

Responsibilities and Procedures for Ethical Review

This document should be read in conjunction with the Colleges research integrity code of practice and ethical framework

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, openness, care and respect in relation to all their activities, including the planning and conduct of research.

All researchers are expected to observe the highest ethical standards and to embed good practice in every aspect of their work. This includes the interpretation and presentation of research results, contributions to the peer review process and the training of new researchers, staff and students as well as the conduct of the research itself. That is, individual actions must comply with the principles of honesty, openness, transparency, respect and research rigour.

The spectrum of inappropriate ethical behaviour is wide, ranging from minor misdemeanours which may happen occasionally and inadvertently, to deliberate acts. Inappropriate ethical behaviour tends to arise from a failure to consider and observe the duty of care implicit in the ethical principles listed above – i.e. inappropriate ethical behaviour arises from a deliberate, careless or unintentional lack of honesty, rigour, transparency, care or respect.

Ethical review is based on the principles of competence, facilitation, independence, and openness.

- 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;
 - a potential risk of significant reputational damage to the College
 - requiring an individual to step outside accepted regulatory or legal norms

require ethical consideration and approval.

- 3 Schools are responsible for ensuring that all research, teaching and 3rd mission, (outreach, community engagement, widening participation, knowledge exchange and translation, public engagement etc.), exercises carried out under their auspices are consistent with established ethical principles and that projects have obtained appropriate 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 their Department colleagues on the ethical aspects of teaching exercises and research proposals, and are normally to be members of School Ethics Committees.

The standard School Ethics Committee Terms of Reference are given at <http://www.bbk.ac.uk/committees/research-integrity/> .

However, the College recognises that Schools may need some autonomy to develop bespoke solutions for their areas. Any necessary local amendments to the terms of reference should be submitted in writing to the CEC for the CEC to approve and these changes should be reviewed as part of the periodic review of research ethics provision across the College.

- 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 <http://www.bbk.ac.uk/committees/research-integrity/> .

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 which has ethical implications, the researcher must complete the Proposal Form for Ethical Review. Students (both undergraduate and postgraduate) and Research Assistants (both employed by the College and not employed by the College) undertaking research projects, advised by their supervisors as appropriate, should also complete the form, with a supervisor countersigning. All research should be considered from the perspective that it may have ethical implications and the DREO should be consulted if there is any doubt.

It should be noted that some funders of research require ethical review as a condition of funding, and it is the responsibility of the lead investigator to ensure this happens

- 7 Any research where ethical issues have been identified can be considered to be either sensitive, extremely sensitive or in line with normal disciplinary practice (i.e. routine).

The most commonly encountered sensitive and extremely sensitive issues in research projects are;

Sensitive:

- a research methodology which raises ethical questions but which has not been previously considered by the appropriate Ethics Committee
- a research methodology where participants are to be subjected to questions, or other procedures which carry a risk of being harmful to their physical or mental well being
- the research requires data from a set of participants who may not have the capacity to give informed consent, for example children and vulnerable populations
- the research involves groups where permission of a gatekeeper is normally required for initial access to members
- Projects where there is a risk to the safety of the researcher
- Projects which involve international partners
- Research where data is drawn from social media or participants are recruited over the internet

Extremely Sensitive:

- the research involves (or might appear to involve) deception, or is conducted without participants' full and informed consent at the time when the study is carried out
- the research involves access to personal information or confidential information on identifiable living individuals *or* the research combines existing datasets in a way where anonymised individuals might become identifiable
 - **** note this point *does not* relate to all human participant research, just human participant research where there is a real risk that anonymity cannot be protected ****
- all cases where the subjects of the research are members of the College (staff or students) or are closely related to members of the College
- all cases of predictable media interest or sensitivity
- all cases where there is a conflict of interest
- all cases where the veracity of source material cannot be readily checked (e.g. material from anonymous sources)
- all cases where there is a significant risk of reputational damage to the College (which includes a consideration of the source of funding for the research)
- all cases where the research team is undertaking security sensitive research. Security sensitive research includes research commissioned by the military or under an EU security call, research that requires the researchers to obtain security clearance or research into terrorist or extremist groups
- all cases where the research team need to access illegal or extreme materials. NB in this case, the phrase extreme materials refers to materials (such as extreme violence/pornography or materials which promote extreme political or religious views) which are not in themselves illegal but may be related to, or closely aligned to, illegal behaviours

It should be noted that this is not an exhaustive list and all proposals should be

considered from the perspective that they may be sensitive or extremely sensitive rather than from the presumption that the research is in line with normal disciplinary practice.

Research in line with normal disciplinary practice (Routine):

- research projects which so closely follow previous research already given ethical approval within the last 3-5 years¹ that the ethical issues are identical and have already been considered
- projects that have less than minimal potential risk of harm to participants and others affected by the proposed research and this risk can be mitigated by following best practice already established within the discipline

Please <http://www.bbk.ac.uk/committees/research-integrity/> for further Guidelines on research with ethical implications.

- 8 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.

The College does not normally expect that ethical review will be undertaken before a research proposal is submitted for funding; however, the research team should fully consider the ethical implications of their research and should honestly and truthfully answer any questions about ethics which are included as part of the application. The research team can submit the concept for ethical review prior to submission if they wish – this might be appropriate, for example, if the ethical aspects of the proposal are quite complex and the research team would value input from the relevant SEC.

- 9 The DREO will review each Proposal Form against a checklist which has been agreed by the College Ethics Committee to be appropriate for the individual department.

If the research is considered to be sensitive the DREO will refer it to the School Ethics Committee in the first instance.

If the research is considered to be extremely sensitive, the DREO will immediately refer it to the College Ethics Committee and will communicate to the applicant the additional information which will need to be provided to the College Ethics Committee (as described in paragraph 13).

If the research is in line with normal disciplinary practice The DREO can approve the application.

Some projects will be basically routine but will have elements which fall into the sensitive or extremely sensitive categories. These projects must be referred to the relevant committee based on the sensitive/extremely sensitive classification to part of the work. Nothing which has elements of extremely sensitive research can be

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

classified as routine.

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 sensitive or extremely sensitive, in which case it should be referred to the School Ethics Committee (SEC) or College Ethics Committee (CEC) as appropriate.
- 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 and passed to the SEC for note. The members of the SEC should review a selection of these proposals periodically to ensure consistent practice across their Schools; similarly, the CEC should review a selection of these proposals periodically to ensure consistency across the College. It should be noted that this is an area where the volume of applications may lead to necessary changes in local practice and these local changes should be approved as described in paragraph 4. CEC should consider both the volume of applications and how strictly the classifications of routine and non-routine are interpreted when approving such local practices.

11 All sensitive and extremely sensitive research proposals; and any proposals where it is unclear (for example, this may be because the DREO feels that specific advice is needed on the nature of ethical issues and their resolution or because unresolved ethical issues have become apparent during peer review or assessment of compliance with the ethical principles outlined in this document) should be submitted to the SEC or CEC for approval prior to commencement.

Normally the review process should be completed within 6 weeks, however mechanisms for expedited review by both the School Ethics Committee and the College Ethics Committee are available if necessary (as described below) and it should be noted that in complex cases more time may be required.

12 Review of proposals by SEC or CEC should ideally take place at a standing meeting with the timetable of these meetings being readily available to all researchers. These meetings should take place monthly if there are proposals to review. There must be at least one physical meeting of the committee per term.

However, there may be cases where it is necessary to review proposals outside this timeframe, in which case the chair can seek advice in writing from all members of the committee and take a decision through Chairs Action on the basis of the advice received. If, however, substantive ethical issues are identified it may not be possible to assess the proposal fully by this mechanism and the decision should wait until the next full meeting of the committee

13 If an extremely sensitive proposal is sent to CEC for review then CEC will also require the following additional information:

- A detailed data management plan
- A written statement from the Research Data Support Manager to confirm that he has discussed the data issues relating to this particular piece of research with the lead researcher and is confident that the data management process described in the data management plan is fit for purpose
- If appropriate, a copy of any advice received from a legal advisor, regulatory body or professional body. Evidence that legal advice has been sought will be mandatory for anyone wishing to undertake security sensitive research or research which needs to access illegal materials. Ethical approval will not be given without this evidence.

Any researcher considering undertaking research which could be classified as extremely sensitive is strongly encouraged to discuss their research concept with the Chair of the CEC prior to the commencement of the project to ensure that the researcher is fully informed about the issues and is made aware of the sources of advice available.

14 Projects that were reviewed between more than 3 - 5 years ago¹ should be re-submitted to the SEC for review to ensure that ethical approval remains valid.

15 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 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
 - Where the SEC judges that the proposal has been misclassified as sensitive and should be re-classified as extremely sensitive

16 CEC 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.

- 17 All research projects with ethical considerations should consider if a formal re-review of their ethical approval is necessary as the research progresses and evolves. Suitable intervals for this review should be specified at the time of the initial review and should be appropriate for the nature of the research being undertaken. This information can be recorded within the data management plan.
- 18 Each SEC should review the ethics processes and decisions of one of their departments annually and this review should be reported to CEC as part of the annual review process. Oversight of CEC is maintained by the Governors, who receive an annual report about the Committee through the Audit Committee oversight process.

Research regulated by external bodies (e.g. NHS and related research)

- 19 Research which would normally be regulated by an external body need not go through Birkbeck's procedures as well, unless this is required by the external body. For example, research involving NHS patients, facilities and staff is subject to rigorous ethical approval through the NHS Research Ethics Committees. However, correspondence relating to the proposals must be copied to the relevant DREO and confirmation of external approval reported to the relevant SEC.

Studies that require review under the HRA Governance Arrangements for Research Ethics Committees (e.g. human clinical trials or research involving human tissue), other health or social care research or research involving animal subjects may have specific requirements. It is the responsibility of the lead investigator to investigate this but advice can be sought from the DREO where appropriate.

Collaborative Research Projects

- 20 Research projects which collaborate with other HEIs would normally only be subject to ethical review by the lead HEI. If the College is the lead HEI it is the responsibility of the lead investigator to inform our partner HEIs about our ethics process, the outcome of our ethical review and the outcomes of any periodic ethical reviews undertaken as the research progresses. If the College is a partner on a research project, it is the responsibility of the lead researcher from the College to pass information about ethical reviews from the lead institution to the Chair of the SEC to note. Similarly, projects across more than one Department or School in the College should be submitted only to the most appropriate DREO (which should be decided based on a consideration of the research to be undertaken and may not be a DREO from any of the departments represented in the specific project).
- 21 Research which involves international external partners (including research using social media which may involve international participants) can be more complex from an ethical perspective. The College would normally expect these proposals to be reviewed by the SEC in the first instance.

The process of ethics review for activities other than research projects

- 22 Research is not the only activity undertaken by members of the College which raises

ethical questions and would benefit from a process of ethical review. Any member of the College involved in working with members of the public (through public engagement, impact and outreach activities) or other external stakeholders should consider the ethical ramifications of this work, using the framework defined in this document as a guide. Further advice can be obtained from the Chair of their School Ethics Committee, the Departmental Ethics Officer, the Chair of the College Ethics Committee or the Head of Research Strategy Support. If a full review and authorisation process is felt to be necessary, the review will follow the principles defined in this document as closely as possible.

Conflicts of Interest

- 23 Any individual involved in any ethical review for the College is expected to declare any conflicts of interest immediately – the DREO and a member of the SEC to the Chair of the SEC (or CEC if the SEC Chair has the conflict). Anyone with a conflict of interest with the proposal under consideration should not be involved in the approval process for that application. If the conflict is with the DREO then the application will be considered by the SEC automatically. If the conflict is with a member of the SEC or CEC then they should excuse themselves from the discussions. The SEC or CEC may choose to call in a discipline-specific advisor in this situation.

Appeals and complaints

- 24 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;
- 25 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.
- 26 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.
- 27 Appeals against decisions of CEC will be considered by the Master of the College or his nominee. Advice will be sought from disciplinary experts (from within or outside the College) as appropriate
- 28 Any participant in a research project from the College who has questions or concerns about the conduct of the research, or who wishes to raise a complaint about how the research has been conducted should follow the procedure described in Procedure for Reporting and Investigating Research Misconduct which can be

found (<http://www.bbk.ac.uk/committees/research-integrity/Research%20misconduct%20procedures%20V11%20after%20CEC%2022%2011.pdf>)

29 This document is approved and kept under review by the College Ethics Committee.

College Ethics Committee
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