

Responsibilities and Procedures for Ethical Review and the Role of the School Ethics Committees

1. The Context

The School Ethics Committee has responsibility to ensure that all research and all teaching exercises carried out under the auspices of the School are consistent with established ethical principles. 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. School staff are part of a changing social system. They are, therefore, required not only to abide by ethical principles such as justice, truthfulness, confidentiality and respect for persons, but also to attend to the evolving understanding of how these principles are expressed in society at a particular time.

2. The School Ethics Committee

The School Ethics Committee shall consist of at least three members – two (or more) appointed annually from the academic staff reflecting the character of the School, and one member appointed annually from outside the School. One of the School's members will also act as School Research Ethics Officer and will Chair the Committee.

The role of the School Research Ethics Officer is given at Annex A.

The remit of the School Ethics Committee is to:

- €# To review projects on the grounds of ethical acceptability and to approve or reject them or refer them to the College Research Ethics Committee where necessary and appropriate
- €# To promote and communicate within the School ethical principles and guidelines
- €# To promote education on matters concerning ethics and ethical issues
- €# To give advice on ethics and ethical issues, matters and procedures
- €# To engage from time to time in any other matters concerning ethics or ethical issues

When necessary the School Ethics Committee shall call upon any person with proper expertise to assist them in their decisions. All members of the School Ethics Committee shall observe the proper conventions regarding confidentiality of information submitted to the Committee.

The School Ethics Committee is answerable to the College Research Ethics Committee (CREC). The School Ethics Committee will ensure that full records are kept of their assessment of ethical proposals.

3. Criteria of Acceptability

There are not, and possibly cannot be, a completely firm set of criteria for classifying research as ethically acceptable. This situation is reflected in, for example, the British Psychological Society's *Ethical Principles for Conducting Research with Human*

Participants and the Social Research Association's *Ethical Guidelines*. The Schools Ethics Committee would work towards ensuring a balance between the need to safeguard the participants and researchers and a workable set of ethical procedures. Where necessary in applying these procedures the School Ethics Committee and researchers must take account of the law as it applies to health and safety, data protection, and the protection of participants, together with the notion of "reasonableness" against threats to the well being of participants.

4. *Applying Ethical Principles*

Ethical principles must be applied to the following activities:

- ⊘ any *teaching* which involves the participation of humans for the demonstration of procedures, tests or other phenomena;
- ⊘ any research which requires the participation of humans. In this context participation covers a range of possibilities.

In planning and conducting specific research, teaching, and carrying out procedures the teacher or researcher should ensure that the risk of physical or psychological harm to participants is minimised by:

- ⊘ detailed analysis of specific risks for any given procedure
- ⊘ careful consideration of a variety of alternative procedures
- ⊘ provision of appropriate monitoring and support procedures both during and after the activities

Before commencing any activities involving the participation of human subjects the teacher or researcher should consider whose consent it is necessary and appropriate to seek. Such consent must be informed. This is achieved by providing the intended participant with a comprehensible explanation of:

- ⊘ possible hazards of the activities
- ⊘ the right to decline participation
- ⊘ the right to withdraw from the activity at any time
- ⊘ the right to have privacy and confidentiality protected
- ⊘ the right to turn off a recording device at any time
- ⊘ the right to ask questions at any time
- ⊘ the right to receive information about the outcome of the activity in an appropriate form

Informed Consent is *usually* obtained in writing from participants after they have been given information about the research and have time to consider the implications of

granting consent. In all cases researchers should take care to ensure that participants are fully informed about the research and have given informed consent freely. (See Annex B for further details).

5. Procedure for ethical review, referral to School Ethics Committee and staff responsibilities

All teachers and researchers are obliged to apply the ethical principles outlined in this document when conducting or supervising research or projects that involve human participants. Annex B provides further ethical guidance on this.

Any person wishing to conduct research that involves human participants needs to comply with School Ethics policy. This is so no matter where the investigations are carried out or whether ethical approval has been given by some other institution, for example, the NHS.

Staff members in the first instance are responsible for assessing the ethical status of their research and the research for those whom they supervise, with reference to peers and appropriate ethical and professional codes. Staff must ensure that full records are kept of their assessment and they should complete a standard School 'Proposal Form for Ethical Review', an example of which is given at Annex C. Each project or piece of new research should be classified into one of two categories, as below:

1. 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 are potentially harmful to their physical or mental well being
- ⚡ specific advice is needed on the nature of ethical problems and their solution
- ⚡ during peer review or complying with the ethical principles outlined in this document unresolved ethical issues are apparent
- ⚡ vulnerable populations are involved
- ⚡ an external agency requires certification of ethical approval

All non-routine research should be submitted to the School Ethics Committee for approval prior to commencement.

2. Routine: Research projects which so closely follow previous research already given ethical approval that the ethical issues are identical. Such projects need not be submitted to the School Ethics Committee, but should be reviewed and signed-off by the School Research Ethics Officer. However, where the previous research was referred to the College Research Ethics Committee (CREC), the new project should be considered anew and as a whole by the School Ethics Committee.

Where there is any doubt about whether a proposal is routine or new, then the proposal should be considered anew by the School Ethics Committee.

The Proposal form and supporting documentation should be submitted to the School Research Ethics Officer as early as possible before the intended start date of the project,

this is of particular importance where the nature of the proposal requires a referral to the CREC (see para. 6). All Proposal forms for student or research assistants' projects must be counter-signed by the supervisor(s).

The School Ethics Committee will then review all non-routine Proposal Forms submitted, and approve or reject them or refer them to CREC where appropriate.

6. Criteria for referral to the College Research Ethics Committee

In the following cases the School Ethics Committee will refer ethical review to the College Research Ethics Committee (CREC). Such referrals will include details of a recommendation from the School Ethics Committee, where appropriate:

- ⊘ All cases involving human tissue
- ⊘ All cases involving a doubt/disagreement/dispute which cannot be resolved at School level; this includes cases where the proposer of the research disagrees with the decision of the School Ethics Committee
- ⊘ Where there is a requirement by an external funder/sponsor for the research to be reviewed at College level
- ⊘ All cases of predictable media interest or ethical sensitivity
- ⊘ All cases where there is a perceived risk of a physical or psychological reaction resulting in more than a transient effect
- ⊘ All cases involving vulnerable populations
- ⊘ Where there are unresolved issues around supervision of the research

7. Genetic Modification

All cases involving genetic modification (plant, animal, human) will be reviewed by the Genetic Modification Sub-Committee of the Safety Committee, who will in turn refer to the College Research Ethics Committee where appropriate (See Annex D).

8. Radiation work

Work involving the use of ionising radiation is monitored by the Radiation Committee (a Sub-Committee of the Safety Committee), who will in turn refer to the College Research Ethics Committee where appropriate (see Annex E).

9. Reporting

The School Ethics Committee will report annually through the School Research Ethics Officer to CREC.

Annex A – The Role of the School Research Ethics Officer

The School Research Ethics Officer should be a research active member of the academic staff of Birkbeck with at least 3 years' post-probationary experience.

Duties include:

- ⌘ To ensure that there is a School procedure for the ethical approval of research projects in place and that a record is kept of approvals and decisions.
- ⌘ To act as the liaison point between the College Research Ethics Committee (CREC) and the School.
- ⌘ To act as the Chair of the School Ethics Committee.
- ⌘ To make a brief annual report to the CREC on the cases considered for ethical approval in the School. This would include:
 - Number of cases considered; type of research; ethical issues; action required (if any); particular difficulties encountered; any changes in School procedures

OR

- A nil report where no cases have been considered and there are no changes to procedures.
- ⌘ To ensure that mechanisms are in place for approval by appropriate external bodies (e.g. NHS) if relevant and to liaise with those bodies where necessary.
- ⌘ To ensure that ethical principles are explicitly taught.
- ⌘ To report to the College Research Ethics Committee any training or development needs related to ethical issues and approval procedures.

Annex B – Some Ethical Guidelines for Researchers

Research involving human subjects must be carried out in accordance with accepted ethical standards. Before commencing a research project you should consider a number of ethical issues that should form part of your research and the way in which it is conducted. These issues will include:

- (a) **justification** – that the proposed research will achieve worthwhile objectives, that these objectives could not be achieved without the informed participation of individuals and that there are adequate resources for the successful completion of the research.
- (b) **access to participant(s)** – when considering potential participants it is important to recognise issues of privacy and that individuals have a right to know how their names were selected and why they are being approached. Access may also involve researchers considering the implications of data protection legislation. The fact that an individual has access to potential participants in one role does not automatically imply that they have those same rights of access once they assume the role of a researcher.
- (c) **informed consent** – this is a fundamental aspect of any research programme and all those who have agreed to be part of any research must be able to do so in an informed way. In all cases you should take care to ensure that participants are fully informed about the project and have given informed consent freely. Informed consent is a continuous requirement and participants have the right to ask questions about a project at any time during the duration of the project. At any time participants have the right to withdraw from the project and to agree how the information they have provided will be used or removed from any database.
- (d) **potential harm to participants** – when considering the nature of the research activity it is important to work through the potential for psychological and physical harm. At the same time it may be important to consider the type of support that may be necessary to have in place if participants experience harm.
- (e) **participants rights** – participants have a number of rights that must be recognized. These include for example: (a) the right at any time to withdraw from the project and to discuss if no prior agreement is in place the way in which their data may be used, (b) the right to confidentiality and anonymity – this will require from time to time discussion and agreement as to how these rights will be maintained and if they cannot be maintained the fact that the participant(s) knows this from the outset and consents to this condition, (c) to refuse to answer any particular question – and in the case of tape recording the right to ask that the tape be turned off, (d) to ask questions about the study at any time during participation, (d) to be given access to a summary of the findings of the project when the project is concluded, (e) to know how the data is going to be used, and (f) to discuss the question of the ownership of the data and to reach agreement on issues of copyright.
- (f) **conflicts of interest** – when considering the nature of the project it is important to consider the potential for conflicts of interest particularly if the work is to be carried out in the same organization or if it is sponsored in some way. Not only do participants have the right to know if someone or organization is sponsoring the project but also the consequences of any conflicts should be made clear so that potential participants can consent to be part of the project in an informed way. It is necessary to recognise that while an individual may have access to certain

information because of their role in an organization that role and their rights change when they adopt the role of a researcher.

Depending on the nature of the research project many of the issues outlined above can be covered by providing potential participants with an information sheet. The information sheet would include the following:

(Remember that informed consent is fundamental to conducting research with human participants in an ethical manner. Informed consent includes the following elements)

- (a) the names of the people responsible for the research project and how they can be contacted
- (b) the procedures which they will be asked to agree to participate in
- (c) what the participants will have to do and how much time will be involved
- (d) how the researcher obtained their name to ask them to consider participating in the project
- (e) how the information will be used
- (f) what will happen to the information when it is obtained
- (g) how confidentiality and anonymity will be protected
- (h) what will happen to the data on completion of the project
- (i) the rights that individuals have if they take part in the project

At times it may be necessary to ask participants to sign a consent form. A typical consent form would contain the following information:

“I have read the Information Sheet and have had the details of the study explained to me. My questions have been answered to my satisfaction, and I understand that I may ask further questions at any time.

I understand I have the right to withdraw from the study at any time and to decline to answer any particular questions.

I agree to provide information to the researcher(s) on the understanding that my name will not be used without my permission *(The information will be used only for this research and publications arising from this research project.)*

I agree/do not agree to the interview being taped.

I agree/do not agree to the interview being video taped.

I confirm that I am over 16 years of age.

I understand that I have the right to ask for the audio/video tape to be turned off at any time during the interview.

I agree to participate in this study under the conditions set out in the Information Sheet.

Signed..... Name..... Date.....”

Annex C

An example of a Proposal Form for Ethical Review

Name(s) of applicant	
Status (e.g. Lecturer, PhD Student)	
Supervisor(s)	
School	
Project status (e.g. doctorate, individual staff research)	
Funding source	
Project Title	

Attachments:

Indicate the attachments enclosed with this form (please tick boxes):

Information sheet: Consent Form: Questionnaire: Other:

Description and rationale of proposed project:

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Ethical issues:

I confirm that the proposed project conforms with College and professional ethical guidelines, as indicated: (please circle)

- | | |
|---|-----------------------|
| 1. Access to participants: | YES / NO / DON'T KNOW |
| 2. Informed consent: | YES / NO / DON'T KNOW |
| 3. Anonymity and Confidentiality: | YES / NO / DON'T KNOW |
| 4. Potential Harm to Participants: | YES / NO / DON'T KNOW |
| 5. Potential Harm to Researcher(s): | YES / NO / DON'T KNOW |
| 6. Potential Harm to the College: | YES / NO / DON'T KNOW |
| 7. Participants' right to decline to take part: | YES / NO / DON'T KNOW |
| 8. Uses of the information (including publication): | YES / NO / DON'T KNOW |
| 9. Conflicts of Interest: | YES / NO / DON'T KNOW |
| 10. Other relevant ethical concerns (please specify): | YES / NO / DON'T KNOW |

Classification of project (please circle): **ROUTINE / NON-ROUTINE**

Signed by:

The applicant: Date:.....

Supervisor (if applicable):..... Date:.....

School Research Ethics Officer: Date:.....

Annex D - The role of the Genetic Modification sub-committee

The Genetic Modification Sub-Committee reports to the College Safety committee.

The Genetic Modification Sub-Committee monitors proposals to undertake experiments that involve the alteration of the genetic makeup of biological systems by changing the content or the sequential order of the DNA code. Alteration of the genetic code imparts biological matter with novel properties that may, in addition, carry a risk to health. The Genetic Modification Sub-Committee acts to both assess and approve the level of biological containment required in relation to the potential impact of the genetically engineered material produced by the experiment on the health of humans, animals and plants.

Within the College there are no genetic modification experiments that involve the deliberate release into the environment of genetically modified material. Therefore all recombinant cells are kept contained within the designated laboratory areas. Eventually, the genetically modified biological materials are inactivated and they are disposed of through the normal solid or liquid waste routes.

The Genetic Modification Sub-Committee's remit of risk management of genetic modification work does not include the direct monitoring of any ethical issues arising from the proposed experiments. However, members of the Genetic Modification Sub-Committee are aware that the use of some sourced biological materials for genetic modification purposes may require additional consideration by the College Research Ethics committee. A possible example of this would be the use of primary human cells [i.e. obtained directly from a cadaver] as a recipient host in a genetic modification protocol. Requests for the approval of a genetic modification experiment where there are such obvious ethics issues would be referred back to the College Research Ethics Committee after due consideration by the Genetic Modification sub-committee with regard to direct genetic modification safety issues.

Dr J. E. Pitts,
College Genetic Modification Officer.

Annex E - Radiation work

The recommendations of the International Commission on Radiological Protection (ICRP) are accepted as the basis for national legislation in the field of radiation protection. One of the general principles that the ICRP recommends for proposed and continuing practices is that no practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes i.e. the practice should be expected to do more good than harm. This is known as the 'justification' of a practice. An example of justification would be the treatment of hospital patients by radiotherapy. Here the health benefits to the patients should outweigh the detriment to other persons and the environment in general from the radiation in patients' bodily waste that will enter the public waste treatment system and eventually reach coastal regions and the sea.

In assessing whether a practice is justified, alternatives to the use of ionising radiations must always be considered and the risks and benefits assessed. No current UK legislation covers 'justification', but it is envisaged that all current uses in university research and teaching should meet future guidelines¹. In the context of radiation protection the term 'justifiable' could be considered to equate to 'ethical'.

The College is required by the Ionising Radiations Regulations 1999 (IRR99) to designate a Radiation Protection Adviser (who is the College Health and Safety Officer) and Radiation Protection Supervisors (RPSs) to monitor work with ionising radiations within the workplace to ensure that IRR 99 is complied with. At Birkbeck each School using ionising radiations has a designated RPS. The RPSs must be informed in writing by researchers in their School of any new proposal for work with radioactive materials. The RPSs attend the meetings of the Radiation Protection Committee (which reports to the College Safety Committee) and report on the state of radiation safety within their school to the sub-committee. A RPS is therefore in a position to report on any new proposal received that they might not consider 'justifiable'.

The Radiation Protection Committee's remit of risk management of work with ionising radiations does not include the direct monitoring of any ethical issues arising from proposed experiments. However, a proposal that a RPS reports to the sub-committee as not 'justifiable' would be referred to the College Research Ethics Committee along with the view of the sub-committee.

¹ The Association of University Radiation Protection Officers Guidance Notes on Working with Ionising Radiations in Research and Teaching - June 2002 Edition, page 1.