

The Ethics and Governance Council's Oversight in Relation to UK Biobank's Administration of the Access Process

Context

In Spring 2012, UK Biobank opened its resource to researchers. Since that time, the Ethics and Governance Council (the EGC) has exercised its oversight responsibilities with regard to access to the resource in three principal ways: first, it has made extensive use of the Level B 'real-time' access that it has to applications; secondly, it has received quarterly reports from UK Biobank with regard to the top-line figures – in particular, the number of registrations and applications, whether applicants and applications come from the academic or commercial sector, whether they come from the UK or from overseas, and so on; and, thirdly, in accordance with the requirements of the Ethics and Governance Framework, the EGC has commented on applications that request re-contact with participants.

Given this experience, both UK Biobank and the EGC now have a much clearer idea of the kinds of ethics and governance issues to which applications might give rise as well as the numbers of applications that are problematic in this respect. Thus far, it seems that many applications do not raise any significant ethics or governance issues; these are applications that are now regarded as relatively 'routine'. However, there are some applications that give rise to issues that were anticipated and that need to be addressed by the EGC (for example, concerning re-contact) as well as applications that raise novel ethics or governance issues and that need to be given careful consideration by both UK Biobank and the EGC.

In this context, it is agreed that the time is right to modify the way that the EGC exercises its oversight. In place of the current arrangements, it is agreed that the EGC's oversight should be operated in accordance with a three-stranded model that brings together elements of alert, report, and audit.

Guiding Principles

The elaboration of the three-stranded oversight model is guided by the following principles:

- **Robustness:** given the EGC's responsibility to ensure that access decisions are made in a way that respects both the interests of participants and the larger public interest, the arrangements for its oversight must be sufficiently robust to enable it to discharge this function and to do so in a way that maintains the confidence of all stakeholders in UK Biobank.
- **Transparency:** as a corollary of the requirement of robustness, the EGC must always have the right to inspect any aspect of the access process.
- **Workability and proportionality:** given that applications need to be processed expeditiously, the arrangements for oversight should make only such demands of UK Biobank as are reasonable and proportionate.

- Efficiency: for both UK Biobank and the EGC, it is important that limited resources are used in the most efficient way; ideally, this means that time and attention should be focused on those applications that raise difficulties, rather than those that are straightforward.

The Three-Stranded Model

The agreed oversight model has three principal elements: Alert (by UK Biobank to the EGC); Report (by UK Biobank to the EGC); and Audit (by a third party, for the EGC, and to be shared and discussed with UK Biobank).

ALERT

The principal feature of alert is that UK Biobank will assume responsibility for alerting the EGC to applications that raise ethics or governance issues that merit the Council's attention. Under this arrangement, the EGC will rely on UK Biobank to advise it that a significant application is in the system. An application will be significant where it involves:

- a request for re-contact; or
- a novel and/or important ethical issue; or
- a novel and/or important governance issue; or
- making a decision that will set a major precedent; or
- some other matter that, in the judgment of UK Biobank, merits the attention of the EGC.

In such cases, UK Biobank should alert the EGC at the earliest opportunity. If in doubt about the significance of an application, UK Biobank should err on the side of caution and alert the EGC.

When UK Biobank alerts the EGC, along with the alert, it should send the EGC a copy of the full application (or enable electronic access to the full application).

Initially, the question of when and how the EGC should respond to an alert will need to be resolved case-by-case. In some cases, UK Biobank will expressly invite the EGC to respond within a particular time-scale; in other cases, the EGC might set its own time-frame for responding; and, in some cases, the best way to proceed might be by discussion in a small joint working group (drawing on both UK Biobank and the EGC).

REPORT

UK Biobank should report on the access process at each quarterly meeting of the EGC.

The report should include the following:

- the usual top-line figures; and
- the Access Sub-Committee Minutes and Record of Decisions; and
- details of applications that, even if not ‘significant’ (in the sense that they will have been the subject of an alert), are in any way ‘salient’; and
- details of applications that have been rejected.

AUDIT

Within a reasonable time after the new system has been in operation, an audit should be conducted to check that UK Biobank is dealing with access applications in accordance with the spirit and letter of this oversight arrangement.

Thereafter, unless an audit recommends otherwise, audits should take place every three years.

The EGC would commission the audit and have input into the terms and conduct of the audit; but the auditors will be drawn from outside the EGC. The audit report would be envisaged as being prepared for the EGC, then to be shared and discussed with UK Biobank.

Commencement

It is agreed that the new oversight model should be put into practice as from January 1, 2015.