Research Ethics Guidelines

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1. Introduction

All research at Royal Holloway requires ethical review and this document sets out how that can be acquired and what is required at each stage. Even if your research project has no ethical issues, you may still find it helpful to consult this document.

In order to protect both the individual and the College it is important that we conduct research with ethical integrity.

All Staff and students who undertake research are expected to adhere to a basic code of ethics which follows the following principles:

Behaving with integrity and professionalism

Researchers are expected to work in accordance with the Royal Holloway 'Research Expectations' document as approved by Academic Board. Researchers have an obligation to conduct their research with integrity and transparency and to accurately present their data and research findings.

Maximising benefit

Ensuring that you maximise the benefits of your work to the public is part of your obligation to research participants and scholarship. This would normally include:

- Ensuring that the aims of the research are transparent
- Designing, reviewing and conducting research in a manner that ensures quality and integrity whilst maximising the chance of obtaining useful results;
- Ensuring that research is effectively and appropriately disseminated.

Being Fair

You are expected to be fair to your participants by respecting their autonomy and not coercing them, minimising any harm by protecting your data and taking other measures to avoid distress, and to avoid discriminating against individuals or groups.

Further guidance on the conduct of research can be found at https://www.royalholloway.ac.uk/iquad/collegepolicies/documents/pdf/research/codeofgoodresearchpractice.pdf

2. Research Ethics Scrutiny

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

Within Departments
Ethical review for undergraduate and postgraduate taught (PGT) research projects is dealt with within departments. All other projects should go through the RHUL online ethical review process.

Research Ethics Committee (REC)
The RHUL Research Ethics Committee deals with the ethical review of staff and postgraduate research (PGR) projects. The Committee is chaired by the Senior Vice-Principal 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.

External Ethics Committees (EEC)
Research may need to be referred to an external ethics committee (EEC) as well as the REC whenever an institution additional to the home institution is involved. Further details about EECs are provided towards the end of this document.

3. RHUL Online Ethical Review Process

For staff research projects, the principal investigator (PI) should complete the online process; for postgraduate research projects the student should complete with their supervisor. The online ethical review process involves two stages:

Stage 1: Initial Assessment
All researchers are required to complete this stage to record basic information about all research projects and assess whether or not a full ethics review is needed. You will be asked to identify: the project, PI or academic supervisor and student, email address, project title and funder (which includes an option for research with no external funder). You will also be asked to complete six basic 'yes/no' questions in order to identify any issues of ethical concern.

When you have completed the initial assessment form online, the system will either confirm that no further action is needed or will lead you to the ethics review process. In either case the system logs the initial assessment form. If no further action is needed, the researcher can download a pdf copy of the initial assessment for their project records.

Stage 2: Ethical Review Form
If any issues of ethical concern are identified in the initial assessment, you will be directed to the ethical review form. This form can be submitted via two routes for ethical review: (a) self-certification or (b) REC panel review. Both routes involve completing the same online form, which will guide you to consider potential ethical issues related to different aspects of your project. In addition to the form itself, you must upload all relevant supporting materials, such as consent forms, recruitment advertising or letters, briefing/ information sheet, materials, handouts, questionnaires etc.

Self-Certification Route. This route is typically suitable for routine projects where there are minimal risks to participants, the environment/society, or the researchers/institution. When you have completed self-certification you will be able to download a pdf copy of the ethical review form. This will contain your ethics certification number, expiry date, and a statement that you have completed the College's ethical review process via self-certification. The REC audits at least 5% of self-certifications annually.

REC Panel Route. This route is typically suitable for projects where:

- the researcher does not consider that the application can be self-certified.
- the research involves matters that lie outside of the researcher's 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 applicant 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 who are vulnerable such as the elderly or those with physical and 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.

Your completed ethical review form will be sent to at least three reviewers on the REC panel as well as the REC Chair. You may be asked to provide further details, clarifications, or actions to address the issues raised in the form. The final form must be approved by at least three reviewers and the Chair. When you have completed REC panel review, you will receive an email verifying that approval has been given, and you will be able to download a pdf copy of the approved version.

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.

4. Ethical Review Form Guidance

In the ethical review form you will be guided to consider the ethical issues of different aspects of you project in a series of 'yes/no' questions. If you answer 'yes' to any questions, you should provide an explanation of the actions you will take to address the ethical issue(s). Below is some general guidance related to the sections in the ethical review form. Please note that you should also use subject-specific guidance where appropriate (see links at the end of this document).

Risks to Participants

The starting point for all research is that it should 'do no harm' to participants. This principle should be considered for all participants, but there may be some vulnerable populations where additional steps need to be taken. These may include:

- Children
- People with learning or communication difficulties (including people with dementia or similar conditions)
- Patients in hospital or people under the care of social services
- People in custody or on probation
- 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 Disclosure and Barring Service (DBS) check.

Design and Data

(i) Informed consent

For studies involving human participants, usual practice should be to obtain written informed consent before starting the research. An information sheet and consent form should be included with the ethics approval application.

For the majority of research projects, 16 is the age at which individuals are able to give consent without additional consent from a guardian. However, in some cases it may be appropriate for additional consent to be sought from the 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 (or otherwise recorded) guardian consent should normally be obtained. Even where a guardian provides formal consent on behalf of those under 16, the consent of the child should also be sought (using simplified wording as necessary).

Passive consent (e.g. guardians are informed that their children will be involved in a research project unless they '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.

For other potentially vulnerable populations (see above), information about the research should be communicated in an appropriate format. In some situations, additional consent may be required from a care-giver or next of kin.

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 General Data Protection Regulation (GDPR). It should be noted that both electronic and structured paper files are covered by the Regulation. Further information on the College's GDPR policy can be obtained from the College Secretariat and our policy can be found here.

When the research involves studying an organisation, researchers should gain agreed consent in writing which lays out the boundaries of the research (e.g. relating to operational details), the arrangements for data collection and anonymity of the organisation and individuals.

For colleagues involved in filming as part of their research, consent should be obtained from participants. Further details of working with those under 18 is available from Media Arts https://www.royalholloway.ac.uk/mediaarts/informationforcurrentstudents/home.aspx

The data collected in a study should not be used for purposes fundamentally different from those originally specified, without the participant's consent.

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. Should this occur all data held will be destroyed.

Signed consent forms should be stored separately from the research data, to preserve anonymity.

There may be situations where you do not need consent e.g. observations in a public place where it is reasonable to assume that people know their actions will be seen by others.

There may be situations where written consent is not possible or appropriate e.g. among illiterate populations. You need to have another way of demonstrating that participants are

aware of what the study is about and how the material will be used, and that they have consented to participate. This could be through video recording.

(ii) Participants identifiable

Express permission must be obtained for any non-confidential use of participant information. Researchers should ensure that they use non-identifying information when discussing participants and/or organisations who wish to remain anonymous. This also includes being careful when using images of people and research locations.

(iii) Pain & distress

Research studies should not give rise to more than a minimal amount of anxiety or distress, or physical discomfort to the participants. They should not lessen the human dignity, lower the self-esteem, infringe the rights, or endanger the safety of participants

In the case of a 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. Training and standard operating procedures should be followed.

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 on 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.

(iv) *Use/ collection of human tissue*

Human Tissue Act compliance

The Human Tissue Act 2004 repealed and replaced the Human Tissue Act 1961 (in England and Wales). The Act makes it unlawful to remove, store or use human tissue from the living or deceased without consent to do so for specified health-related purposes or public display, and is punishable by a fine and/or 3 years' imprisonment. In addition, there are a number of activities in the Act that require a license from the Human Tissue Authority before they can be lawfully undertaken.

The Human Tissue Authority (HTA) was set up to regulate the removal, storage, use and disposal of human bodies, organs and tissue for a number of Scheduled Purposes (such as research, transplantation, and education and training) set out in the Human Tissue Act. In

order to carry out research that leads to human benefit, or is for teaching purposes, Royal Holloway and New Bedford College uses and stores tissue that falls within the remit of the HTA. The College therefore has obligations under the Human Tissue Act.

Definition of relevant material

The definition of relevant material in the Human Tissue Act 2004 (excluding human application) is:

Section 53: Relevant Material

1. In this Act, "relevant material" means material, other than gametes, which consists of or includes human cells.

2. In this Act, references to relevant material from a human body do not include:

(a) embryos outside the human body, or

(b) hair and nail from the body of a living person.

To supplement the HTA's broader policy framework on relevant material, a list has been produced to provide stakeholders with guidance on whether specific materials fall within the definition of relevant material under the Human Tissue Act. Please see the supplementary list of materials for the purposes of the Human Tissue Act 2004.

If you do obtain a HTA licence you are still required to seek ethical approval via the REC, a HTA licence does not permit the ‘use of tissue for research or approve an individual research project or clinical trial.

Not all human tissue requires a licence, if the tissue comes from living people and there is project specific approval from a recognised REC, then you are allowed to store the material. Material (tissue or primary cells) must be appropriately destroyed at the end of the project.

(v) Use of administrative or secure data

Researchers using existing datasets should ensure that they gain appropriate approval and follow the guidelines for the use of confidential material.

(vi) Financial inducements

The payment of participants should be for inconvenience and/or for the reimbursement of expenses, never for undergoing risk.

Risks to the Environment / Society

The following are general principles to be followed by all investigators who carry out studies involving environmental research in field sites:

- Permission should be obtained to conduct research on private or government property
- Permission should be obtained to take geological or sedimentological samples
- Appropriate permission should be given for the removal of, and use of, cultural or archaeological artefacts.

Research which involves animal experimentation

Risks to Researchers / Institution

Research should not place the researcher in a position of undue physical and/or emotional harm. Researchers should reflect on the possible dangers in their research and state how they will minimise these. Completion of this ethics approval form does not negate the requirement to complete a risk assessment form where this is required by the College's Health & Safety procedures.

If the research involves the study of illegal practices, the researcher needs to state clearly whether there is a legal requirement to report evidence of illegality and how participants will be informed of this. The College does not support researchers undertaking illegal practices themselves as part of their research.

Supporting Material

There is no requirement to add supporting material due the variety of projects. However, most applications will require submission of some/ all of the following:

- Information sheet for participants – this includes an overview of the research, as well as details of what the participant would need to do, information about opting out, anonymity, data storage and payment.
- Consent form
- Questionnaire
- Overview of interview questions/ themes
- Feedback sheet for participants

5. External Ethics Committees (EECs) and the NHS

Research may need to be referred to an EEC as well as the Department or REC 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.

If your study involves the NHS in England, you should use HRA Approval, the process for that brings together the assessment of governance and legal compliance with independent REC opinion provided through the UK research ethics service.

HRA approval replaces the need for local checks of legal compliance and related matters be each participating organisation in England.

As of 31 March 2016, HRA Approval became the process for applying for approvals for all project-based research in the NHS led from England. This means that:

- HRA Approval will be used wherever the project involves NHS organisations in England.
- Where a project also involves NHS/HSC organisation(s) elsewhere in the UK (i.e. other than in England) the study will be supported through existing UK-wide compatibility systems, by which each country accepts the centralised assurances, as far as they apply, from national coordinating functions without unnecessary duplication.
- Projects that have previously sought or gained NHS Permission for participating NHS organisations in England, or applied for REC review, now come under HRA Approval.

The HRA provides detailed guidance on the processes and how to apply, which you should read carefully before submitting an application. The guidance also contains a link through to IRAS, the online applications system. www.hra.nhs.uk

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

The Research Ethics Committee should be kept informed of progress with the EEC and external approval must be recorded by the REC before any research takes place. Approval by an external committee does not negate the need to obtain College approval, and research should never commence until REC 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 REC 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.

6. Links to further guidance

From major funders:

- BBSRC: http://www.bbsrc.ac.uk/engagement/accountability/ethical-monitoring-process
- ESRC: http://www.esrc.ac.uk/about-esrc/information/framework-for-research-ethics/index.aspx
- NERC: http://www.nerc.ac.uk/about/policy/policies/nerc-ethics-policy/
- MRC: http://www.mrc.ac.uk/funding/guidance-for-applicants/5-ethics-and-approvals
- EU: http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm
- Wellcome Trust: http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/

7. Issues Arising from Research

There may be issues that arise from research projects undertaken that need to be reported, or where participants have concerns that they wish to raise with the College. In these cases the secretary to the Ethics Committee should be contacted at Ethics.rhul.ac.uk.

Where research gains press attention for ethical matters this should be raised immediately with the Director of Communications and the Chair of the Ethics panel, via the secretary at ethics.rhul.ac.uk.

Approved by Research Ethics Committee: