

UK Biobank Ethics and Governance Council

The UK Biobank Ethics and Governance Council

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

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1. The EGF and EGC

UK Biobank Ethics and Governance Framework:

- 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 to 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 protecting the confidentiality of both samples and data

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UK Biobank Ethics and Governance Framework (cont.):

- 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 requirements (including the obligatory publication of findings and accessible archiving of data and findings for future use)
- Describes the arrangements for management and accountability

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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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Ethical governance and the creation of the EGC

Why have an Ethics and Governance Council?

- 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 is not in Research Ethics Committee remit

An additional safeguard and a foundation of trust – the trusted third party or 'critical friend'.

2. In practice: The EGC 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
- 10 members
- Four Council meetings per year
- Subgroups on specific topics that meet as required

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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.

'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.' EGF III.A.2

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Recent headline issues

Finalising the access process and developing the EGC's 'oversight' role and responsibilities (in the light of experience and the increasing number of applications).

Responding to enhancements of the resource at UK Biobank and, in particular, engaging with issues of 'feedback' and 'incidental findings' (e.g. in relation to the imaging enhancement pilot).

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3. Reflections on 10 years of work

- Initially the EGC engaged primarily with its *advisory role* (e.g. commenting on draft participant materials and policies and procedures related to the EGF).
- Later the *monitoring role* was engaged (e.g. in relation to access, data security and follow-up).
- The EGC has been both *reactive* (e.g. responding to re-contact requests and proposals for enhancement) and *proactive* (e.g. reviewing feedback policies).
- It has moved away from giving specific advice and towards offering points for UK Biobank to consider when drawing-up its policies (recognising that there is a range of 'reasonable' approaches).

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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 (recognising that there will be both foreseen and unforeseen challenges).
- 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 of particular importance as a compliment to traditional research ethics committees which do not offer an active monitoring role.

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In conclusion (2 of 2)

- By acting as a 'critical friend' a body like the Council can promote and facilitate good governance and good science in the public interest.
- The EGC's focus and methods of working have changed over time and will no doubt continue to evolve (advisory vs. monitoring; reactive vs. proactive; specific advice/opinions vs. offering points for consideration).

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Past, present, future:
the ethics and governance
of big biobanks conference

UK Biobank
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3-5 November 2014
Wellcome Trust, 215 Euston Road, London NW1 2DB



Annual Review 2014

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