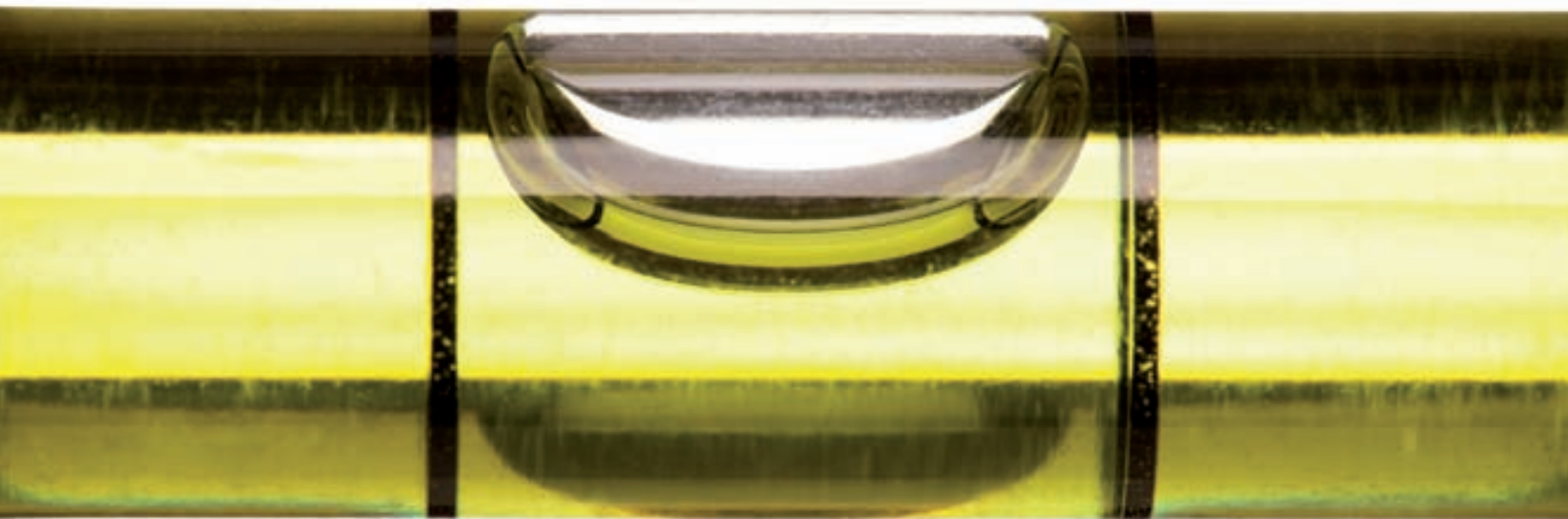


UK Biobank Ethics and Governance Council



**Annual
Review
2006**

The UK Biobank Resource is a managed research resource for the public good; the remit of the Council is to protect participants' interests and the public interest more generally.

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The chair's introduction



Welcome to the second Annual Review of the UK Biobank Ethics and Governance Council. I took over as chair of the Ethics and Governance Council in September 2006 from my predecessor, Professor Alastair Campbell, who safely steered the Council through the first few years of its existence and the set-up stage of the UK Biobank project.

I am fortunate to have joined at an exciting time as UK Biobank prepares to roll out the project across the country, beginning in April 2007 in Manchester, the home of UK Biobank. The work of the Council in the set-up phase was concerned primarily with getting policies and procedures right: how will UK Biobank ensure that participants give free and valid consent? What will the researchers do with requests for feedback? How will complaints be handled?

The Council has monitored and advised on these and many other policies that are essential to the proper functioning of UK Biobank and it is satisfied that everything is in place for the launch. As we look to the future, with six new members who joined in December 2006, the Council is preparing for a broader role in anticipating new challenges for UK Biobank and in helping it to aim towards a gold standard of ethical governance; after all, the Ethics and Governance Council is a world first and it is our responsibility to set the standard very high.

We must remember too that UK Biobank is a very long-term project – there may not be any research results for many years to come and the real beneficiaries will be the generations after us. Notwithstanding this, we envisage that requests for access to the resource will come sooner rather than later and this will require a clear and transparent access and intellectual property policy that is in keeping with the Ethics and Governance Framework. To this end, we foresee that the Council

will need to establish working groups to concentrate on emerging issues for UK Biobank, such as access requests.

As for the Council itself, we have taken steps to make the governance process more robust by commissioning research on concepts of 'public good' and 'public interest'. The UK Biobank Resource is a managed research resource for the public good; the remit of the Council is to protect participants' interests and the public interest more generally. By better understanding what we mean by these concepts, we hope to achieve better and more transparent decision making and have a more effective advisory role. There is much to do.

On a final, personal note I would like to thank colleagues on the Council, and most particularly the Council Secretary, Ms Adrienne Hunt, for making my first few months both enjoyable and challenging.

I hope that you find this review helpful and informative. We welcome comments and suggestions on how we can refine and improve our role, and if you have such contributions, we look forward to hearing from you.

Graeme Laurie

1 The UK Biobank project



The purpose of UK Biobank is to build a resource that will support a diverse range of research intended to improve the prevention, diagnosis and treatment of illnesses (such as cancer, heart disease, diabetes, dementia and joint problems) and the promotion of health throughout society.

The project is due to begin in spring 2007. The resource is expected to contain data and biological samples from 500,000 people living in the UK who are currently aged 40 to 69. It is not intended that the participants of UK Biobank will benefit directly from the project. The benefit will be for future generations. However, the success of UK Biobank relies on the participation of these 500,000 people.

When UK Biobank invites a person to participate in the project it will ask them to:

- provide information about their health, lifestyle, memory, work and family history
- undergo a few physical measurements (including blood pressure, pulse rate, height and weight)
- provide biological samples (including blood and urine)
- allow UK Biobank to access information about their health through the person's health-related records (including their NHS medical record).

Each person will also be asked to grant permission for researchers to access their data and samples for uses that meet UK Biobank's purpose. The information that is provided to researchers will be anonymised, that is, the researchers will not be given any identifiable information relating to the person (unless UK Biobank has sought and gained consent from the person for such disclosure).

Over time, this bank of information will become an internationally valuable research resource. It will help researchers study how health is affected by lifestyle, environment and genes and to investigate why some people develop particular diseases while others do not.

UK Biobank aims to improve the health of future generations by supporting this kind of research.

2 The ethics

When considering how to govern a large and complex research project, it is important to think in terms of best practice 'ethical' governance.

Aiming at a high, innovative standard of ethical governance.

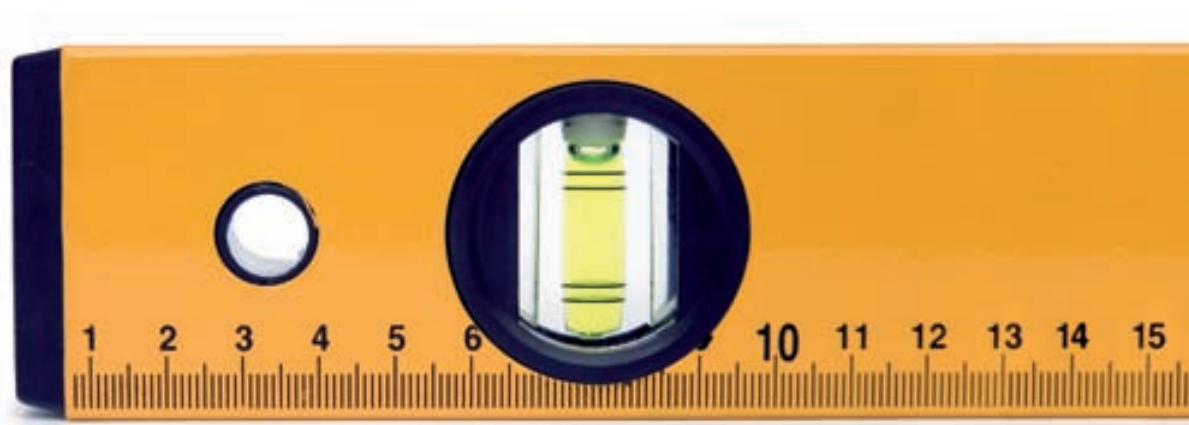
UK Biobank is not the first resource of this kind. There have been a number of previous studies, often relating to specific diseases. UK Biobank invites a re-evaluation of the traditional methods of governance for such resources given its scale and long-term nature. Can UK Biobank do more than conform to the relevant norms and legislation? What could it mean to promote 'ethical' governance?

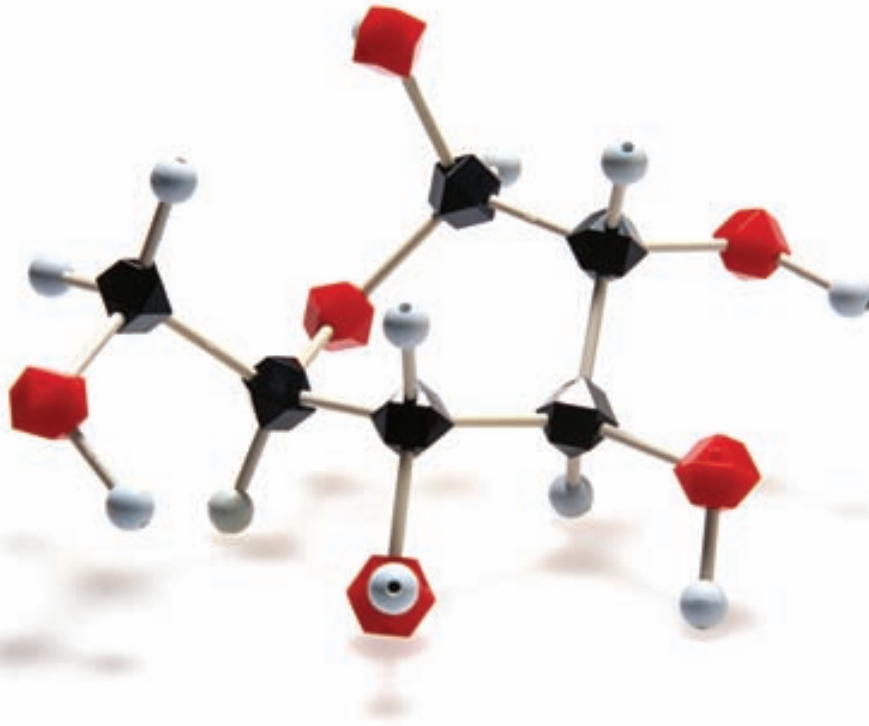
The Wellcome Trust and the Medical Research Council, the principal funders of UK Biobank, addressed these questions from the earliest phases of UK Biobank. As a result of those discussions in 2003, the funders established an Ethics and Governance Framework (EGF) for the project. The framework describes a series of standards to which UK Biobank will operate during the creation, maintenance and use of the resource. In addition, it elaborates on the commitments that are involved, not only to those participating in the project but also to researchers and the public more broadly.

The EGF is intended to provide a foundation for trust.

The framework has a number of aims, all of which will endure throughout the life of the project:

- to facilitate ethical science
- to ensure fidelity to UK Biobank's purpose
- to respect participants' privacy and the security of their samples
- to encourage and control access and information-sharing in order to promote the widest possible health benefits
- to establish an independent monitoring and advisory body focusing on all the above.





UK Biobank and participants

The EGF:

- affirms the voluntary nature of participation
- describes the commitment to reducing barriers to participation
- establishes that consent will be sought 'to participate in UK Biobank', based on an explanation and understanding of a number of features of participation (such as the kinds of information and samples that will be collected at enrolment and the possibility of being re-contacted in future by UK Biobank)
- affirms the right to withdraw at any time
- makes a commitment to protecting the confidentiality of both samples and data.

UK Biobank and researchers

The EGF:

- confirms UK Biobank's role as steward of the resource and legal owner of the database and the sample collection
- describes the principles which govern access to the resource by researchers.

UK Biobank and society

The EGF:

- describes the arrangements for management and accountability
- confirms that this is a research resource and that non-research access, for example by the police, would be allowed only on the strength of a court order (which UK Biobank would rigorously oppose)
- describes the broad benefit-sharing that will be required (including the obligatory publication of findings and accessible archiving of data and findings for future use).

3 The council



The UK Biobank Ethics and Governance Council is the independent guardian of the EGF.

The UK Biobank Ethics and Governance Council (EGC) offers advice to UK Biobank, helping it to respond to changes in, for example, the legislative or regulatory context or to safeguard the interests of research participants and the general public in relation to the project. The EGC also provides a monitoring role, checking UK Biobank's conformity to the commitments it has made in the EGF.

3.1 Our independence is our strength

Our independence comes from the members who, acting in their individual capacity, form a collective Council view. Our members have been selected through an open appointment process in keeping with the Nolan Principles of Public Life. This process involved public advertising of the positions and the formation of an Appointments Committee to advise the funders.

As a Council we have independence of thought and action.

Naturally, we need to have an appropriate relationship with our funders (the Wellcome Trust and the Medical Research Council) and with UK Biobank in order to carry out our work effectively. We also need to be aware that we function within an established research governance environment. UK Biobank has received research ethics committee approval for its scientific protocol, as is standard for this type of project.

The activities of the Council are intended to complement existing mechanisms for research governance. For example, proactively monitoring research is not in a research ethics committee's remit. This is where the Council steps in and is the kind of activity that makes UK Biobank a world leader in innovative, gold-standard approaches to ethical governance.

The EGC provides an additional safeguard and reassurance to UK Biobank's participants and the public.

3.2 Who are we?

We are a multi-disciplinary group that draws together a wide range of expertise in law, ethics, biomedical science, policy and consumer issues.

Membership of the Council will change over the years, reinforcing the need for us to establish robust and well documented procedures and records of our discussions and advice making (while recognising that the Council operates in a changing world in terms of expectations and values). These procedures and records will provide the 'memory' of the Council.

We would like to thank those members who stepped down in 2006 for their contributions to the Council. The following list reflects membership as of 1 December 2006.

01 Graeme Laurie



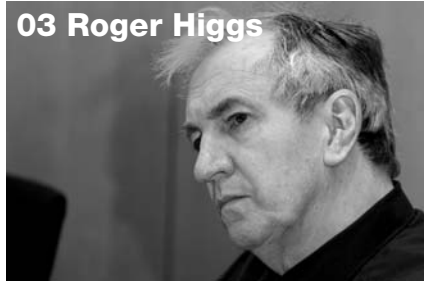
02 Andrea Cook



08 Roger Moore



03 Roger Higgs



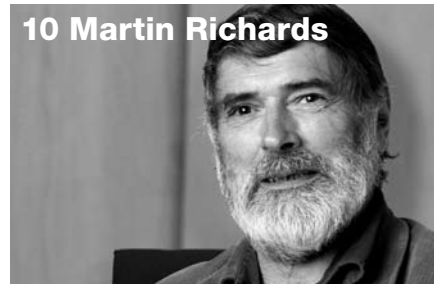
09 Hilary Newiss



04 Adrienne Hunt



10 Martin Richards



05 Erica Haines



11 Sally Smith



06 Ian Hughes



12 Heather Widdows



07 Anneke Lucassen



13 Chris Wild



The council members

01

Graeme Laurie, Chair of the EGC, is Professor of Medical Jurisprudence at the University of Edinburgh and co-director of the Arts and Humanities Research Council (AHRC) Research Centre for Studies in Intellectual Property and Technology Law. His research interests include the role of law in promoting and regulating science, medicine and technology.

02

Andrea Cook, Vice Chair of the EGC, is Chair of the Consumer Council for Water's Northern Region and a member of its national board representing consumer interests in the water and sewerage industry. Ms Cook is a member of the Advisory Board of the Institute of Public Policy Research (North). She is also a member of the Law Society's Consumer Complaints Board and an independent member of the Parole Board.

03

Roger Higgs, Vice Chair of the EGC, is Professor Emeritus and former deputy head of division at GKT School of Medicine, King's College, London. He retired from the Department of General Practice and Primary Care at King's at the end of July 2004, and until March that year worked as a general medical practitioner within the inner-city practice that he founded in 1975.

04

Adrienne Hunt, Secretary of the EGC, is responsible for the executive and administrative support of the Council. Trained as a biochemist, she spent several years working on the Human Genome Project. More recently, she worked in academia undertaking research on the ethical issues raised in the context of public health interventions.

05

Erica Haines is Professor of Sociology at Newcastle University and is also Executive Director of PEALS (Policy, Ethics and Life Sciences) Research Institute, a partnership between the universities of Newcastle and Durham and the International Centre for Life, Newcastle. She undertakes interdisciplinary research on the social, ethical and legal aspects of the life sciences, covering a range of topics including participation in genetic databases.

06

Ian Hughes is a Professor of Pharmacology at the School of Biomedical Sciences, University of Leeds. He is Chair of Leeds Mental Health NHS Teaching Trust and has held non-executive director appointments in the NHS since 1986. Professor Hughes' research has focused on both the scientific and educational aspects of pharmacology and he has published over 70 refereed full papers.

07

Anneke Lucassen is a Clinical Geneticist and Senior Lecturer at Southampton University. Her clinical and research interests include the ethico-legal issues encountered in genetic medicine. She is a member of both an NHS clinical ethics committee and Vice Chair of an NHS research ethics committee.

08

Roger Moore is an engineer by profession with broad interests in public policy and citizen involvement. In 2006 he retired as chief executive of the NHS Appointments Commission after a varied career within academia, the Department of Health and the National Health Service.

09

Hilary Newiss is a lawyer and independent consultant with a background in intellectual property law, mediation and bioethics. She also works in public policy, and has previously served on the government advisory bodies, the Human Genetics Commission and the Intellectual Property Advisory Committee.

10

Martin Richards is Emeritus Professor of Family Research and former Director of the Centre for Family Research, University of Cambridge, which he founded in 1967. His research as a social scientist focuses on parent-child relationships, aspects of family life and genetics and reproductive technologies.

11

Sally Smith QC was called to the Bar in 1977 by Inner Temple and has been a practising barrister ever since. She was appointed Queen's Counsel in 1997. She specialises in medical law, with a particular interest in class actions, and has represented the NHS in major litigation including the Benzodiazapine Litigation, the Breast Radiation Litigation and currently the Nationwide Organ Retention Litigation.

12

Heather Widdows is a Senior Lecturer in Global Ethics at the Centre for the Study of Global Ethics, University of Birmingham. With a background in Moral Philosophy, she works on the conceptual issues of Global Ethics. Her research interests include the foundations of moral value from a philosophical perspective; communication across belief systems and value frameworks in the context of liberal democracies; and bioethical issues, particularly reproductive, research and genetic ethics.

13

Chris Wild is Professor of Molecular Epidemiology and Director of the Institute of Genetics, Health and Therapeutics at the University of Leeds. His research focuses on the application of biological measurements to human population studies in order to better understand the interaction of environmental and genetic risk factors in disease.

4 Our activities in 2006



UK Biobank: from principles to practice

A pilot phase of the project was conducted in 2006 in Altrincham, Cheshire, involving approximately 4,000 people. The pilot was intended to test the entire process, including the participant invitation letter and consent materials as well as the sample-processing and IT systems that are in place. You could say that in the lead-up to the pilot, 'principles turned to practice' as UK Biobank set about developing the Standard Operating Procedures (SOPs) to support the pilot. These SOPs are detailed, written instructions that aim to achieve uniformity in the performance of a specific function (for example, taking a blood sample). Reflecting the work of UK Biobank, we have reviewed several SOPs in 2006 associated with UK Biobank's management of the recruitment visit (for example, the procedures which UK Biobank staff undertake when asking for consent). We have also advised UK Biobank on the need for certain SOPs to be developed in advance of the start of recruitment, for example, how any incidental findings that are made during enrolment (such as significantly high blood pressure in a participant) will be managed by UK Biobank staff.

In addition to looking at the procedures 'on paper', several members of the Council went to observe the procedures in practice in Altrincham during the pilot phase. This led to a number of recommendations, including the suggestion that more attention should be paid to the 'oral' privacy of participants so that the interviews with participants are not overheard.

UK Biobank produced a comprehensive summary of the findings of the pilot phase. We reviewed this document and were particularly interested in the findings of the postal survey of ten per cent of participants. The survey asked them how they found the recruitment experience and tested their understanding of consent. We were satisfied that this survey showed high levels of understanding among participants and we endorse UK Biobank's intention to continue to conduct this survey during full-scale recruitment.

The main phase of recruitment, informed by the outcomes of this pilot, is due to start in spring 2007.



Making sure that potential UK Biobank participants receive the right kind of information.

The EGF lists a number of aspects of UK Biobank which a participant should be informed of before they are asked to take part in the project. This list includes subjects like the long-term nature of the resource, the variety of potential research users and the uses to which data might be put. UK Biobank has developed information leaflets and consent materials to supply to potential participants. We have spent time in 2006 reviewing these materials and ensuring that they reflect the commitments made in the EGF. UK Biobank had already developed consent materials with the EGF in mind. We, however, offered suggestions on how things could be improved still further.

Examples:

1. What does the EGF say?

“Potential participants should be informed about the fact that there will be a link to the full record of medical and other health-relevant information (past and ongoing).”

How did we advise UK Biobank?

The early formulation of the consent materials stated that a participant agreed ‘to allow your health to be followed for many years by UK Biobank directly through routine medical and other records’. We consider it important that, if UK Biobank intends to access the full medical record (that is, past and future health information), this should be stated explicitly in the materials. Further, we felt it would be informative to give a few examples of which ‘other records’ will be accessed. Both of these points have been addressed by UK Biobank in the latest version of the materials and, we hope, are useful to the participants.

2. What does the EGF say?

“Potential participants should be informed about the expectation that commercial entities will apply to use UK Biobank.”

Public consultation has highlighted the fact that there is a broad spectrum of opinion regarding commercial use of resources like UK Biobank. Some members of the public are uncomfortable with the idea of commercial companies using data, while other groups express a willingness to accept commercial access so long as there are controls on how access is managed. Consultation work conducted specifically on UK Biobank has stressed that transparency and openness in relation to commercial interests in the resource will be critical to earn and maintain trust. In response to this final point, the EGF states that potential participants should be explicitly informed about the expectation that commercial entities will apply to use UK Biobank. Having been provided with this information, the potential participant can determine whether they are willing to participate in the project.

How did we advise UK Biobank?

The original materials stated that ‘companies’ might have access to the resource. Given that there is a range of company types (including charitable companies), we advised that this should be changed to ‘commercial companies’ so that the point is clearer to participants. Furthermore, we suggested that the word ‘commercial’ be added to the consent form in which participants are asked to agree to the statement that they ‘will not benefit financially from taking part (for example, if research leads to commercial development of a new treatment)’. Once again, UK Biobank took these recommendations on board.



Ensuring robust and transparent access to the resource

Many researchers will want to have access to the information and samples held by UK Biobank. It is not possible to say now who the researchers will be and what research uses they will apply for (within the context of UK Biobank's purpose). It is possible, however, to describe now the principles by which this future access will be permitted. The Intellectual Property and Access (IP and A) policy (available on UK Biobank's website for participants and the public alike) sets out to do just this. Access to the resource will be managed so as to:

- protect participants, honour commitments made to them and act within the scope of their consents
- ensure compliance with legal and regulatory requirements (for example, the Data Protection Act 1998)
- strategise access to those parts of the resource that are limited in availability (particularly samples, which could become depleted)
- manage intellectual property rights in the resource and the results that flow from it.

This policy is being actively developed by UK Biobank as it moves from describing the principles to describing the processes of access. The EGC is advising on this policy and will ultimately be involved in monitoring access to the resource to check UK Biobank's conformity with not only the EGF but also the more detailed IP and A policy. We have agreed to establish an EGC sub-group to review and advise on the development of this policy.

The vital role of public attitudes in our work

There are a number of ways in which our activities can be informed by the opinions of the participants in UK Biobank and the public more generally. One way is to hold public events, as we have previously done and plan to do again in 2007. Another way is to commission research. This year we have commissioned a study to investigate the current literature regarding public attitudes to UK Biobank-related issues. This study will report its findings early in 2007. We are going to use the findings of this study to select an area that is in need of further investigation and pertinent to UK Biobank and to the EGC's remit, and where we can add value to current thinking.

These activities are just a few elements of a broader communications strategy that we will develop further in future. We welcome suggestions on how we can better engage with the public over our work.

In addition to commissioning and learning from people through public attitude surveys and public events, we have commissioned research on the concepts of the 'public interest' and the 'public good'. Both of these concepts are used in relation to UK Biobank. For example, the resource is described as being managed 'for the public good' and part of the EGC's remit is to advise on the interests of research participants and the public. But how should we define the public interest and what does it mean when we say that the resource will be managed for the public good? This research is due to be complete in 2007 and it should help us in our role as monitors of and advisers to UK Biobank.

Sharing knowledge and best practice with others

For any organisation it is important to learn from others. For the EGC, this means talking to people who run resources like UK Biobank or to academics who do theoretical work in this area. We have had a number of visitors over the past year and have attended meetings and conferences nationally and internationally. We know that we can learn from all of these discussions and interactions.

Our international visitors:

Name	Organisation
Dr Tohru Masui	National Institute of Biomedical Innovation, JCRB Cellbank, Japan
Delegation led by Dr Wu, Shuh-Min, Director, Taiwan Biobank Pilot Research (Ethics, Legal and Social Implications Team)	Taiwan Biobank
Delegation led by Dr Satoko Tatsui, Professor of Law at Yokohama National University Law School	Biobank Japan
Dr Ole-Andreas Brekke and Dr Thorvald Sirnes	The Stein Rokkan Centre for Interdisciplinary Social Studies, Norway
Ms Michaela Mayrhofer	Life-Science-Governance, Department of Political Science, University of Vienna, Austria

Representatives of the Council have also been to or presented our work at a number of meetings and conferences, including:

Title of event	Organiser	Attended and/or presentation made by	Date
Conference 'Codes, conduct, genetics and ethics'	The Association of Research Ethics Committees	Adrienne Hunt presented, 'Ethics and Governance Committee and Guardian'	June 2006
Governing Genetic Databases Project Seminar Series	Ethox Centre, University of Oxford	Alastair V Campbell presented 'Biobanks: The Ethical Challenges'	June 2006
'Gene Banks and Commercialisation of Genetic Research – Current Challenges'	ESRC Genomics Research and Policy Forum	Attended by Adrienne Hunt	August 2006
8th World Congress of Bioethics	International Association of Bioethics	Alastair V Campbell presented 'UK Biobank: the Ethical and Governance Issues'	August 2006
Property Regulation in European Science, Ethics and Law Project Final Conference	Birmingham University	Adrienne Hunt presented 'UK Biobank: Ethics and Governance'	September 2006
Annual general meeting	Public Population Project in Genomics	Attended by Adrienne Hunt	September 2006
Biobanking workshop	TUBITAK DNA/Cell Bank, Hacettepe University, Turkey	Adrienne Hunt presented 'UK Biobank: Ethics and Governance'	November 2006

5 The challenges



Ensuring that advice to such a dynamic project is relevant and timely.

Responding to changes in the external environment

UK Biobank is being developed in an ever-changing research and social context. New laws may be introduced which UK Biobank has to respond to and with which it must conform. New opinions may prevail in society that the EGC should take into account when providing its advice to UK Biobank.

Thus UK Biobank and the Council have to keep themselves informed about the environment in which they are operating. For the Council's part, we aim to achieve this by drawing on the expertise of our members, who cover a range of disciplines, and by sharing knowledge with others who work in the field.

Responding to changes in the UK Biobank project

UK Biobank's policies and procedures are often the subject of the Council's deliberations and advice. It is important for us to review these documents sufficiently early for us to be able to comment in a way that is useful to the project. It is also essential that we are kept informed of UK Biobank's progress and plans.

This challenge is being addressed by keeping the lines of communication between the Council and UK Biobank open on a day-to-day basis. In addition, methods of working are being developed and formalised between the two parties. For example, this year both parties have signed a Memorandum of Understanding that describes the need for the timely exchange of relevant information.

Another practical example of the necessary provision of information relates to UK Biobank's handling of complaints. The EGC has a role to play in monitoring the reasons for, and any trends in, complaints received by UK Biobank. Recently, UK Biobank and the EGC have agreed that a bi-annual report summarising the complaints received will be supplied to the EGC and that any serious complaints will be brought to the Council's attention on a case-by-case basis. This agreement will provide the foundation of our complaints monitoring activities in the future.

6 The finances

The UK Biobank Ethics and Governance Council is funded by the **Wellcome Trust** and the **Medical Research Council**.

The total spend on EGC operations in 2005/06 was approximately £95,000. This includes the cost of one full-time Secretary and a pro rata salary of £7,000 and £2,000 for the Chair and Vice Chairs of the Council respectively. Members' fees (paid at a rate of £200 per meeting) and all reasonable travelling expenses of the members are also included in the total spend, along with office and meeting administration costs.

7 More information

About the Council

If you would like further information about the Council's work, we recommend that you have a look at our website (www.egcukbiobank.org.uk). We post all our meeting reports there. These reports contain more detail about what we have been discussing and advising on in 2006. If you do not have access to the Internet, please request hard copies from our Secretary, Adrienne Hunt, by writing to her at the address below. You are also welcome to contact her if you have any comments or questions about our work:

Adrienne Hunt
**UK Biobank Ethics
and Governance Council**
Wellcome Trust
Gibbs Building
215 Euston Road
London NW1 2BE
E: EGCinfo@wellcome.ac.uk

Our Press relations are handled through Barry Taylor, Communications and Marketing Director of Bristol University. You can contact him at:

E: barry.taylor@bristol.ac.uk

About UK Biobank

If you would like more information about UK Biobank, please see the projects website at:

www.ukbiobank.ac.uk

If you have any enquiries, you can contact the project team at:

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