

Revision of the UK Biobank Ethics and Governance Framework: 'No further use' withdrawal option

Background

The ability to withdraw from participation is an important aspect of consent and is intimately linked with the broad nature of consent employed by UK Biobank. Three options for withdrawal are offered by UK Biobank and described in the Ethics and Governance Framework (EGF) and the participant information leaflet (PIL).

The July 2006 EGF described the 'No further use' withdrawal option as follows:

"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). Only some administrative details (such as their signed consent and withdrawal) would be kept as a record of their wishes. Such a withdrawal would prevent information about them from contributing to further analyses, but it would not be feasible to remove their data from analyses that had already been done." (emphasis added)

Revision of the EGF: Reasons and process

In June 2007 Professor Collins sought the Council's advice regarding the 'No further use' option of withdrawal. It had come to light that it is not possible for UK Biobank to destroy all of a participant's health-related information due to the project's back-up and audit system. Importantly, however, **UK Biobank can still guarantee the main principle behind this option i.e. that there will be no further use of the data by researchers.**

Following initial discussions the Council requested and received a briefing note from UK Biobank describing in detail the technical problem surrounding the withdrawal of data from the resource. The Council subsequently recommended that UK Biobank consider at least the following four matters:

- i. Reiterating the absolute guarantee of no further use on withdrawal (as the main principle)
- ii. Amending the EGF and PIL to reflect the new reality
- iii. Explaining which (additional) technical measures will be in place to protect such persons' privacy
- iv. Explain whether and how UK Biobank will inform existing participants, e.g. via website.

In addition, the Council proposed some revised text to appear in the EGF and PIL and recommended that a note appear on the project's website informing readers of the reasons for this revision.

These recommendations were conveyed to UK Biobank by email and followed-up with a phone call between the Council Chair and UK Biobank's Chief Executive.

Outcomes

The Council considers that the fundamental guarantee described in the July 2006 Ethics and Governance Framework is that there will be no further use of the data by researchers. This guarantee has not changed. The following actions were taken and considered to be a proportionate response to the situation:

1. The EGF was revised accordingly and now the PIL reads:

'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.** Your signed consent and withdrawal would be kept as a record of your wishes. Such a withdrawal would prevent information about you from contributing to further analyses, but it would not be possible to remove your data from analyses that had already been done." (emphasis added)

2. Additional text was also inserted into the EGF as follows:

"(N.B. UK Biobank is completely committed to ensuring that participants are informed about important developments with the project. One such development to emerge during the establishment of the IT systems is that, although data from participants who choose the 'No further use' withdrawal option can be made unusable, it is not possible to destroy it completely. This is due to the development of complex IT systems designed to protect the integrity and security of the data.)"

3. UK Biobank's Systems Architect attended the following Council meeting to introduce the project's Information Technology and Data Management Strategy and to describe the technical and physical procedures involved when a participant withdraws from the project.