



UK Biobank's Ethics Advisory Committee (EAC)

The independent Ethics and Governance Council (EGC) has made a considerable contribution to the UK Biobank resource since its establishment in 2007. In the intervening years, UK Biobank has developed at a considerable pace and, as a consequence, the EGC has recommended that its oversight role would be more effectively discharged by better integration within UK Biobank as an advisory committee of the UK Biobank Board. This recommendation has been accepted by the Funders and by the UK Biobank Board.

The remit of this Ethics Advisory Committee (EAC) shall be to provide advice to the Board on ethical issues that arise during the maintenance, development and use of the UK Biobank resource, including:

- *identifying, defining and examining relevant ethical issues:*
- *providing advice, guidance and recommendations on relevant ethical issues; and*
- *reviewing and advising on policies which have an ethical dimension that is relevant to UK Biobank.*

In terms of communication and engagement with participants, UK Biobank sends them newsletters annually (as well as providing additional communications related to specific matters) and organises local meetings around the country with groups of participants. The role of the EAC will include advising UK Biobank on its engagement and communication strategy.

With respect to the governance of UK Biobank, as it relates to the management and operation of the project, this is a matter for the Board of UK Biobank (whose members are also charitable trustees). The principal funders of UK Biobank (The Wellcome Trust and Medical Research Council) shall review the current reporting structures, and put in place any necessary additional processes, to ensure that the Board functions effectively and is properly accountable for the conduct of UK Biobank.

Terms of Reference

1. Membership

- 1.1 The Chair of the EAC shall be a member of the UK Biobank Board. The composition of the EAC shall be up to 3 Board members (including the Chair) and up to 3 external members. All of the members shall be independent of the day-to-day management of UK Biobank.
- 1.2 Members of the EAC shall be selected and appointed by the Board after consultation with the funders. EAC members shall between them have relevant expertise in epidemiology and biobanking, bioethics and public policy, and community engagement and communications
- 1.3 Only members of the EAC and the Secretary (with representatives of the principal funders as observers) have the right to attend its meetings. Other members of the UK Biobank Executive Management Team (EMT) and others (such as external ethics or scientific experts) may be invited to attend meetings on a recurring or one-off basis.
- 1.4 Appointments to the EAC shall be for a period of up to 3 years. Members of the EAC may serve a second term of up to 3 years and (exceptionally) a third term of up to 3 years, provided the member still meets the criteria for membership of the EAC.

2. Remit

- 2.1 The general remit of the ESC is to advise and make recommendations to the Board and the Access Sub-Committee (ASC) on ethics issues which relate to the development, maintenance, and use of the UK Biobank resource, particularly as such issues may impact on the participants.
- 2.2 This remit will include:
 - 2.2.1 identifying, defining and examining relevant ethical issues;
 - 2.2.2 providing advice, guidance and recommendations on relevant ethical issues;
 - 2.2.3 reviewing and advising on policies which have a relevant ethical dimension; and
 - 2.2.4 advice in relation to communication and participant engagement.
- 2.3 Matters which may be considered by the EAC can either be:
 - 2.3.1 matters which the EAC determines that they wish to review, and/or
 - 2.3.2 matters which the Board, ASC or EMT specifically asks the EAC to reviewwhich may have an impact on UK Biobank or its participants.
- 2.4 The Board is ultimately responsible for ensuring that all UK Biobank policies and activities conform to the EGF and is responsible for its review and revision. Specific items which fall under the remit of the EAC include providing advice on:
 - 2.4.1 the activities of UK Biobank as they relate to, and conform with, the participants' consent and the Ethics and Governance Framework (EGF);
 - 2.4.2 policies developed by UK Biobank, including on access to data and samples and on re-contact of participants;

- 2.4.3 updates to the EGF that may be required (in light of UK Biobank's actual and activities), and the way in which such updates are communicated to participants;
 - 2.4.4 the ethical implications of developments in science or technology, and changes in the regulatory, social or legal framework as they may relate to UK Biobank; and
 - 2.4.5 engagement with participants, and on the proposed engagements themselves.
- 2.5 In order to ensure that there is no overlap with the working of other internal and external committees, there are certain items which fall outside the remit of the EAC, such as:
- 2.5.1 the North West Research Ethics Committee (REC), which is the responsible REC for UK Biobank (although the EAC is entitled to review a determination of the REC and to seek advice through the UK Biobank PI from the REC); and/or
 - 2.5.2 review of individual access applications (which is the role of the ASC) unless either asked to do so by the ASC or where the EAC considers that a clear and important ethical or legal issue is at stake in relation to a particular application.

3. **Secretary**

The Board Secretary, or the Assistant Secretary, shall act as the secretary of the EAC and is responsible for ensuring that it receives relevant information and papers in a timely manner to enable full and proper consideration to be given to issues.

4. **Quorum**

The quorum necessary for the transaction of business shall be 3. A duly convened meeting of the EAC at which a quorum is present shall be competent to exercise all or any of the authorities, powers and discretions vested in or exercisable by the EAC. Meetings may be held by remote means.

5. **Frequency of meetings**

- 5.1 The EAC shall meet at least twice a year and, depending on the amount of business (which shall be determined by the Chair of the EAC), up to quarterly. Ad hoc meetings may be called by the EAC Chair in response to a request from the Board for advice on a specific issue. In general, the EAC will aim to meet a reasonable period of time before the next upcoming Board meeting to enable it to provide a contemporaneous report to the Board.
- 5.2 Outside the formal meeting programme, the EAC Chair will maintain a dialogue with key individuals involved in the determination of UK Biobank's ethical issues, including the Board Chair, the Chief Executive/Principal Investigator, the Chair of the ASC, and representatives of the funders.

6. **Notice of meetings**

- 6.1 Meetings of the EAC shall be called by the Chair of the EAC in consultation with the Secretary and/or at the request of any of its members.
- 6.2 Unless otherwise agreed, notice of each meeting confirming the venue, time and date, together with an agenda of items to be discussed and supporting papers, shall be forwarded to each member of the EAC no later than 5 working days before the date of the meeting. The meeting schedule will be agreed, as far as possible, on an advance rolling 12-month basis.

7. Minutes of meetings

7.1 The Secretary, the Assistant Secretary or his nominee, shall minute the proceedings, including recording the names of those present and in attendance.

7.2 Once approved by the EAC, minutes shall be distributed to the Board in the relevant circulation for its next meeting.

8. Other matters

8.1 The EAC shall:

8.1.1 have access to sufficient resources in order to carry out its duties, including access to the company secretariat for assistance as required;

8.1.2 give due consideration to laws and regulations relevant to UK Biobank;

8.1.3 liaise, as necessary, with other Board committees (in particular, the ASC) and, if requested, work with the PI and/or the EMT on a particular issue; and

8.1.4 members will be reimbursed for all reasonable costs for attending meetings.

8.2 EAC members shall comply with the UK Biobank group policy on Conflicts of Interest.

9. Resources Available

9.1 The EAC is authorised by the Board to:

9.1.1 obtain, at UK Biobank's expense, such reasonable external ethics, legal or other advice on matters as it may reasonably see fit within its terms of reference;

9.1.2 subject to agreement in advance with the EMT, PI and/or the Board (as appropriate), commission specific research on topics relevant to its remit;

9.1.3 seek any information it reasonably requires from any employee of the company in order to perform its duties; and

9.1.4 request any employee of the company to attend a meeting of the EAC to address such questions as may be reasonably required.