will hold on individual participants (e.g. household and social data), members asked if it would be reasonable to limit the amount of data made available to researchers for any given participant in order to limit the participant's identifiability. Professor Collins responded that data would be available through an approved access process. The access screening process will include a decision regarding what data are required for the piece of research and whether any parts of it make it likely that an individual could be identified. Further, a researcher will be required by contract not to try to identify participants and penalties will be put into place for contract breaches.

Mr Sellors confirmed that UK Biobank is the sole data controller under the Data Protection Act of the data it collects, while CTSU manages the data as a data processor on behalf of UK Biobank under a contractual agreement.

The Council expressed its thanks for Dr Peakman's paper which clearly described the current status of UK Biobank's IT systems and the roles and responsibilities of various individuals involved. Members asked if similar information might be made available to participants via the project's website. Professor Collins confirmed that UK Biobank is in the process of modifying its website with two focuses: First, the access application process for researchers. Second, to enhance communications with participants and to promote discussion about the way in which the resource is being used.

8. Update from UK Biobank: Access and intellectual property procedures

A member asked how many applications for access UK Biobank is expecting to receive per month (in order to give the Council an indication of the future workload for the project and for the Council itself as it is charged to keep under review the applications for access). Professor Collins commented that the success of the resource will be indicated by its wide use by researchers for appropriate purposes. With this in mind UK Biobank wants to build a system that has the capacity for high usage so that users do not have to deal with unnecessary delays between making a request and being granted access.

The primary purpose of UK Biobank is to assess the impact of various factors obtained at baseline on disease that develops during the long-term follow-up. The strengths of UK Biobank are in the generalisability of its data and its prospective nature. Professor Collins commented that care needed to be taken about using the biological samples extensively in the short term for cross-sectional work because such use would deplete the amount of sample available for prospective studies in the future. Furthermore, cross-sectional work would not be particularly useful for looking at distributions within the population because the UK Biobank cohort is not intended to be representative. By contrast, the data held by UK Biobank are not depletable and so the more use that can be made of these data for cross-sectional work the better.

While it is difficult to anticipate the number of applications per month, Professor Collins commented that the project needs a system that is capable of dealing with

hundreds of applications through a straight-forward and fast process that is also able to detect applications that require additional scrutiny (e.g. by the EGC).

UK Biobank intends to create a system that allows the EGC and any Access Committee (AC) to view the access applications and to see how they are being processed. Under this system the EGC could decide which applications it wishes to see as well as reviewing those applications referred to it by UK Biobank. Professor Collins envisages the roles of the EGC and AC as complementary, with the AC reviewing scientific issues such as the depletability of samples while the EGC reviews the ethics and governance aspects. The Council clarified that it is for UK Biobank to assure itself that the ethics aspects are appropriately considered and dealt with during the application process (e.g. through review by UK Biobank staff or the AC). All parties agreed that the Council's role is to monitor that such processes are in place, rather than to be part of the initial ethical review or otherwise act as UK Biobank's internal ethics committee.

Professor Collins confirmed that UK Biobank will develop a check-list of items to be considered when reviewing access applications (including ethics and public good criteria). UK Biobank will also develop the process whereby an application is categorised according to the level of scrutiny it requires (e.g. review by UK Biobank staff, review by the AC, advice sought from the EGC etc).

If the project is to receive large numbers of applications per month, UK Biobank does not consider it to be practical for an AC to review all applications. Instead, review of some applications would probably need to occur within UK Biobank. Recognising this, UK Biobank's funding renewal proposal will include provision for a suitable number of senior staff at the Cheadle co-ordinating centre to review applications against the developed check-list. The UK Biobank staff would also be trained to look for particular issues which might require further advice from the AC, EGC or an ethics committee.

UK Biobank is investigating the option of Research Tissue Bank (RTB) approval which can cover all research using the resource so that each potential researcher would not necessarily have to apply for separate REC approval. If UK Biobank obtains RTB approval then it takes on a level of responsibility for ensuring that the research has been subject to scientific critique, is appropriately designed to meet its objectives, and is consistent with the participant consent. UK Biobank, therefore, is giving ongoing consideration to the pros and cons of RTB approval including the implications for the review process (which still allows the option of requiring research ethics review for more complicated applications). The alternative to RTB approval is to require each research applicant to obtain separate ethics approval, which could cause certain MRECs to be overwhelmed by applications.

In its earlier feedback, the Council suggested that UK Biobank might consider establishing an Interim Access Committee (AC) in the course of 2010 to assist with the production of an access mechanism. This body might then evolve into the permanent AC. In addition, the Council recommended that any AC might usefully include membership from a variety of disciplines including ethics, law and social science as well as from the scientific community. Professor Collins commented that the first priority for UK Biobank is to develop the procedures and seek feedback from

a wide range of groups (including potential users). A decision regarding an Interim AC would be taken after that time.

The Council advised UK Biobank to consider whether or not there are any equality and diversity issues to be considered in relation to the AIP procedures. This is part of the Council's general position on equality and diversity, viz, that assessments should become a matter of course for all policies and procedures adopted by UK Biobank. Professor Collins confirmed that a preliminary report of the equality and diversity audit has been prepared by an independent consultant but that they required further data before the report could be finalised. The report, which looks in particular at the recruitment process, will be presented to the Council in a paper to its March meeting. Professor Collins confirmed that UK Biobank might then proceed to commission an audit of its access and other procedures.

As part of the access process, UK Biobank will require researchers to enter a formal agreement which commits them to return their research results to UK Biobank for use by other researchers. Members asked what penalties UK Biobank might invoke should a researcher fail to meet this contractual requirement. In the first instance Professor Collins clarified the extent to which data and samples might be sent out to researchers. For example, it is envisaged that sample assays will mostly be carried out by UK Biobank or a laboratory under contract to UK Biobank, rather than samples being sent out to individual researchers. Where samples are sent to a contracted laboratory, the assay results would be returned to UK Biobank under the service agreement, before being sent to the requesting researcher. While it is not intended for samples to be routinely distributed to individual researchers, it is envisaged that a minority of specialised assays will have to be processed at specialised laboratories.

Although all researchers will be under contract to return their results, it is likely that this requirement will be more enforceable against UK-based researchers as compared to researchers elsewhere. However, UK Biobank could use other non-legal means to promote the return of results from international researchers. For example, if a US researcher did not return results UK Biobank could let this be known to the National Institute of Health (the primary Federal agency for conducting and supporting medical research) and potentially to academic journals.

UK Biobank's skeleton AIP procedures were accompanied by a background document which described the timetable for further development. Professor Collins described the next steps as populating the skeleton and drafting the application form and access agreement, taking account of feedback from the funders and the EGC.

The Council offered to send Professor Collins the paper prepared by the Secretary including the EGC annotated skeleton procedures, the list of core issues which members raised in relation to the procedures and the EGC's list of questions which has been revised in light of the skeleton procedures. Professor Collins confirmed that UK Biobank will be able to answer the questions already submitted by the EGC in its initial feedback to UK Biobank and its Board of Directors.

9. Closed discussion of matters arising under items 7 – 8

Members reflected on their discussion with colleagues from UK Biobank and agreed the following:

Access and intellectual property procedures

The Council agreed to ask UK Biobank how addressing the EGC's questions fits in with UK Biobank's timetable for developing its procedures. For example, does UK Biobank aim to address all of the questions in the first draft procedures or will some questions only be addressed in later drafts? An answer to this question would be welcome as soon as possible and before the March 2010 Council meeting. The Council has, for example, tried to make it clear to UK Biobank in its initial feedback which questions it considers should be addressed as a matter of priority; this is in recognition of the fact that the full details of the policy and procedures will necessarily have to be developed over time.

UK Biobank's IT and data management strategy

The Council agreed to recommend that UK Biobank publish up-to-date information about the project's data management and security processes for participants e.g. through revision of the 'Confidentiality' section of the EGF (the current wording of which could be read to imply that all personal data are held centrally at UK Biobank's co-ordinating centre) and/or through publication of a separate lay summary of the processes and actors involved, to be published on UK Biobank's website. This last option is highly desirable given evidence that privacy concerns remain high on the agenda and a source of quick reassurance on a dedicated page might help to allay any fears.

10. EGC expenditure and budget

Members noted that the total spend on EGC operations in 2008/2009 was approximately £95,936 (81% of the budget). £145,786 has been allocated for the 2009/2010 budget year (including costs associated with the workshop on public involvement).

11. Communications activities

External speaking opportunities

The Chair, the Vice Chair (Professor Martin Richards) and the Secretary will meet with researchers associated with the Mitsubishi Research Institute (MRI) on 16/12/09. MRI is conducting research for the Japanese government regarding the management of ethics and the operation of ethics committees in relation to human genomic and other research.

Professor Joanna Wardlaw, Professor of Applied Neuroimaging at Edinburgh University, has invited the EGC Chair to present a paper on the legal considerations

in relation to Magnetic Resonance research imaging at a meeting to be held at the Wellcome Trust on 1 July 2010 entitled 'Ethical Management of Research Imaging'.

External enquiries to the EGC

Members noted that the EGC response to Professor Jones' *Lancet* comment has now been published in the journal in abbreviated form². The full response is available on the EGC website³.

Workshop programme

Members briefly discussed the programme for the next days' workshop 'Involving publics in biobank research and governance'.

12. Report on meetings attended

Genome Canada expert meeting 'GPS: Where Genomics, Public Policy and Society Meet' 27/11/09

The Chair recently presented the Council's work at a meeting co-sponsored by Genome Canada and the Office of the Privacy Commissioner of Canada, in collaboration with the Canadian Institutes of Health Research, the Council of Canadian Academies, the Public Policy Forum, the Policy Research Initiative of Canada and Carleton University School of Public Policy and Administration⁴.

Attendees were very interested in the model of governance adopted for UK Biobank. The discussion included the utility of the broad consent model along with consideration of opt-in and opt-out models.

Board of Directors meeting 04/12/09

Professor Richards attended the Board of Directors meeting on 04/12/09 at which discussion included the proposed imaging assessment visit, UK Biobank's IT systems and the proposal to establish a Biocentre under the UK Biobank Ltd company.

13. Any other business

A member brought to the Council's attention the recent press coverage regarding the uncertain future of the England NHS Spine (which is part of the NHS Care Records Service and through which an electronic Summary Care Record was going to be developed). Members agreed to keep abreast of further developments.

² Laurie, G. 'Role of the UK Biobank Ethics and Governance Council' *The Lancet* Vol 374 No. 9702 p 1676 (2009)

³ www.egcukbiobank.org.uk/assets/wtx056674.pdf

⁴ A podcast of the presentation is available at: <http://www.genomecanada.ca/en/ge3ls/policy-portal/podcasts.aspx> (accessed 28 January 2010)

The March 2010 public and Council meeting dates have been changed from 15 and 16 March to 22 March. The meetings will take place in Sheffield as originally envisaged.

Professor Erica Haines has resigned from the Council with effect from January 2010 having recently been invited to join the Ethics and Public Policy Committee of the International Society of Stem Cell Research and, as a co-opted member, the Ethics and Law Advisory Committee of the Human Fertilisation and Embryology Authority. The Chair thanked Professor Haines for her contribution to the ethics and governance of UK Biobank. Not only has Professor Haines contributed through her time on the Council but she also sat on the Interim Advisory Group that advised UK Biobank's funders, in 2003, to establish an Ethics and Governance Framework and a permanent Ethics and Governance Council for the project. On behalf of the Council the Chair wished her well for the future and her new appointments.

14. Date of next meetings

22 March 2010 - Evening public and Council meeting, Sheffield
7 June 2010 - Council meeting, London

Annex A Recommendations: Access and intellectual property procedures

The Ethics and Governance Council, particularly through its sub-group on Access and Intellectual Property (AIP), welcomes sight of these draft skeleton procedures. It considers these to be a useful start in the process towards the development of a robust access mechanism that is fit for purpose for the model on which UK Biobank is founded.

The Council has a number of questions and queries about specific aspects of the draft procedures and is happy to share these with UK Biobank. We consider, however, that there are certain fundamental matters which require clarification before attention is turned to any further level of detail.

UK Biobank is founded on a model of trust and broad consent and with the primary objective of building a resource to be managed in the public interest. We believe that continued and on-going consideration must therefore be given to the interests of participants and to the use of the resource in the public interest and that this ought to be adequately reflected in any access mechanism adopted by UK Biobank.

Public interests - It is clear that there is a strong public interest in scientifically sound health-related research, but the UK Biobank access policy and procedures cannot proceed on this basis alone. Other public interests may be at stake with any given proposal, such as (lack of) public support for the uses to which the resource will be put or public concern about the ways in which research results are commercialised. A robust access mechanism must be able to identify and respond appropriately to the potential range of public interests at stake, and it must be clear about how conflicts between public interests will be resolved.

Privacy and other private interests - The protection of privacy is central to the interests of participants which are at stake in the maintenance and operation of UK Biobank. Even if a request for access to data (or samples) appears straightforward and valuable in scientific terms, the likely impact on privacy must be considered. A robust access mechanism must be able to assess and weigh in the balance any privacy risks and must do so at the earliest possible juncture within access procedures. Furthermore, other interests of participants might be at risk with different kinds of request for access, for example, those involving re-contact.

Decision-makers - The unique governance model of UK Biobank, the range of public and private interests at stake and the broader ethical and social issues involved must all be reflected in the UK Biobank access mechanism. The draft skeleton procedures identify key decision-makers as (a) UK Biobank itself (and its Board), (b) an Access Committee, (c) the Ethics and Governance Council and (d) Ethics Committee. However, there is no information on how access applications will be classified in order to receive appropriate scrutiny (including how public interest will be judged). Clarity regarding the roles, training and responsibilities of key decision-makers is required in addition to clarity regarding their relationships to each other.

We understand that the full details will emerge over time and for this reason we have recommended that UK Biobank should be working towards the production of Pilot Procedures by December 2010, to be tested thereafter. Furthermore, it is recommended that in the first instance the Access Committee should be involved in all decisions until greater clarity emerges. Its composition should include individuals drawn from ethics, law and social science as well as from the scientific community.