

UK Biobank Ethics and Governance Council Thirteenth Meeting

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

Thursday 1 November 2007 at 10.30am

Agenda

1. **Apologies**
2. **Minutes** of twelfth meeting held on 12 June 2007
3. **Matters arising**
 - (i) Summary of decisions and recommendations from twelfth meeting held on 12 June 2007
 - (ii) Tracking of requests to UK Biobank
 - (iii) Discussion: Access to the UK Biobank resource: Concepts of the public interest and the public good
 - (iv) Update: An exploratory project to study opinions regarding the terms of 'third party' access to UK Biobank
 - (v) Update: EGC recruitment and renewal process
4. **Update from UK Biobank** (Professor Rory Collins, Chief Executive Officer, UK Biobank)
 - (i) General update from UK Biobank
 - (ii) Update regarding recommendations from EGC12
 - (iii) Update: Development of UK Biobank's access and intellectual property policy
 - (iv) Biannual report on enquiries and complaints received by UK Biobank
5. **UK Biobank's IT and data management strategy** (Mr Andrew Harris, Systems Architect, UK Biobank)
6. **EGC communications activities**
 - (i) Update: 3 December public meeting
 - (ii) Subgroup work
 - (iii) EGC commissioning research involving UK Biobank participants
 - (iv) Query from UK Biobank participant
7. **EGC expenditure for 2006/2007 and 2007/2008 budget**
8. **Report on meetings attended**
 - (i) Taiwan biobank symposium (14/08/07)
 - (ii) P3G meeting (22 and 23/10/07)
 - (iii) ESRC Genomics Network conference (25/10/07)
 - (iv) UK Biobank Board of Directors (26/10/07)
9. **Any other business**
10. **Date of next meetings**

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|-----------------|--------------------------|
| 3 December 2007 | Public meeting (Oxford) |
| 17 March 2008 | Council meeting (London) |

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

**1 November 2007
Wellcome Trust, London**

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

In attendance from EGC Secretariat: Ms Adrienne Hunt.

Observers: Dr Caroline Stone (Medical Research Council) and Dr Alan Doyle (Wellcome Trust) for the whole meeting.

Speakers: Professor Rory Collins (Principal Investigator and Chief Executive, UK Biobank) for items 4 and 5 only and Mr Andrew Harris (Systems Architect, UK Biobank) for agenda item 5 only.

1. Apologies

Apologies were received from Ms Sally Smith QC, Professor Erica Haines, Dr Heather Widdows and Professor Anneke Lucassen.

Ms Hilary Newiss has tendered her resignation from the EGC due to other work commitments. The Chair thanked Ms Newiss for her valuable contribution and, on behalf of the Council, wished her great success in the future.

2. Minutes of the last meeting held on 12 June 2007

The Council approved the circulated minutes.

3. Matters arising

Summary of decisions and recommendations from twelfth meeting held on 12 June 2007

The Council approved the circulated summary of decisions and recommendations.

Points 5, 6 and 7 on the summary document relate to the further information requests to UK Biobank and will be addressed by Professor Collins under agenda item 4.

Point 8 on the summary document relates to the 'No further use' option of withdrawal from UK Biobank. This option stated that UK Biobank will "destroy all of your information and samples collected previously (although it may not be possible to trace all distributed sample remnants)". At a previous meeting, the Council was

informed that it is not possible for UK Biobank to destroy all of a participant's data due to the project's back-up and audit system. However, the principle behind the withdrawal option remains the same (i.e. that researchers will not be able to access or use the participant's information once they have withdrawn).

Subsequent to its last meeting the Council requested and received further information relating to the technical difficulties in deleting data from the system and advised UK Biobank that the Ethics and Governance Framework (EGF) and the Participant Information Leaflet (PIL) should be revised. The revised PIL now states: "This means that, in addition to no longer contacting you or obtaining further information about you, any information and samples collected previously would no longer be available to researchers. UK Biobank would destroy your samples (although it may not be possible to trace all distributed sample remnants) and would only hold your information for archival audit purposes."

This issue was discussed further with Professor Collins under agenda item 4.

ACTION: The Secretary will establish and maintain a database listing the EGC's main achievements. [AH]

The Secretary and Chair have developed a series of Frequently Asked Questions (FAQs) based on questions that have been addressed to the Council at, for example, EGC public meetings, conferences or by email. Once developed, the FAQs will be posted on the EGC's website.

ACTION: The Secretary will revise the FAQs document based on members' comments. [AH]

Tracking of requests to UK Biobank

The Council noted the four requests for further information to UK Biobank.

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

The final report was discussed with reference to a commentary, prepared by the EGC Chair, which highlighted the key messages of practical significance to the EGC. The report's conclusions are those of the authors and do not necessarily represent the view of the EGC. The Council agreed to clarify its thinking and understanding of the report's findings before deciding on if, how or where to publish the report. The Council agreed that it might be beneficial to invite the report's primary author to present the findings at a future meeting.

ACTION: The Chair's commentary will be sent to the authors of the report for their comment. [AH]

ACTION: The Council will further develop its understanding of the public interest and public good, e.g. through the development of the commentary paper. [GTL and AH]

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

Professor Andrew Webster and colleagues at the Science and Technology Studies Unit, the Department of Sociology, the University of York, have been commissioned to conduct the EGC funded exploratory project to study opinions regarding the terms of 'third party' access to UK Biobank. A draft report will be submitted to the Secretary and distributed to the Council in December 2007.

ACTION: The Secretary will compile members' comments on the draft report and provide feedback to the research team in January 2008. [AH]

Update: EGC recruitment and renewal process

The Funders have approved the revised EGC recruitment and renewal process, including two changes to previous practice:

- The Funders previously managed the recruitment process for new members. In future, recruitment of members will be managed by the Council itself (appointments will continue to be subject to the Funders' approval). The responsibility for managing the recruitment of a Chair will continue to rest with the Funders.
- Members wishing to serve a second term were previously required to submit an application as part of an open recruitment process and, if short-listed, attend for interview. The new process permits members to apply for a second term of 3 years, subject to an appraisal process, without open competition. Renewals are subject to the Funders' approval.

The Chair thanked Dr Roger Moore for help provided to the Secretary during the development of the process.

The Council will conduct a round of recruitment for new members in 2008.

ACTION: Members interested in serving on the Appointment Panel were asked to contact the Secretary. [EGC members]

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

Assessment centre recruitment (current operations and future plans)

UK Biobank has received Department of Health approval to access central contact details. In light of this a formal recruitment roll-out plan has been developed. Assessment centres are currently operating in Manchester, Oxford, Glasgow and Cardiff with a centre in Edinburgh opening shortly. The Oxford centre will close in November 2007. The Manchester centre will close at the end of 2007 but will re-open in a new location within the city. Future assessment centre locations are being considered e.g. in Stoke, Newcastle, Leeds, Reading and London.

UK Biobank aims to have 6 assessment centres running concurrently by the end of the first quarter of 2008, opening one assessment centre per month for the next 2-3 years. The number of centres running concurrently will depend on response rates i.e. the higher the response rate, the less centres will be open. Conversely if response rates are low more centres will be opened. It is envisaged that a maximum of 7 centres will run concurrently (staff training, monitoring and sample processing would become limiting steps if more than the equivalent of 7 centres are concurrently operational).

UK Biobank has budgeted for 95 - 100 people to attend an assessment centre per day. The Oxford assessment centre was receiving 140 - 150 confirmed appointments per day which, taking into account a 10% 'did not attend' rate, equated to 120 - 130 people per day actually attending. If the project achieves attendance rates higher than those envisaged by the budget it will have the potential to create contingency to enhance the protocol in other ways (e.g. to directly target hard to reach groups).

On average the response rate to the initial invitation to participate is 10% (although this has been lower in Manchester). 30 000 people have so far agreed to participate.

British Heart Foundation presence at the Manchester assessment centre

A 20 minute consultation with a British Heart Foundation (BHF) nurse is being piloted at the Manchester assessment centre. The consultation provides participants with advice about cardiovascular risk and is separate from the UK Biobank assessment. Initially, simple leaflets informing participants of this option were handed out at the conclusion of the assessment centre visit. Despite receiving no prior notice, approximately two thirds of participants chose to have the consultation. The BHF leaflet is now being included in the initial invitation letter. UK Biobank anticipates that there will be a related increase in the uptake of the service (e.g. to 80%). This increase would require at least 3 BHF nurses throughout the day, a fact UK Biobank is considering when planning new assessment centres. (The BHF pays for the space and for the nurses present at the centres.) The pilot of the BHF consultation in Manchester will be assessed before it is made available at other centres.

The Council asked if the presence of BHF nurses might cause some confusion e.g. that participants might be confused about whether or not this is part of their UK Biobank assessment. Professor Collins commented that the size, shape and colour of the BHF leaflet have been designed in such a way that makes the leaflet distinct from the UK Biobank materials in order to mitigate any confusion.

The provision of advice on cardiovascular health may prove to be an incentive to participate. The Council asked if this might bias the constitution of UK Biobank's cohort e.g. by attracting and recruiting more people with a family history of heart disease. Professor Collins advised that in terms of a prospective study, the cohort does not need to be representative but instead be generalisable. Any increase in recruitment rates would decrease costs, allowing increased spending and targeted recruitment of more difficult to recruit groups in order to increase the heterogeneity of the cohort.

ACTONS: Professor Collins offered to supply the EGC with the BHF information leaflet and to check whether any participants had gone back to UK Biobank staff to ask questions after their BHF consultation. [RC]

UK Biobank's communications with General Practitioners

At present UK Biobank sends a letter to potential participants' General Practitioners (GPs) informing them of the project and of the fact that some of their patients are being invited to take part. It has transpired that this contact is not sufficient in all cases and that many GPs remain unaware of the project. Given that individuals have sought the advice of their GP both before and after their assessment centre visit, it is in UK Biobank's interest to devise other methods of raising awareness amongst GPs. UK Biobank plans to invite GPs to an evening meeting and drinks reception prior to each assessment centre opening.

Enhancement and follow up working groups

UK Biobank will submit a proposal, based on work by the Enhancement working group (led by Professor Paul Elliott) to the Summer 2008 meeting of UK Biobank's International Scientific Advisory Board. The proposal for enhancement will be refined in light of the Board's advice and submitted to the Funders for approval. Additional enhancement measures being considered include web based diet assessments and information regarding physical activity (derived, for example, by asking people to wear a pedometer for a few days after their assessment and asking them to then mail back the device to UK Biobank).

The Follow-up working group, led by Professor Mike Pringle, intends to undertake a scoping study during which health information will be requested for 5 000 – 10 000 people from each of England, Wales and Scotland. It is anticipated that the data will be received in the first half of 2008 at which time the working group will assess what information can be gleaned from the respective health systems and what format it is in.

Update regarding recommendations from EGC11

Recruitment of ethnic minorities

An Ethnicity Recruitment Subgroup operated during the set-up phase of UK Biobank (as a subgroup of the Science Committee). The subgroup investigated strategies for the recruitment of ethnic minority groups and proposed that UK Biobank should seek to include about 5% of participants from ethnic minority groups. This rate has been achieved during the recruitment to date although the distribution across assessment centres is not even (i.e. there are high rates of ethnic minority participation in Manchester but low rates in Oxford). UK Biobank recognises the need to place assessment centres strategically to maximise participation of individuals from minority groups.

UK Biobank's access and intellectual property policy (13 May 2007)

UK Biobank has employed a new Company Secretary who specialises in intellectual property law. Drawing on policies from other research programmes, the Company Secretary will develop the policy with a view to moving from policy to procedures. A revised version will be submitted to the Council in due course.

Monitoring assessment centre operations with regards to recruitment of individuals with physical or mental incapacity

Information is recorded in UK Biobank's assessment centre monitoring system when potential participants are assisted through, or excluded from, the assessment centre process due to a lack of capacity (mental or physical) or an inability to speak a sufficient level of English. Professor Collins provided information on this system and also on the number of people falling into the two categories.

The number of participants with recorded special requirements included people who were:

- pregnant (4 people)
- dyslexic (3 people)
- registered disabled and/or wheelchair access was required (99 people)
- speech impairment where assistance with the interview may be required (5 people)
- English not first language but bringing their own translator (13 people)
- mental capacity (including people who informed UK Biobank ahead of the visit that they have learning difficulties, cerebral palsy or recovering from stroke) (8 people)
- registered blind or partially sighted (34 people)
- registered deaf or hearing impaired (22 people).

The number of people excluded from participation for reasons including:

- They could not understand the written consent information (including people who spoke no English and had no translator, instances where the translator had insufficient English themselves and a small number of people who were unable to read) (38 people).

The Council recommended the use of the telephone translation service, often used by general practitioners, for those potential participants for whom English is not their first language and no translator is available at the assessment centre.

- A learning difficulty meant insufficient capacity to provide consent (1 person).

The Council re-iterated a previous recommendation that UK Biobank should use the three stage test for mental capacity described in the

Mental Capacity Act 2005, namely that a participant understands, believes and retains the information provided to them.

- They were intoxicated (1 person).

The 'No further use' option of withdrawal from UK Biobank

Further to the Council's discussion under agenda item 3, the 'No further use' withdrawal option was raised with Professor Collins. The Chair suggested that the Council and UK Biobank could put a co-ordinated response on their respective websites regarding the change in process and re-wording of the Ethics and Governance Framework (EGF) and Participant Information Leaflet.

A strategy for ongoing communication with participants will be essential if UK Biobank is to effectively inform participants of this type of policy or process change and the project's progress in general (e.g. via regular newsletters).

ACTION: The Secretary will post information on the EGC website regarding the revision of the 'No further use' option of withdrawal in the EGF. The EGC recommended that UK Biobank posts corresponding information on its website and possibly include the change in process in a future UK Biobank newsletter to participants. [AH]

ACTION: Professor Collins proposed that Andrew Trehearne write a summary report regarding the progress being made in the development of an 'ongoing communication' strategy. [RC and AT]

Biannual report on enquiries and complaints received by UK Biobank

The Council is charged to monitor UK Biobank's conformance with the Ethics and Governance Framework. One element of this is to review UK Biobank's handling of complaints and enquiries to ensure that an appropriate and effective process is in place, and to monitor the pattern of, and reasons for, complaint. A report of the enquiries and complaints received by UK Biobank during the project's first six months of operation was presented to the Council.

Calls to the Participant Resource Centre (PRC) are recorded and used by a management team to monitor call handling. PRC staff and the monitoring team regularly meet and review their experience of handling complaints. In addition the monitoring team attend the PRC at regular intervals in order to 'sit in' on procedures.

Enquiries and complaints received by the PRC are classified and, where necessary, escalated to UK Biobank's Chief Scientific Officer. The content of conversations regarding escalated enquiries and complaints is recorded. Enquiries and complaints received by the co-ordinating centre are rapidly dealt with by UK Biobank's Head of Communications and signed by Professor Collins.

The types of enquiries and complaints received in the first six months of operation have been similar to those received during the pilot phase. Professor Collins

informed the Council that the system by which enquiries and complaints are handled, and where necessary escalated to senior staff members, is working well.

Specific categories of enquiries and complaint listed in the report were discussed:

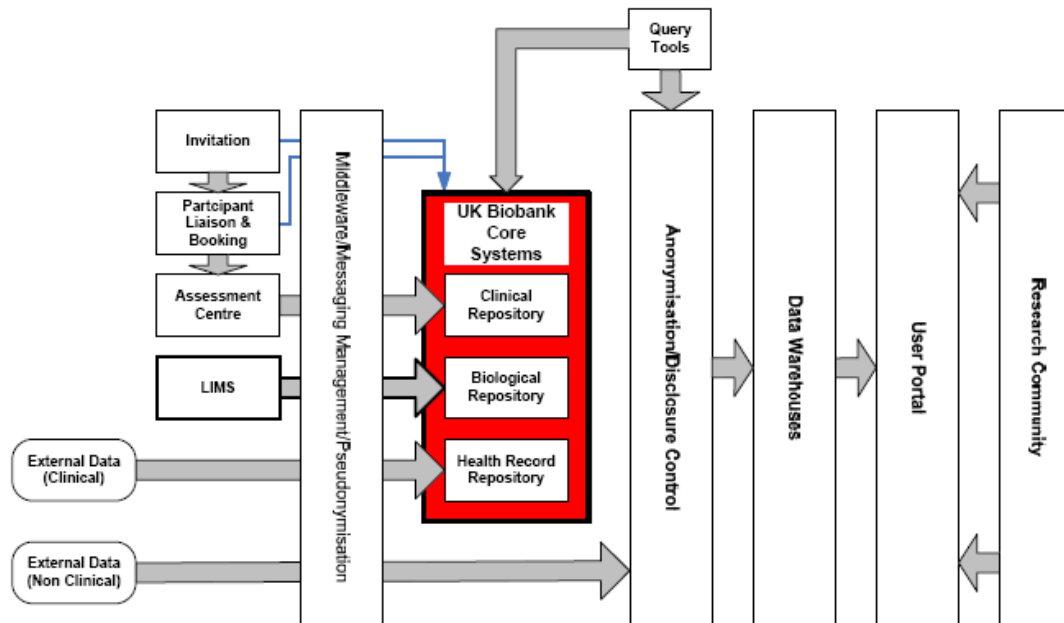
- *Release of contact details.* A low level of concern over the release of contact details has been found. In several of these cases, while appreciating that UK Biobank has operated appropriately and within legal requirements, the individual has disagreed on principle that contact details should be made available to projects like UK Biobank without an individual's consent.
- *Unsolicited mail from stockbroker.* Several participants in Manchester contacted UK Biobank having received unsolicited letters offering them shares in 'biobank research'. UK Biobank has assured participants that the letter is unrelated to the project and that UK Biobank has not and will never disclose participant contact details to any third party.
- *Assessment centre feedback form.* Participants have contacted UK Biobank regarding the accuracy of the results described on the feedback form (listing key physical measures taken during the assessment visit).

The report described the main reasons that invited individuals give for not participating. Noting that the second highest reason is 'not interested' the Council asked if UK Biobank is aiming to generate more interest in the project. Professor Collins informed the Council that the 'not interested' response is mainly attributed to younger men, people who live further from the assessment centres and people who have less control over their day (e.g. those in full-time employment). A number of strategies are employed by UK Biobank in order to generate interest. First, UK Biobank has written to local companies asking them to support the project by permitting their staff to attend the assessment centre during work time. Second, by increasing awareness through local press and celebrity endorsement. Third, by making the assessment centre visit a pleasant experience so that participants might speak to their neighbours, friends and families about the project. The Council advised that UK Biobank should strike a balance between providing enough information (which may not reach the hard to reach groups) and over promotion (including perceptions of coercion to participate).

A further reason given for not participating is 'too unwell'. The Council asked if there are any scientific implications for the project if unwell people do not participate. Professor Collins informed the Council that UK Biobank encourages all types of people to participate and that the information leaflet explicitly states that all people, including those unwell, are invited to participate.

5. UK Biobank's information technology and data management strategy

Mr Andy Harris, UK Biobank's Systems Architect, presented the project's information technology (IT) and data management strategy to the Council. He began by providing an overview of the conceptual architecture:



UK Biobank has adopted the operational standard ISO 9001:2000. This Quality Management System is primarily used for laboratory operations (e.g. to monitor whether or not staff are following certain procedures and to monitor the quality of samples) but can also be applied to information technology. An internal audit was recently completed and an external audit will be conducted before December 2007.

UK Biobank has also agreed a policy to implement ISO/IEC 27001, an auditable, transparent operational standard that is specific to information security management. There are three key principles of security management:

- Confidentiality (making sure that data remains confidential and that there is only necessary linking to personal information).
- Integrity (making sure that the information is correct and that sets of data can be successfully linked back together, as and when necessary).
- Availability (making sure that data are backed up and that disaster recovery plans are in place).

ISO/IEC 27001 covers several areas of operation including security organisation; asset classification and control; personnel security; physical and environmental security; communications and operations management; access control; system development and maintenance; business continuity management; compliance.

A process for implementation has been agreed and involves the following steps:

- Decision to implement ISO 27001
- Obtain management commitment
- Define Information Security Policy
- Define Scope
- Perform risk assessment
- Decide how to manage risk
- Select objectives and controls
- Implement controls
- Seek accreditation (involving audit and continual review of UK Biobank's systems)

The current status of ISO/IEC 27001 implementation is:

- Integration with the Quality Management System utilising Q-Pulse compliance management software for control of documentation, procedures, equipment, suppliers etc.
- Policies and Procedures
 - Information Security Policy and Acceptable Use Policy in place
 - Regular information security team meetings
 - Security incident reporting procedures in place
 - Office (general staff) procedures in place e.g. end-user management; end-user manuals; patch management
 - Risk Assessments on organisation wide information assets being finalised. 111 assets (e.g. hardware, software, people) have been identified along with 92 identified threats (e.g. hardware or software failure, hackers). Each threat has been classified by the level of associated risk (from very high, high, medium to low risk).
- Backups and Disaster recovery
 - Daily backup and offsite storage procedures in operation (with a third party being used for offsite storage).
 - First round Disaster Recovery tests completed
- Auditing
 - External penetration testing by third party – successfully completed for UK Biobank coordinating centre and standardised assessment centre build in April 2007
 - Internal penetration tests to be conducted in November 2007 – both in the coordinating centre and (probably) the Manchester Assessment centre
 - Annual Funder review

UK Biobank has described several classifications of information which relate to five categories of sensitivity: public, internal to the project, confidential, sensitive and highly sensitive. For example, 'public' data might be that relating to research conducted on UK Biobank, internal data might include certain operational, financial and information security data; confidential data might relate to coded information supplied by a participant at the assessment centre, primary care data or clinical data; sensitive data and highly sensitive data relate to identifiable participant data e.g. addresses, name etc. Each data set has a set of separate identifiers. E.g. the samples taken from a participant have a different code to the questionnaire data, both of which have a different code to the primary care records. Further, when data are transferred from the assessment centre to core systems, new identifying codes are assigned such that there is no direct connect back with the assessment centre data (i.e. by assessment centre staff).

Contact details of potential participants are currently processed in confidence by the Clinical Trial Service Unit at Oxford University on behalf of the NHS. The first point at which UK Biobank collects data and samples about individuals is at the assessment centre. At this stage, UK Biobank's reference to an individual is by a 9 digit participant code assigned to them during the invitation process. That is, UK Biobank collects data and samples which it knows relate to someone but it does not know specifically to whom they relate. Although it is intended for UK Biobank to store

personal data in the future, the current situation has the advantage that if someone hacked into UK Biobank's computers they would not be able to access participants' personal details (e.g. name, address, NHS number).

At the level of an individual UK Biobank employee, the standard contract of employment contains commitments to confidentiality. Key coding for staff is being investigated such that certain keys will be needed by staff to access certain data on UK Biobank's system. UK Biobank is also investigating and implementing encryption mechanisms for protecting information held on employees' laptops. At present the core systems (containing e.g. assessment centre data) can only be accessed by five UK Biobank IT staff, with some areas limited to three members of staff only. Of these, only one employee interrogates the data if a problem is reported (e.g. if a particular assessment centre measurement needs to be checked).

Withdrawal from UK Biobank

Mr Harris briefly outlined the procedure involved when a participant withdraws from the project:

- Participant Resource Centre receives withdrawal request
- Forwarded to coordinating centre, who validate identity of participant with source data
- Coordinating centre issues System Withdrawal Request to all systems that may be holding participant data
- Individual systems follow specific procedures
- Systems report withdrawal sign-off back to coordinating centre
- Once all system withdrawals have been received, coordinating centre signs off withdrawal and confirms withdrawal with participant.

For core systems, individual consent statements are recorded and these can be updated to reflect the withdrawal status of a participant (e.g. 'No further contact', 'No further access' or 'No further use'). Subsequent data requests will use this consent/withdrawal status to disallow access to withdrawn data.

Mr Harris addressed the topic of the 'No further use' option of withdrawal (as discussed under agenda items 3 and 4) and the difficulty in removing all of a participant's data from the back-up and archive system. He explained that in transactional systems, such as that used by UK Biobank, there are multiple layers between the user and database system. As part of the audit trail of actions performed on the data, the database system internally marks the fact that data have been deleted. There is a formal process under development to ensure that all information systems that store such data do not make it available for further use once a participant has withdrawn. For example, the Laboratory Information Management System will flag associated data as 'non-displayable'.

In closed session, after Mr Harris and Professor Collins' departure, the Council agreed that the update on the IT and data management strategy had been incredibly helpful and that regular future updates would assist the EGC to fulfil its remit.

ACTION: The EGC will request biannual updates on UK Biobank's IT and data management strategy, but with the proviso for exception reports from Professor Collins as and when necessary. [AH]

The Council commented that UK Biobank will require continuing levels of funding to maintain the high security systems. A representative of the Funders commented that it is anticipated that UK Biobank's application for continued funding will include the maintenance of its security systems, in particular if these are deemed to be a high risk aspect of the project. The Council noted that the set-up costs of such systems are bigger than the running costs.

The Council noted that the methods of pass-wording, encryption and firewalls described in the Ethics and Governance Framework, are being supplemented by a technique of separating different categories of information by using separate key-codes. The Council re-iterated a recommendation from a previous meeting, that UK Biobank should provide a lay explanation on its website of how data and samples are protected.

ACTION: The Secretary will communicate the Council's recommendation to UK Biobank that it should provide a lay explanation on its website of how data and samples are protected. [AH]

ACTION: The Council agreed that it would be beneficial to have an information technology expert on the EGC. A round of recruitment will take place during 2008 during which this need will be addressed (e.g. by specifying in the advert that an expert in IT is sought).

6. EGC communications activities

Update: 3 December public meeting

The 3 December public meeting will take place at the Ashmolean Museum of Art and Archaeology, Oxford. The meeting will comprise 3 presentations and Question and Answer session (running from 18.00 – 19.30) followed by a drinks reception.

Dr Oonagh Corrigan, Lecturer in Sociology, Law and Social Science at Plymouth University, has agreed to Chair the meeting. Dr Corrigan's research interests include bioethics; biomedical research; genetics and informed consent and she has co-authored the book (2004) *Genetic Databases: Socio-ethical Issues in the Collection and Use of DNA*, London: Routledge. Tutton, R. & Corrigan, O.P. (eds.).

Dr Jane Kaye, Research Officer in Law in the Oxford Genetics Knowledge Park, the Ethox Centre, University of Oxford, has agreed to present the introductory talk at the meeting, setting the context of what biobanking research is and how UK Biobank fits in the international scene. Dr Kaye is responsible for the management of a project entitled 'Governing Genetic Databases'. She has carried out research on the regulatory, privacy and data protection issues around genetic databases; carried out socio-legal research on the Icelandic Health Sector Database; lead the Law Team of

an EC Framework 5 project called ELSAGEN (The Ethical, Legal and Social Aspects of Human Genetic Databases: A European Comparison).

The further two presentations will be given by Professor Collins and the EGC Chair regarding UK Biobank and the EGC, respectively.

Subgroup work

The EGC communications subgroup met for the second time on 16 July 2007. The Council considered a paper describing the subgroup's discussion including the following issues:

- The June public meeting and the implications of this meeting on the style and content of the proposed December public meeting.
- The ways in which the EGC currently promotes itself (i.e. through the distribution of leaflets and annual reviews) and what strategies may be adopted in future (e.g. the EGC might try and raise awareness through contact with intermediary organisations such as medical charities).
- The respective roles of, and relationship between, UK Biobank and the EGC in terms of the handling of ethical queries relating to the project. The Council discussed two types of queries, those relating to ethical issues about the project and those relating to the EGC's work.

Reflecting on the detail of the first biannual complaints and enquiries report, discussed under item 4, the Council agreed to ask UK Biobank for additional detail on non-routine queries or complaints of an ethical nature (while recognising that it may be difficult to define what constitutes 'ethical'). Such a category of enquiries and complaints might include those relating to commercial use of the resource, to future use of the resource and reasons given (if any) for withdrawal from the project. In asking for this additional information, the Council hopes to inform itself of the issues of importance to the enquirer or complainant. The Council is not asking for the extra detail in order to monitor the quality of UK Biobank's responses.

ACTION: The Council will request further information on select categories of complaints and enquiries, to be included in the next biannual report. [AH]

ACTION: UK Biobank may on occasion receive queries or complaints that relate to the EGC. The Secretary will make a request to UK Biobank to send any such enquiries or complaints to the EGC (with the enquirers permission). [AH]

The Council discussed the use of the words 'guardian' and 'watchdog' as a means of conveying the EGC's role. The word 'watchdog' was felt to be misleading as it may suggest the Council has powers above and beyond its advisory and monitoring role. The word 'guardian', as appears in the EGC's remit, was favoured as this draws on the role of the EGC as the overseer of the project and suggests a flexible role which can respond to the changing environment in which UK Biobank and the EGC operate.

The Chair informed the Council that UK Biobank is developing a short video which 'follows the blood' from the participant's assessment centre visit to the storage of the

sample at Cheadle. The video will be shown widely e.g. at the assessment centre and on the project's website.

ACTION: A new EGC leaflet will be developed describing the Council's role in accessible terms while being true to its formal remit. [Communications subgroup and AH]

EGC commissioning research involving UK Biobank participants

UK Biobank's draft Access and Intellectual Property Policy (A&IP Policy, January 2005) provides a high level description of how access to the resource (including sample, data and re-contact with participants) will be managed. The detailed processes underlying this policy have yet to be established.

Professor Webster's research tender proposed to invite UK Biobank participants to take part in the public attitude study (with initial contact being undertaken by UK Biobank's Chief Scientific Officer). The Chair expressed the opinion that, while the processes and mechanisms for access have not yet been established, it would be unfortunate for the EGC to set a bad precedent by commissioning work in such a way that effectively bypasses the albeit brief requirement of the draft A&IP Policy. Furthermore, as the independent overseer of the project, the EGC has a role to play in advising UK Biobank on the merit of each application to the resource, in particular advising on applications which request re-contact with participants. There may, therefore, be a real or perceived conflict between this role and the EGC itself commissioning research which seeks access to participants.

The Council agreed that, although it would be scientifically valuable to include a cohort of UK Biobank participants in Professor Webster's study, it is not appropriate to re-contact participants at this point in time.

Query from UK Biobank participant

The Secretary informed the Council of a recent query received from a UK Biobank participant regarding the future uses of the resource.

7. EGC expenditure for 2006/2007 and 2007/2008 budget

The Council noted the £104,238 expenditure during the period 1 October 2006 to 30 September 2007 (78% of the budget for that period).

The EGC has been allocated £211,359 to support its activities during the period 1 October 2007 to 30 September 2008. The increase relates to increased expenditure on commissioned work and to allow flexibility in the number of public meetings to be held in this period.

8. Report on meetings attended

Taiwan biobank symposium (14/08/07)

The Chair attended a biobank symposium organised by representatives of Taiwan Biobank. The Council noted that the project, which is hoping to recruit individuals through community connections, has adopted an Ethics and Governance Framework (EGF) which is heavily based on UK Biobank's EGF.

Public Population Project on Genomics (P3G) meeting (22 and 23/10/07)

The Secretary recently attended a P3G meeting and attended sessions on governance, consent, access and intellectual property rights. Discussions included various strategies for, and the meaning of the term, 'governance'; the key audiences to be addressed through an access policy and the core elements of a material transfer agreement. A generic participant information leaflet and consent form were finalised and will be posted on P3G's Observatory website.

ESRC Genomics Network conference (25/10/07)

The Chair recently presented a talk outlining the Council's role in UK Biobank's Access and Intellectual Property Policy at the ESRC Genomics Network conference 'Today's Answers, Tomorrow's Questions'.

UK Biobank Board of Directors (26/10/07)

The Chair attended the UK Biobank Board of Directors meeting on 26/10/07 at which the Council's recently commissioned public attitude survey was discussed.

ACTION: As a follow-up to the Board's discussion the Secretary will send a briefing note to the Board explaining the process by which the research was commissioned and the expected reporting dates. [AH]

9. Any other business

EGC review

The Council's activities will be subject to Funder review in 2008, at which time the Council will request future funding.

10. Date of next meeting

A public meeting will be held on 3 December 2007. The next Council meeting will take place on 17 March 2008.