

UK Biobank Ethics and Governance Council

**UK Biobank:
Fostering public trust through
innovative ethical governance**

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An independent council funded by the Wellcome Trust and the Medical Research Council

UK Biobank Ethics and Governance Council

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1. Introduction to UK Biobank

- The project's purpose: 'to provide a resource for research with the aim of improving the prevention, diagnosis and treatment of illness and promoting health throughout society for public benefit.'
- The resource will contain health and lifestyle data and biological samples from voluntary participants from the UK aged 40-69.
- £61million initial funding; a further £6million recently awarded.

Target: 500,000 participants

Current total: 385,000

Introduction to UK Biobank

Recruitment

- 24 recruitment sites throughout the UK; approximately 6 recruitment centres operating at any one time.
- Centres located in accessible and well-known parts of the city (e.g. in shopping centres, near bus stations).
- Recruiting a total of 600 people per day = ~18,000 samples per day to process and store.
- A custom-built £4.5 million high-tech blood and urine store has been designed to hold the ~10 million samples at - 80 degrees C for the next 30 years

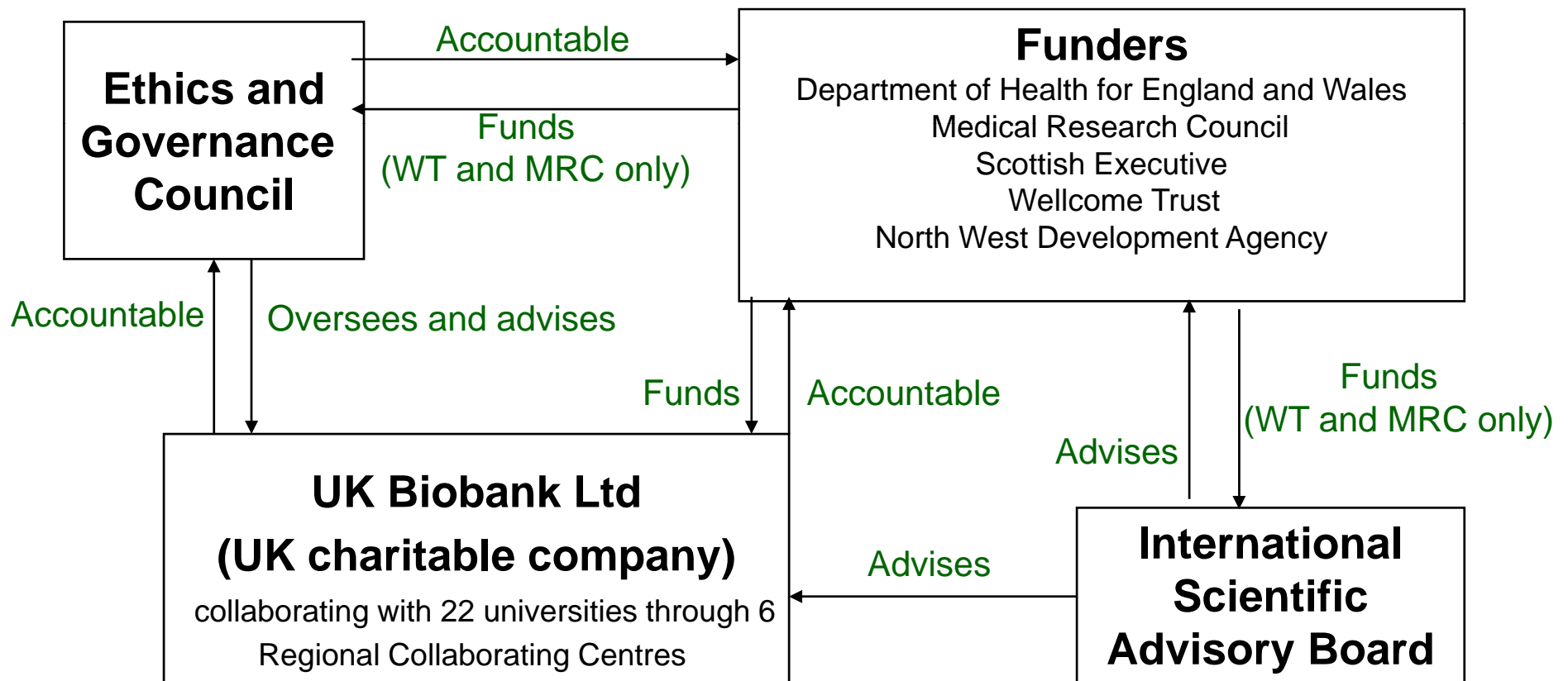
Introduction to UK Biobank

Participation involves

- providing information about health, lifestyle, memory, work and family history
- undergoing some physical measurements (including ocular, blood pressure, pulse rate, height and weight)
- providing biological samples (incl blood and urine)
- allowing UK Biobank to access information from 'health-related' records (including individual NHS medical records)
- granting consent for researchers to access data and samples for uses that meet the purposes of the project.

Introduction to UK Biobank

Internal governance features



2. Ethical Governance

2. Ethical Governance

The Ethics and Governance Framework:

- Describes the commitments and standards under which UK Biobank will operate during the creation, maintenance and use of the resource
- Describes UK Biobank's relationship with participants, research users and society
- Intended as a high-level, public document that is expected to evolve

A key, innovative feature of UK Biobank's governance

Ethical Governance

UK Biobank Ethics and Governance Framework (1 of 2)

- Establishes that consent will be sought to ‘participate in UK Biobank’.
- Affirms the right to withdraw at any time.
- Makes a commitment to protecting the confidentiality of both samples and data.

Ethical Governance

UK Biobank Ethics and Governance Framework (2 of 2)

- Confirms UK Biobank's role as steward of the resource and legal owner of the database and the sample collection.
- Describes the principles of access.
- Describes broad benefit-sharing expectations
- Describes the arrangements for management and accountability.

Ethical Governance

Creating the ethical framework

In parallel with the development of the scientific protocol:

- Process of consultations with public, health professionals, experts in ethics, law and science
- Formation of the Interim Advisory Group on Ethics and Governance, while protocol is being developed
- Development, publication and consultation on the Framework
- Formation of the Ethics & Governance Council

Ethical Governance

The independent Ethics and Governance Council

- Monitors UK Biobank's conformance with the Framework.
- Advises the project on revisions to the Framework.
- Advises UK Biobank on the interests of the participants and public in relation to the project (in particular in relation to access requests).
- Members are appointed by the Medical Research Council and the Wellcome Trust following "Nolan" principles.

Ethical Governance

Ethical governance and the creation of the Council

Why have an Ethics and Governance Council, in addition?

- The breadth of the project's purpose (broad consent)
- The long term nature of the endeavour
- Limitations in the remit of existing mechanisms, e.g. monitoring research was not in REC remit

**An additional safeguard and a foundation of trust –
the trusted third party.**

The "mantra" of the Council is that it speak *about* not *for* UK Biobank

3. In practice: The Council and its work

- Established in November 2004
- A multi-disciplinary group that draws together a wide range of expertise in law, ethics, biomedical science, social science, policy and consumer issues
- 12 members
- Meets 4 times a year and holds at least one public meeting per year

In practice: The Council and its work

Relationship with UK Biobank (1 of 2)

In advising, reviewing and reporting on UK Biobank's activities, the Council will serve as a "mirror" for UK Biobank, providing critical and constructive advice.

'Normally the Council will communicate its reflections and criticisms informally. If the Council is not satisfied with UK Biobank's response, it could make a formal statement of concern (e.g. to the Board or funders) or, if necessary, make a public statement that certain action should or should not be taken.' The Framework III.A.2

In practice: The Council and its work

Relationship with UK Biobank (2 of 2)

Things the Council has *not* been established to do:

- Assume responsibility for the ethical management of the resource
- Speak on behalf of UK Biobank (instead the Council speaks *about* UK Biobank)
- Own and develop the Framework and associate policies

In practice: The Council and its work

Reflecting the changes in the UK Biobank project

The focus of the Council's remit has changed over time:

- **Advisory:** The Framework and associated policies and procedures, content of information leaflets and consent form
- **Monitoring:** Complaints and enquiries, information security provisions, proposals for follow-up and implementation of the project's plans for ongoing engagement with participants
- **Foresight:** Access procedures

In practice: The Council and its work

Council commissioned research

- A scoping study of public attitude surveys regarding biobanking related issues.
- A study to investigate public attitudes with respect to access issues (including commercialisation and benefit sharing).
- A conceptual analysis of the terms the ‘public interest’ and the ‘public good’.

Strengthening and demonstrating independence

In practice: The Council and its work

Unforeseen challenges: Withdrawal from UK Biobank (1 of 2)

“No further use”: In addition to no longer contacting the participant or obtaining further information, UK Biobank will destroy all of their health-related information and samples collected previously (although the participant would be told that it may not be possible to trace and destroy all distributed anonymised sample remnants).

(emphasis added)

In practice: The Council and its work

Unforeseen challenges: Withdrawal from UK Biobank (2 of 2)

- “No further use”: 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. ...
- The Framework and information leaflet revised
- New pages on UK Biobank and Council website

4. Involving publics and the trust relationship

Publics were actively engaged during the development of UK Biobank and the Framework. The idea of the Council resulted from one such consultation:

“Participants generally recommended that some form of oversight body (OB) should be established and that the body should be capable of acting independently of the users and sponsors.”

“Participants said that generally, any such OB should ensure that standards of behaviour and ethics were maintained and continued to reflect the public mood as the public consensus changes but within the original terms of the consent given by volunteers.”

Involving publics and the trust relationship

The need for ongoing engagement

The model of 'broad consent' adopted by UK Biobank can encompass a wide range of future uses of the resource. This model requires important, complimentary obligations on behalf of the researcher including that participants will be kept informed of the research being conducted on the resource (e.g. via newsletters).

Effective communication is essential to maintain the trust relationship

Involving publics and the trust relationship

Current methods for involving publics

The Council:

- Public meetings with the explicit purpose of gauging attendees' views on the project to advise UK Biobank
- Commissioning public attitude surveys.

UK Biobank:

- Communications to date mostly concern awareness raising in the towns and cities where it is recruiting.
- Surveys of participants' experiences in pilot and main phase of the project.

Involving publics and the trust relationship

Future methods for involving publics

The Council:

- One-day workshop in December 2009 to consider how the Council, UK Biobank and funders might best involve publics (including participants) in future decisions relating to the project.

UK Biobank:

- The Framework states UK Biobank's commitment to ongoing engagement with participants and, accordingly, the project is actively developing its long-term communications plans.

Drawing on the outcomes of the December workshop the Council will advise UK Biobank on its long-term communication strategy and will monitor its implementation.

Involving publics and the trust relationship

Reflections on maintaining the trust relationship

- 1 in 10 of those invited agree “to participate in UK Biobank”.
- Only a few potential challenges to the trust relationship so far (e.g. withdrawal option)
- Big challenges lie ahead in terms of how access will be managed and against which ‘public good’ criteria applications will be judged.
- Anecdotal evidence suggests that the existence of the EGC, now and into the future, is seen by participants extremely positively.

Keeping participants informed about the uses of the resource is a fundamental element of the trust relationship.

4. In conclusion

- The Council was established in direct response to the broad model of consent adopted by UK Biobank and to the long term nature of the resource.
- The Ethics and Governance Framework and the Council itself are intended to provide an extra safeguard for participants and the public and both are intended to provide a foundation for trust.
- The monitoring aspect of the Council's remit is important as a compliment to traditional research ethics committees which do not offer an active monitoring role.

In conclusion (continued)

- All long-term projects like UK Biobank will encounter changes - both foreseen and unforeseen.
- A body like the Council provides informed, responsive input over time, acting in the public interest and keeping key principles at the heart of its decisions.
- Broad consent brings complementary obligations for researchers to keep participants informed about the uses of the resource and changes in the project.

Through its work a body like the Council can promote and facilitate good governance and good science in the public interest.

UK Biobank Ethics and Governance Council

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