

## **Responsibilities and Procedures for Ethical Review**

### **Introduction**

1. Ethical requirements arise from an evolving understanding of the rights and duties of human beings. Ethics are broader than law, though the law can both reflect and clarify ethical duties. Birkbeck staff and students are expected to exercise ethical principles of honesty, rigour, transparency, care and respect in relation to all their activities, including the planning and conduct of research.
2. All activities carried out by Birkbeck staff and students that involve one or more of:
  - intervention or interaction with human participants;
  - the collection and / or study of data derived from human participants;
  - a potential impact on animals or the environment;require ethical consideration and approval.
3. Schools are responsible for ensuring that all research and all teaching exercises carried out under their auspices are consistent with established ethical principles and that projects have obtained ethical approval before they start. To that end, all Schools must:
  - have a School Ethics Committee to consider research ethics proposals and other ethical issues as they arise and make an annual report to the College Ethics Committee
  - appoint Departmental Research Ethics Officers (DREO) from among the academic staff, whose role is to advise on their Department colleagues on the ethical aspects of research proposals, and normally to be members of School Ethics Committees (the full role of the DREO is given at Annex A).
4. The College Ethics Committee has responsibility for developing policy and defining good practice for research ethics proposal and review; and research integrity and good conduct. It considers and approves the School Ethics Committees' annual reports, as well as individual research proposals where College consideration is required, either by the ethical issues raised in the proposal or by an external agency.
5. All staff and students at Birkbeck must apply the ethical procedures and principles outlined in this document when conducting or supervising research or projects. There are further ethical guidelines at Annexes F and G.

### **The process of research ethics proposal and review**

6. Individual staff members in the first instance are responsible for ensuring that appropriate ethical assessment is conducted for their research and the research for those whom they supervise. Staff members who lead research projects must ensure

that full records are kept of proposals and their assessment. For any research proposal which has ethical implications, the researcher must complete the Proposal Form for Ethical Review (Annex B). Students and Research Assistants undertaking research projects, advised by their supervisors as appropriate, should also complete the form, with a supervisor countersigning. The appropriate DREO should be consulted if there is any doubt over whether a proposal has ethical implications. Please see Annex F Guidelines on research with ethical implications.

- 7 The Proposal Form for Ethical Review and supporting documentation should be submitted to the DREO as early as possible before the intended start date of the project.
- 8 The DREO will review each Proposal Form. The DREO will pass proposals for research to be funded by the ESRC to a DREO from a different department (the alternate DREO) for initial review. If the alternate DREO considers that the project carries more than a minimal risk of harm to research participants, researchers or the institution, the proposal will be referred to the College Ethics Committee for evaluation. The ESRC's guidance on what would normally be considered more than minimal risk is given as Annex G.
- 9 For research not funded by the ESRC; and for ESRC funded research classified by the alternate DREO as not carrying more than a minimal risk of harm; the home department DREO will determine whether the proposal is routine or non-routine.

**Routine:** This includes research projects which so closely follow previous research already given ethical approval within the last 3-5 years<sup>1</sup> that the ethical issues are identical, and projects that have less than minimal potential risk of harm to participants and others affected by the proposed research.

**Non-routine:** Research which has not previously been scrutinised by the School Ethics Committee and which cannot be classified as Routine. This also includes circumstances where:

- participants are to be subjected to questions, or other procedures which carry beyond a minimal risk of being harmful to their physical or mental well being
- participants may not have the capacity to give informed consent, for example children and vulnerable populations
- specific advice is needed on the nature of ethical issues and their resolution
- unresolved ethical issues become apparent during peer review or assessment of compliance with the ethical principles outlined in this document
- research involves groups where permission of a gatekeeper is normally required for initial access to members
- research might appear to involve deception, or is conducted without participants' full and informed consent at the time when the study is carried out
- research involving access to personal information or confidential information on identifiable living individuals

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<sup>1</sup> The exact time frame to be decided by each School Ethics Committee, based on what is appropriate for its academic discipline.

- all cases of predictable media interest or sensitivity
- all cases where there is a conflict of interest
- an external agency requires certification of ethical approval

10 The DREO's review will result in one of the following outcomes:

- Rejection of the proposal on ethical grounds. This would only occur if there were fundamental ethical issues with the research, as defined in this policy and by professional ethical guidelines.
- Referral back to the proposer for clarification or amendment to address ethical concerns. It is the responsibility of the proposer to make any recommended changes and re-submit the proposal form together with supporting documentation.
- Identification of the proposal as non-routine, in which case it should be referred to the School Ethics Committee (SEC).
- Approval of a routine proposal. Routine projects need not be submitted to the SEC, but the proposal form should be signed off by the DREO.

11 All non-routine research proposals; and any proposals where it is unclear whether the proposal is routine; should be submitted to the SEC for approval prior to commencement.

12 Projects that were reviewed between more than 3 - 5 years ago<sup>1</sup> should be re-submitted for review to ensure that ethical approval remains valid.

13 SEC review of proposals will result in one of the following outcomes:

- Rejection of the proposal on ethical grounds. This would only occur if there were fundamental ethical issues with the research, as defined in this policy and by professional ethical guidelines.
- Referral back to the proposer for amendment to address ethical concerns. It is the responsibility of the proposer to make any recommended changes and re-submit the proposal form together with supporting documentation.
- Approval of the proposal.
- Referral to the College Research Ethics Committee (CEC) in the following circumstances:
  - Where there is a doubt or disagreement which cannot be resolved at School level
  - Where guidance or advice is required
  - Where an external funding body requires certification at the institutional level. Note that this includes all non-routine ESRC-funded projects

#### NHS and related research

14 Research involving human tissues and DNA samples, NHS patients, facilities and staff is subject to rigorous ethical approval through the NHS Research Ethics Committees. Proposals being made to NHS research ethics committees need not go through Birkbeck's procedures as well, unless this is required for NHS clearance, but correspondence relating to the proposals must be copied to the relevant DREO

and confirmation of NHS approval reported to the relevant SEC.

### **Appeals and complaints**

- 15 Appeals against decisions made under these procedures must be based on one or more of the following criteria:
  - A failure to follow these procedures;
  - There is additional information that was not available at the time when the decision was made;
- 16 Appeals against decisions of DREOs will be considered by the Chair of the SEC unless the relevant DREO is the Chair of the SEC, in which case the appeal will be considered by an alternate DREO. The outcome will be reported to the next meeting of the SEC.
- 17 Appeals against decisions of SECs will be considered by the Chair of the College Ethics Committee, in consultation with the independent member of the CEC, and their decision shall be final. The outcome will be reported to the next meeting of the CEC. The Chair may at his or her discretion refer the appeal to the CEC for consideration, at a meeting or through correspondence.
- 18 This document is approved and kept under review by the College Ethics Committee.

College Ethics Committee  
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