

**Governance models and benefit sharing:
The UK Biobank Ethics & Governance Council
An Exercise in Added Value?**

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UK Biobank Ethics and Governance Council

- **Introduction to UK Biobank and the EGC**
- **In principle: Why is there an independent Council?**
- **In practice: The EGC and its work**
 - **Going beyond law?**
 - **Providing additional privacy protection?**
 - **Balancing privacy & access?**
 - **Exploring benefit sharing and public interest?**
- **Conclusions**

1. Introduction to UK Biobank and the EGC

- The purpose of UK Biobank is ‘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 is expected to contain health and lifestyle data and biological samples from 500,000 voluntary participants from the UK aged 40-69.

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Participation involves

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

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Two notable governance features:

- **Ethics and Governance Framework**
- **Ethics and Governance Council**

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UK Biobank Ethics & Governance Framework (1 of 2)

- Establishes that consent will be sought ‘to ‘participate in UK Biobank’. This is 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, the possibility of being re-contacted in future by UK Biobank and a broad description of potential research uses of data).
- Affirms the right to withdraw at any time.
- Makes a commitment to protect the confidentiality of both samples and data.

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UK Biobank Ethics & 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 which govern access to the resource by researchers.
- 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).

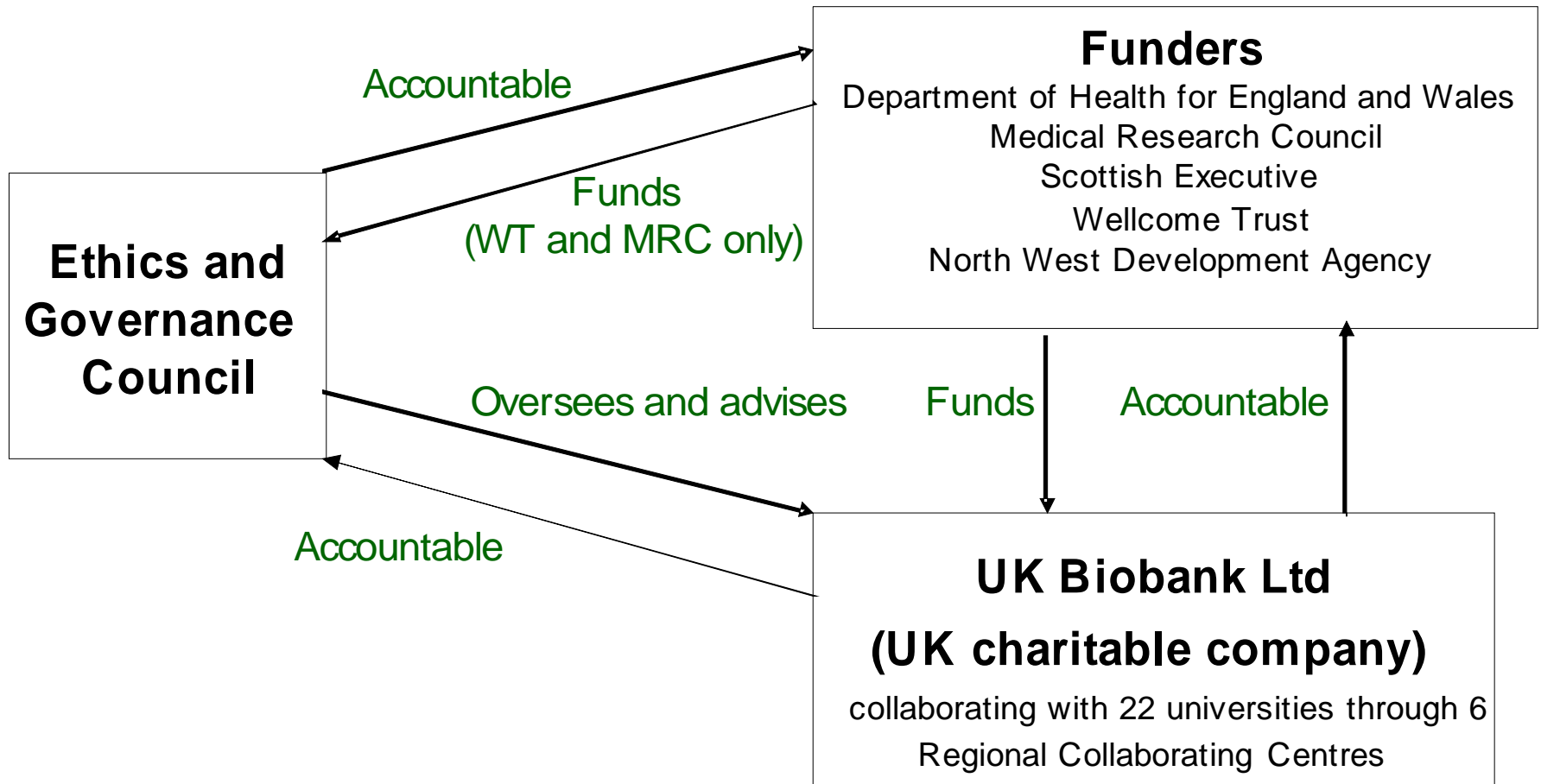
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The independent Ethics and Governance Council

- Monitors UK Biobank's conformance with the Ethics and Governance 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.
- Members are appointed by the Medical Research Council and the Wellcome Trust following Nolan principles.

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Relationships



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- **In principle: Why is there an independent Council?**

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Research governance and regulation

- Legislation (e.g. Human Tissue Act 2004, Mental Capacity Act 2005, Data Protection Act 1998)
- Regulators (Human Tissue Authority, Information Commissioner's Office; Charity Commission, Companies House)
- Other governance mechanisms (research ethics committees, NHS as data controller)
- Good practice (e.g. MRC, professional bodies etc)

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Research governance and regulation: a critique

Kaye & Gibbons (*Medical Law International*, 2008):

- Undue complexity, yet framework remains incomplete
- Over-dependent on self-regulation or 'soft' options
- Legitimacy deficit:
 - lack of transparency
 - lack of accountability
 - lack of consistency

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Ethical governance and the creation of the EGC

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
- Public engagement exercises showed support.

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

3. In practice: The EGC and its work

- Established in November 2004 (17 meetings)
- 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 (on-going recruitment)
- Meets 4 times a year and holds at least one public meeting per year

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Relationship with UK Biobank

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

Things the EGC 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 EGF and associate policies

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Reflecting the changes in the UK Biobank project

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

- Advisory: The EGF and associated policies/procedures
- Monitoring: Complaints and enquiries
- Foresight: Access procedures

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Privacy concerns: 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)

Privacy concerns: withdrawal from UK Biobank (2/2)

- “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. ...
- EGF and information leaflet revised
- New pages on UK Biobank and EGC website

Policy on the feedback of health information

Currently: limited feedback of measures taken during the assessment centre visit only. No feedback of subsequent findings.

Proposed new data collection re: MRIs needs to be considered in light of this policy - is the policy appropriate to the proposed new measures and questionnaires?

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Access and intellectual property: challenges

1. Who should have access, who decides and how?
2. How are scientific decisions taken which might require use of (depletable) samples?
3. What role might an Access Committee play? And what of an Ethics Council?
4. What IP policies or principles should guide use of the resource?
5. What might benefit sharing look like in practice?

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Core principles and the EGF

UK Biobank is a managed research resource for public good.

- Access is to be managed in order to:
 - Protect participants, honour commitments made to them and act within the scope of their consents;
 - Ensure compliance with legal and regulatory requirements
 - Prioritise access to those parts of the resource that are limited in availability (i.e. samples that are depletable);
 - Manage intellectual property rights in the resource and the results that flow from it.

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Core principles and the EGF

Subject to these constraints, UK Biobank will encourage and provide access to the resource and the results that flow from it as widely and openly as possible in order to maximise its use and value for research.

This will include access for researchers from the academic, commercial, charity and public sectors, both in the UK and overseas.

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Non-Access

Para 1.2.5:

No identifiable individual's test results will be provided to their doctors, their relatives or anyone else (e.g. employers or insurance companies). Nor will UK Biobank allow access to the resource by the police, security services or lawyers, unless forced to do so by the courts, and it will resist such access (in particular by seeking to be represented in all court applications).

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Benefit sharing

- UKB is managed for the public good
- Users to disseminate results as widely and rapidly as possible (with caveats)
- Encouraged to share findings and data as openly as possible
- Copy of all results to UKB, including negative findings for use by others (even if there is IP)

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Benefit sharing: do we expect too much?

Entitlement

- “Common Claim” (common heritage)
- “Giving Back” (commodity exchange)
- “Feeding Back” (obligation/incentivisation?)

Deficit

- Democratic
- Participatory
- Legitimacy

Justice

- Distributive: “Passing on”
- Retributive: “Profit Pay-Off”

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Benefit sharing as the *right* kind of governance?

Benefit sharing can take the form of a number of realities

Is there a necessary link between benefit sharing and good governance?

Governance must take many different forms to respond to many kinds of biobanks/benefits

Population-based studies for the *public good*

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Advising for the public good/public interest

- UK Biobank Ethics & Governance Framework:

“The Ethics and Governance Council will keep use of the resource under review in order to advise on conformance with this Framework and the IP and Access Policy, and to assure itself, and others, that the resource is being used in the *public interest*.”
- EGC Commissioned report on public interest and the public good (Capps, Campbell & ter Meulen 2008)

Advising for the public good/public interest

- EGC Living Document on “Advising on the public interest and the public good” (2008)

“Public interest may be seen as a system to which all, or a majority of, *reasonable* individuals would approve and which promotes accepted community values and goods while not leaving individuals disproportionately or irrevocably worse off.”

Advising for the public good/public interest

- EGC Living Document on “Advising on the public interest and the public good” (2008)

“Public interest should not be thought of as a conglomeration or amalgam of individual interests. If measured as a sum of opinion, it can lead to uncertainty, whims and “tyranny of the majority”. This has lessons for the value of public attitude surveys and the way they are used to inform advice and policy.”

Privacy and public attitudes

- Concerns about commercialisation
- Commissioned research on public attitudes to third party access (Webster et al, 2008):
 - Data security/anonymity
 - Ambivalence on police access policy
 - Heightened concerns about international access/transfer

EGC: An exercise in added value?

- An Ethics+ approach
- An exercise in *reflexive governance*
- Public engagement and public commitment
- Commissioning research
- EGC Review 2008 - future challenges:
 - Evolutionary nature of project
 - Responsive role/Pro-active role
 - The challenges of internationalisation

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EGC Public event: Thursday 12 February 2009,
The Royal Hotel, 10 St Mary Street, Cardiff, 6pm

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Website: www.egcukbiobank.org.uk