



Research Ethics Guidelines

Contact: ethics@rhul.ac.uk

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1. Introduction

All research conducted by staff or students and involving human subjects requires ethical scrutiny. Increasingly, this is an explicit requirement of external funders such as research councils and charities and oversight bodies such as funding councils. There are, however, different levels at which scrutiny can most effectively be conducted. This document provides general guidance on the type of research that requires ethical scrutiny, and forms for departmental and College-level consideration of projects that raise ethical concerns. Applicants should also be aware of appropriate subject-specific guidelines (see appendix I for some sources of further information).

2. Good ethical conduct in research.

The following are general principles to be followed by all investigators who carry out experiments/studies involving human subjects:

- Ethical approval is required for all research involving human subjects, including where there is no face-to-face interaction between researcher and participants (for example, postal questionnaires, telephone interviews, and internet surveys)
- All researchers are obliged to protect their participants from possible harm, to preserve their dignity and rights, and to safeguard their anonymity and confidentiality. Experiments/studies should not give rise to more than a minimal amount of anxiety or distress, or physical discomfort
- Experiments/studies should not lessen the human dignity, lower the self-esteem, infringe the rights, or endanger the safety of participants
- If deception is necessary as part of the project, it should not concern any aspect of the experiment/study, which, if made known to the participant, might remove his or her willingness to participate
- In the case of an experiment/study involving the administration of drugs (including alcohol and caffeine), contact with potentially harmful materials, or the use of hypnosis or invasive procedures, the investigator must possess appropriate experience and must check that the participant is not likely to react adversely to the substances or procedures in question (the participant's assurance on this point will normally be adequate); and medical help should be readily available in the case of an adverse effect
- The payment of participants should be for inconvenience and/or for the reimbursement of expenses, never for undergoing risk
- Researchers must obtain and record consent from participants or their guardians, on the basis of information given to them before their participation
- There should be no coercion in the recruitment of participants
- Participants must be given the right to withdraw from any given research, at any time without penalty and without providing reason. Participants (and/or parents) can also require that their (or their child's) data be withdrawn from the study. This should be stated clearly in the information sheet for each project
- Anonymity and confidentiality.
 - Participants must be assured that all information they give will be treated with the utmost confidentiality and that their anonymity will be respected at all times unless otherwise determined by law. Where relevant, participants should be told about where information about them will be stored, who will have access to it, what use will be made of it and when it will be destroyed. Procedures for data storage must conform to the Data Protection Act 1998. It should be noted that both electronic and structured paper files are covered by the Act;

- The data collected in an experiment/study should not be used for purposes fundamentally different from those originally specified, without the participant's consent.
- Express permission must be obtained for any non-confidential use of participant information.
- Signed consent forms should be stored separately from the research data, to preserve anonymity.
- Recruitment of participants for a given study should apply exclusion criteria that protect the health and well being of participants (for example, exclusion on the grounds of psychological vulnerability or a pre-existing medical condition).
- Researchers are obliged to monitor ongoing research for adverse effects on participants and to stop the research if there is cause for concern about their health and well-being.
- There is a duty of care on researchers to ameliorate any adverse effects of their research participants (either personally or by referral to an appropriately qualified person). As a general rule, researchers should debrief participants at the end of the research either verbally or in writing.
- Appropriate supervision. Student investigators (both undergraduate and postgraduate) must be under the supervision of a member of Academic Staff. It is the supervisor's responsibility to ensure that the student is aware of relevant Guidelines and of the need to observe them
- Participants should be told as much as possible about the experiment/study that they are being asked to take part in, and their explicit consent must be obtained, in writing. Researchers must be responsive to the concerns of participants during the course of the experiment.
- Although specific procedures might vary across disciplines, as a general principle all research participants/subjects should provide informed and signed consent, regardless of their age.
- With children and other vulnerable populations, consent may need to be provided by 'gatekeepers' (head teachers youth group leaders etc.), although if at all possible this should be in addition to the subjects themselves. Such populations may include: people with learning or communication difficulties; patients in hospital or people under the care of social services; people in custody or on probation, and people engaged in illegal activities, such as drug abuse. Particular attention should be paid to the needs of such populations to ensure that research does not cause harm to the subject(s). Research with vulnerable populations may require Criminal Records Bureau clearance.
- For the majority of research projects, 16 is the age at which individuals are able to give consent without additional consent for parent or gatekeeper. However, in some cases it may be appropriate for additional consent to be sought from the parent/guardian of individuals aged 16-18. Alternatively, the minimum recruitment age may be limited to 18 years for certain studies.
- For those under 16 years, signed parental consent should normally be obtained (active parental consent)
- Passive consent (e.g. parents are informed that their children will be involved in a research project unless the parents 'opt out' in writing) should be used only in exceptional circumstances, where the research is innocuous and where the gatekeeper (such as head teacher or sports club leader) has already approved the study and has deemed that passive consent is acceptable. The need to increase the number of participants is not a sufficient reason on its own to use an 'opt out' approach. The Ethics Committee's judgment will rely on a full, detailed description of the procedure involved in the study.

- Even where a parent or guardian (or gatekeeper) provides formal consent on behalf of those under 16, the consent of the child should also be sought (using simplified wording as necessary).
- Criminal Records Bureau clearance should always be sought when conducting research with children under the age of 16. The permission of the school or other organisation through which children are recruited should always be obtained before any research is conducted.
- If deception is involved in any experiment/study, participants should be carefully debriefed retrospectively. Second consent should be obtained once the real purposes of the research have been disclosed, and the right of participants to withhold the data collected about them in such an experiment/study should be respected.
- It should be made clear to a participant that he or she may decline to participate in any particular aspect of the research and may withdraw from the experiment/study at any time without giving a reason
- The extent and nature of participants' commitment must be explained prior to obtaining consent e.g. How much of their time might be needed for the completion of a questionnaire or an interview
- Any elements of risk must be explained carefully to participants prior to obtaining consent and researchers must assure themselves that the participants are appropriate for the study
- Researchers must respect and take appropriate account of the diversity of human conditions eg. Ethnicity, gender, disability, age and sexual orientation in the design, undertaking and reporting of research
- The findings of the research should be made available to participants upon request, except where this will cause distress or damage to the participant.
- Researchers who encounter ethical problems during the course of their experiment/study must return to whichever Ethics Committee approved their research to report this and to seek further advice immediately
- Amendments to studies will require further approval by the departmental/College Ethics Committee, even if NHS approval has already been obtained.

3. Research requiring ethical scrutiny

- **The potential ethical implications of all research involving human subjects should be assessed.** While many research projects raise no significant concerns, certain activities should not be undertaken without approval by an ethics committee. The following list is indicative rather than exhaustive: the administration of drugs (including alcohol and caffeine)
- contact with any potentially harmful items or substances
- the use of invasive procedures
- the use of hypnosis;
- doubt about the participant's capacity to give consent to take part in the experiment/study (which may arise, for example, in experiments/studies involving learning disabled individuals, or children
- the use of children as participants where the experiment/study falls outside the usual range of experiments/studies in perception, memory, everyday skills etc
- the participant is suffering, or potentially suffering distress or anxiety, or physical discomfort
- deception with regard to what will happen during the experiment/study, to the real purpose of the experiment/study, or to the basis on which participants are selected where the participants might object to having been deceived

- the use of patients under medical supervision as participants, who may be particularly sensitive to the procedures employed
- asking participants sensitive questions which involve encroachment on their privacy to a degree where the questions might be considered by them as offensive or stressful to answer
- experiments or observational or survey studies which may cause changes to the behaviour or life expectations of the social group from whom the participants are drawn.

Researchers envisaging a series of studies using the same research design may seek generic approval, to cover all projects using the same methodology. New approval should be obtained, however, if any non-trivial changes in methodology are made.

All research requires ethical approval by one or more of the following:

- Department Ethics Committee (DEC): for most routine research.
- Institutional Ethics Committee (CEC): for non-routine.
- External Ethics Committee (EEC): for research that is externally regulated (e.g. research conducted within the NHS). Copies of approval provided by NHS committees should be forwarded to the College Ethics Committee (and the departmental committee, if appropriate).

4. Application Process

There are two RHUL approval forms.

a. the simplified form

This can be used for many projects that involve human subjects, but do not raise any significant ethical questions, (Appendix IV). If completing this form highlights any ethical questions that require further consideration, the full form should be used and sent to either your departmental ethics committee or the College ethics committee as appropriate.

Research approved using this form should be recorded within the department, and reported to the College Ethics Committee annually (1 August to 31 July), reports to be submitted by 30 September each year.

b. the complete form

- All applications to the College Ethics Committee should be submitted on this form.
- All applicants in Psychology should use the full version of the form and attach the appropriate subject-specific annex.

If completing the full application form, you should attach all appendices to the form, relevant supporting materials, including consent forms, recruitment advertising or letters, briefing, materials, handouts and a list of questionnaires (please see checklist at appendix II). If the questionnaires to be employed are widely used and have previously been approved, it is not necessary to submit these, but new or rarely used questionnaires should be submitted for ethical scrutiny.

5. Departmental Ethics Committees (DEC)

For specific advice on departmental procedures (deadlines, preferred method of submission etc), please consult departmental guidance on website.

In the case of undergraduate and postgraduate student research, there should be pre-screening of research proposals carried out by the supervisor. Supervisors decide whether to refer the research proposal to the DEC or to an Institutional Ethics Committee

Departmental contacts:

Psychology: Dr Alison Woodcock, Chair of Departmental Ethics Committee: PSY-DEC@rhul.ac.uk.

For Psychology staff: https://www.pc.rhul.ac.uk/staff_intranet/DEC/

For Psychology students: https://www.pc.rhul.ac.uk/student_intranet/DEC-Students/

Health and Social Care: Professor Ray Lee: r.m.lee@rhul.ac.uk

6. College Ethics Committee (CEC)

Applications to be considered by the College Committee should be sent to ethics@rhul.ac.uk, or by post to Ethics Committee Secretary, Orchard Building.

All forms must be signed by the applicant, head of department and supervisor as appropriate (for electronic submissions, scanned copies are acceptable).

Some research projects involve more than just routine procedures and, for good practice require ethics and/or governance approval from outside the discipline and are therefore referred up to an institution-wide committee. The RHUL College Ethics Committee is chaired by the Vice-Principal (Planning and Resources) and members include a lay member of Council, a consultant psychiatrist, and a number of senior academics. Where necessary, additional members with subject expertise not on the Committee are consulted. Applications that are typically referred up to this committee are those where:

- the independence of the DEC to the research is at issue.
- the research involves matters that lie outside of the DEC members' joint competence.
- the proposal raises ethical questions of concern to the institution as a whole.
- the proposal raises issues that cannot be resolved satisfactorily by the DEC and requires further advice.
- the proposal involves potential risk to the participants themselves or to the wider community.
- the proposal involves the study of individuals who might be deemed to be participating in criminal activities.
- the proposal involves people in custody, patients, or people with learning/communication difficulties; in these cases the proposal will typically also need to be referred to an EEC.
- the proposal involves staff from 2 or more Departments within the same institution; alternatively, DEC's from co-operating Departments may opt to jointly consider the proposal.

Applications to the College Ethics Committee should be submitted in the first instance to the Secretary of the Research Ethics Committee, Orchard Building, or by sending a scanned version of the signed application form to ethics@rhul.ac.uk.

In addition to the form itself, the committee should receive all relevant supporting materials, such as consent forms, recruitment advertising or letters, briefing, materials, handouts, questionnaires etc.

7. External Ethics Committees (EECs)

Research may need to be referred to an EEC as well as the DEC or CEC whenever an institution additional to the home institution is involved. All research involving clinical trials and any research involving NHS patients, staff, premises or equipment requires special arrangements for ethical approval. **As of summer 2008, NHS ethical approval is**

obtained via the new Integrated Research Application System (IRAS),
<https://www.myresearchproject.org.uk/>

Research conducted overseas will often require local ethical approval. Specific requirements may vary in different countries.

The departmental or College committees (or both) should be kept informed of progress with the EEC and external approval must be recorded by the DEC or CEC before any research takes place. Approval by an external committee does not negate the need to obtain departmental or College approval, and research should never commence until DEC/CEC approval has been granted. However, evidence of approval by an external committee may expedite the process of obtaining RHUL approval. In the case of applications **ONLY** involving NHS staff, patients or facilities, it is sufficient to complete only the administrative details at the start of the RHUL form and submit this to DEC and RHUL EC along with the electronic application to the NHS REC. Please provide any interim communication about amendments required. Final approval by the College can only be provided once evidence of NHS approval has been provided. The researcher should then provide an electronic version of the final approved EEC application, with all its attachments and a photocopy/scanned copy of the final letter of approval from the EEC.

Checklist for Ethical Approval

Discuss your project with your line manager/supervisor and complete the 'Simple Form' available on the website:

<http://www.rhul.ac.uk/research-and-enterprise/CategoryTemplate.asp?LEVEL=TERTIARY&DID=1&CID=7&TID=0>

(delete as appropriate)

YES/NO

YES/NO

YES/NO

YES/NO

YES/NO

1. Will the study be *covert* in any way?

2. Will resulting data be used for purposes outside this study?

3. Are you working with a vulnerable population?

4. Is it possible that your study will cause distress or harm to participants?

- If your line manager/supervisor feels that the work involved gives rise to ethical problems, he/she may recommend for the form to be referred to the Departmental or the College Ethics Committee.
- If no referral is necessary then the line manager/supervisor and the applicant should each keep a copy of the signed form.

Applications to the College Ethics Committee

1. Application involves only NHS participants

- Complete Page 1 of the Full form and send with a copy of your initial NHS ethics application to your departmental ethics coordinator and the college ethics committee secretary.
- Please also provide any interim communication about amendments required by the NHS
- Send evidence of NHS approval to the college ethics committee secretary.
- Approval by Chair's Action

2. Application involves both NHS and non-NHS participants

- Send to College REC for review by the full committee with consent form(s), information sheets and any other materials in support of your application. If relevant, please also append the appropriate department-specific annex.
- Send evidence of NHS Approval to College REC
- Approval by Committee

3. Application involves only external participants and no NHS participants

- Send to College REC for review by the full committee with consent form(s) and information sheets and any other materials in support of your application. If relevant, please also append the

appropriate department-specific annex.

4. Approval from other ie. international committees is being sought.

5. **Attachments to include with your submission**

- Proposal Form
 - Departmental plus College form if separate.
- Appendices
 - Information Sheet for participants
 - Consent Form
 - Description of methods that are not standard practice. i.e. unpublished measures. If methods have been used before then a reference should be provided.
 - NHS approval form, if applicable.
 - Evidence of approval from the local research site, if applicable.
 - If it is a multi-site study, approval from all sites should be provided.

**RHUL College Ethics Committee
Application for Ethical Approval – Process Flowchart**

