ETHICS GUIDANCE AND PROCEDURES FOR UNDERTAKING RESEARCH INVOLVING HUMAN SUBJECTS
CONTENTS

GUIDANCE

Section 1 : Introduction
Section 2 : Guiding Principles
Section 3 : Protecting Rights, Ensuring Safety
Section 4 : Funding Agencies

PROCEDURES

Section 5 : Which studies require ethical approval?
Section 6 : Ethical clearance procedures
Section 7 : Education and Training in Research Ethics: Opportunities for Staff and Students

Appendix 1 : Legal Responsibilities
Appendix 2 : Further references and background

The ethics application form can be downloaded from http://www.kingston.ac.uk/research/research-policies-and-guides/
SECTION 1: INTRODUCTION

1.1 This handbook provides general guidance for academic staff, undergraduate and postgraduate students about the ethical issues which can arise in the conduct, supervision and utilisation of research involving human subjects and emphasises the need to work within professional codes of conduct and legal statutes. Further information accompanies the application form.

SECTION 2: GUIDING PRINCIPLES

2.1 Research involving human subjects is a moral enterprise invested by mutual respect and trust between participants and investigators. Maintenance of integrity in the professional conduct of research encompasses responsibilities to participants, funding agencies, employers, colleagues and students. Professional bodies emphasize the need for democratic values, respect for persons, knowledge and the quality of research to inform its conduct, whilst acknowledging conscientiousness, honesty, courage, and diplomacy to be desirable attributes of researchers.

2.2 In the conduct of research, the risk of foreseeable harm to the physical, psychological, social well being, health, values and dignity of participants should be minimized. It is the potential vulnerability of participants and their need for respect and protection that justifies ethical reviews of research and against which its acceptability is judged. “Every research project involving human subjects should be preceded by a careful assessment of the predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the interests of the subject must always prevail over the interests of science and society” (Declaration of Helsinki).

2.3 Respect for autonomy, beneficence, non-maleficence, and justice are fundamental and widely accepted ethical principles relevant to research. Respect for these principles lies at the heart of recent human rights legislation (Human Rights Act 1998). Three articles within this act are particularly relevant to safeguarding the rights of research participants, minimising risks, and ensuring informed consent, privacy, anonymity and confidentiality.

- Article 3: No-one shall be subjected to torture or inhuman or degrading treatment
- Article 8: Everyone has the right to respect for his/her private and family life, his/her home and correspondence
- Article 9: Everyone has a right to freedom of thought, conscience and religion.

2.4 Respect for autonomy – ‘self-rule’ – requires that individuals have the right whether or not to participate in a research study, free from coercion and without prejudice. Researchers in positions of authority should bear in mind that a coercive element might be inadvertently introduced in recruitment of participants i.e. students recruited into a study by academic staff, or by use of financial inducements. Respect for autonomy also imposes obligations on researchers to respect the anonymity, privacy and confidentiality of information relating to participants.

2.5 The principle of beneficence requires that researchers act to do good i.e. promote the well being of participants; non-maleficence emphasizes the need “above all to do no harm”. Researchers owe a duty of care to participants and liability can arise where this duty is breached and harm is incurred.

2.6 Considerations of beneficence and non-maleficence make it necessary for researchers and ethics committees to evaluate potential benefits versus risks to participants. Benefits to participants can include access to an intervention which is beneficial and which in normal
life might be restricted; increase in knowledge and esteem resulting from interaction with a non judgmental and impartial researcher; financial gain and altruistic satisfaction that results of the research may benefit society.

2.7 Set against these benefits are potential risks which may be trivial or sufficient to result in discomfort or distress. Normally, risks to participants should not exceed minimal risk i.e. not greater than that ordinarily encountered in daily life. Within the context of risk, attention is drawn to the following.

- The need for researchers to recognise and work within their boundaries of expertise and competence.
- The need to inform participants of any emerging information during an investigation that could present psychological or physical problems or pose a risk to the well being of the participant.
- The need to identify factors in a research protocol or procedure which could exacerbate risk e.g. a pre-existing medical condition. Participants should be advised of these and any preventative actions.
- The need to be aware of situations either foreseeable or unexpected which can arise in research and require an intervention on ethical grounds to safeguard the welfare of participants. This may require abandoning data collection.

2.8 The principle of justice as fairness encompasses the rights of research subjects to fair treatment and privacy. This includes the following:

- Non-discriminatory selection of subjects based on inclusion criteria which allows an equitable sharing of risks and benefits.
- Respecting rights of individuals to decline to take part in a study or withdraw at any time without penalty, irrespective of any financial agreement.
- Safeguarding participants’ rights in accordance with the Human Rights Act (1998) regarding privacy, anonymity, confidentiality.
- Facilitating participants’ access to researchers to clarify points of information and providing immediate help should any harmful physical or psychological effects be experienced.
- Honouring financial agreements agreed at the time that informed consent was obtained from participants.
- Adherence by researchers to research protocols agreed by University and Faculty Committees concerned with research ethics. Amendments to protocols should be approved.
- Debriefing participants at the conclusion of a study or following the completion of data collection to provide information, clarify any issues or misconceptions, monitor any negative effects which were unforeseen and require intervention.
SECTION 3: PROTECTING RIGHTS, ENSURING SAFETY OF RESEARCH PARTICIPANTS

3.1 Identifiable safeguards should be in place at the onset of a research study which are designed to protect against physical, psychological and social harm. If there is a foreseeable possibility of discomfort or distress, individuals should be warned of this at the time that informed consent is obtained.

3.2 Potential risks or costs to research participants can arise from intensive, invasive techniques of biological, psychological or social origin, loss of privacy, time or financial resources. Faculty Committees concerned with research ethics, through their procedures and protocols ensure appropriate screening is in place, designed to minimise risks and costs. Various standards for use of specific techniques and tests have been developed by professional expert groups and professional bodies.

3.3 Researchers should incorporate sensitivity in their approach, and be aware of the need for mindfulness and respect regarding religion, cultural and gendered differences in research populations.

3.4 Voluntary, informed consent should be sought from participants in a research study i.e. a voluntary, un-coerced decision, made by a sufficiently competent or autonomous person on the basis of adequate information and deliberation, to accept rather than reject a proposed course of action. Note, appropriate time should be allowed for participants to reflect on and consider information before they agree to take part.

3.5 In seeking voluntary consent, researchers should emphasise that potential participants have a right to refuse to take part and to withdraw at any time without detriment. Participants may withdraw at the concluding, debriefing stage of a study and require destruction of their personal data.

3.6 Consent should be obtained in writing, although verbal consent is acceptable in certain circumstances. Written consent is recommended for studies involving minimal risk or discomfort. In obtaining consent the following are important components:

- Participants should be provided with information about the purposes of an investigation, duration, sources of funding and the nature of commitment required from them.
- Potential foreseeable risks/discomforts should be explained.
- Information should be provided in clearly understood language or consent is invalid. Avoid jargon and use of complex technical terms.
- The nature of confidentiality and anonymity should be made clear to participants.
- It should be ensured that participants fully understand all the uses to which the data will be put, including potential future use.
- Points of access for further information should be identified, and the arrangements, if appropriate, for debriefing.
- In some forms of field research it may be necessary for consent to be re-negotiated over time and not regarded as a one-off event.
- A person who is fully informed and who volunteers to complete a research questionnaire implicitly consents to participation in that research.

3.7 It is recognised that, although as a general rule studies involving human participants should be carried out with consent, there are some exceptional circumstances and methodological approaches where consent is not obtained for justifiable reasons. Guidelines are available from professional bodies concerning such research approaches, and should be followed. Faculty committees concerned with research ethics can provide further guidance on this matter. Covert research and deception is also addressed within the guidelines of specific professional bodies.

3.8 Children or vulnerable adults are those who do not have full autonomy of thought, will or action. This can be variable in degree and may render the individuals vulnerable to side
effects or other risks due to their physical, emotional, cultural or social status. Problems which can arise include failure to comprehend or weigh up information, or to be physically incapable of signing a consent form. Children (minors), pregnant women, older adults and those with mental illness, learning disability, chronic illnesses and neurological impairment are exemplars of vulnerability.

3.9 Special arrangements relate to obtaining informed consent in vulnerable groups, as in the examples given below. Witnessed consent may be necessary in the presence of impairment.

**Children (Minors)**
- Assent of a child over 7 years of age should usually be sought directly from the child. In addition, consent should be sought from a parent/guardian if the child is under 16.
- Guidelines involving research in children have been developed by a number of professional bodies. BERA\(^1\) (2004) states that: ‘Care should be taken when interviewing children and students up to school-leaving age; permission should be obtained from the school and if they so suggest, the parents’. The RCP\(^2\) (1996) and BPA\(^3\) (1992) both make the point that consent should be obtained directly from children, with supplementary assent/consent from parents/guardians.
- Further to this, the BPA point out that if children give consent to participate and subsequently avoid the research procedure/test, this should be taken as evidence of failure to consent and effective withdrawal from the study.

**Pregnancy**
- CIOMS/WHO\(^4\) [1993] guidelines advise that no special problems of eliciting consent exist in the case of pregnant and nursing mothers. However, many Committees require that consent is not sought in the time period around childbirth.

**Mental Capacity**

**Learning Disability**
- Many individuals are competent to understand the implications of research participation; difficulties arise where competence/rationality is impaired. In the latter case, the RCP (1996) guidelines covering non-therapeutic and therapeutic research offer clear direction to researchers. It should be emphasised that UREC/FREC do not consider proposals relating to hospitalised individuals which should be submitted to an NHS LREC.

**Mental Health**
- A key issue is the need to gauge whether or not a potential participant is too vulnerable to take part in the first place. Occasionally researchers will be asked by a participant directly for advice or information which conflicts with their role as researcher or interviewer. It will be helpful to have a list of local resources and helplines, including advocacy services to help in this situation to avoid being drawn into helping someone with an individual problem. The context and subject of the research will have some bearing on the need for support. If research is being undertaken with people in hospital or in a vulnerable situation, the need to have some forms of support available will be greater. Researchers should note that participants’ mental capacity may change over time and should consider how this will be monitored and dealt with.

3.10 **Confidentiality**

---

1. British Educational Research Association  
2. Royal College of Physicians  
3. British Paediatric Association  
All research should conform with legislation related to data protection. Researchers should make clear to participants the nature of any promises on confidentiality or restrictions on the use of data. Unless agreed to the contrary in advance, information about participants is confidential. Anonymity is subject to the same conditions.

SECTION 4: FUNDING AGENCIES

4.1 In negotiations with funding agencies and other key stakeholders it is advisable that researchers consider the following prior to signing contracts:

- Funding agencies/sponsors should be disclosed by researchers (maximum openness desirable).
- The starting point is that the University as the employer of a researcher will own all data, results and intellectual property rights created by a researcher in research studies conducted in their employment. However, exceptions apply according to the contractual arrangements with the sponsor. For example if a sponsor is paying 100% of the full economic cost of a project, they will usually expect the resulting IPR to be assigned to them. Even so, most sponsors will be happy to licence that IPR to the University for research and academic purposes and this should usually be requested.
- The starting point for students (who are not also employed by the University), is that they own their own IPR. It is therefore usually advisable where non-employed students are involved in a project, to obtain their written assignment of their IPR to the University, before commencing work on the project.
- Researchers should consider whether they are bringing any existing IPR to the project, and whether they are happy for the sponsor to be able to continue using this IPR after the project has finished.
- Funding agencies/sponsors and other organisations should respect the rights of researchers to maintain confidentiality of data.
- Funding agencies/sponsors and other organisations should respect the freedom of researchers to publish findings without censorship. (Defined as exerting undue influence/interference in the conduct, analysis, findings and dissemination of research). Contractual clauses relating to the sponsor’s right to prohibit publication in order to protect their IPR, must be considered carefully.
- Appointment of advisory groups can be helpful in project management of contract research. Such groups represent legitimate interests of key stakeholders and should operate within clearly defined terms of reference.

4.2 Obligations of funders and researchers should be clearly stated in a written contract of negotiated terms and conditions. Researchers have a responsibility to be fully conversant with the content of such contracts, and conditions should not be accepted which conflict with a researcher's professional codes of conduct. The following points should be borne in mind in any contract negotiations:

- During contract negotiation researchers should clarify rights to publish and disseminate results of their work.
- During contract negotiation researchers should clarify the rights to intellectual property rights, whether arising from the research, or in existence before the research. Who will own the resulting IPR? Who has the rights to use the existing and resulting IPR once the research has been concluded?
- Researchers cannot engage in contract research without the agreement of the University.
- Researchers should make clear to funders the benefits and limitations which may result from proposed investigations, but they should make it clear that they are not guaranteeing any particular outcome or result.

6 Normally the Faculty Dean.
• Researchers should not undertake research outside of their expertise
• Research should not be undertaken where resources (time, personnel, finance, equipment) are inadequate to achieve the project aims.

Funding agencies are entitled to receive financial audits/records of expenditure on research grants, reports, (interim and/or concluding) detailing methods, findings, implications, and recommendations of an investigation. Funders may exercise the right to see a final report before publication.

Researchers have responsibilities to notify/seek approval from funders (and faculty committees concerned with ethics) of any departure from an agreed plan or conditions of investigation. Referral for independent arbitration or mediation may be necessary where resolution of a dispute cannot be achieved. It is vital that researchers should identify any conflicts of interest which may arise in the conduct of a project and require pre-emptive resolution.
PROCEDURES

SECTION 5: WHICH STUDIES REQUIRE ETHICAL APPROVAL?

5.1 It is the responsibility of all researchers to ensure that their projects are conducted in accordance with the University’s Guide to Good Research Practice and the ethical principles appropriate to their discipline/professional body.

5.2 Any research involving human participants should be subject to an appropriate level of ethical scrutiny in order to protect participants, researchers and the University; a paper trail for all research projects involving humans is required and this may be subject to audit.

5.3 Ethical review should be proportionate to the degree of risk involved. The ethical review process must be sufficiently rigorous to capture any projects which have ethical implications, whilst sufficiently flexible to allow for the quick processing of projects which employ low risk routine methodologies. The University has introduced a three pathway approach to deal with this. The three pathways are block release, fast-track application or full application.

5.4 For all projects, the pre-application checklist below should be used to determine whether ethical approval is required:

- Will your research involve living human participants?
- Will your research involve data on humans?
- Will your research involve human biological material?

If the answer to any of these questions is YES, then either an RE4 form must be approved for the project (fast-track form or full application) or a block release agreement must be in place.

5.5 Studies using human subjects which fall into the categories below are likely to require full applications due to the ethical and/or legal issues involved:

- investigations involving invasive biological techniques
- investigations that intrude psychologically, socially or culturally
- investigations involving vulnerable groups/individuals;
- studies leading to loss of participants' privacy, time and financial resources.

5.6 Studies which involve links with certain external organisations/countries in relation to funding of proposals, sponsorship of research students, or collaboration/research partnerships can give rise to ethical concerns, whether or not they require the participation of human subjects. These encompass:

- external organisations which sell products injurious to health or life;
- external organisations which damage or pollute the environment;
- countries with oppressive political regimes/human rights records;
- organisations involved in animal experimentation.

Where human subjects are not involved, approval for such projects should be directed to the Faculty Research Committee in the first instance.

5.7 There are a number of straightforward research proposals involving human subjects where a full application may not be required. Proposals which may come into this category include the following:
• questionnaires and interview schedules where there are no major issues relating to confidentiality, or sensitive information;
• research already given approval by other ethics committees which have established reciprocal arrangements with the University through UREC;
• procedures authorized by faculty committees as being appropriate for self-regulation.

In these cases the researcher still has a responsibility to ensure that ethical approval for the project is in place through either a block release agreement or a fast-track application.

5.8 If after reading these guidelines together with those of the relevant professional body, any uncertainty exists about the need for ethical approval, advice should be sought from the Chair of the Faculty Research Ethics Committee.

SECTION 6  ETHICAL CLEARANCE PROCEDURE

6.1 For all projects, the pre-application checklist should be used to determine whether ethical approval is required:
• Will your research involve living human participants?
• Will your research involve data on humans?
• Will your research involve human biological material?
If the answer to any of these questions is YES, then either an RE4 form must be approved for the project (fast-track form or full application) or a block release agreement must be in place. The researcher is responsible for determining which pathway is most appropriate, with the advice of the chair of the Faculty Research Ethics Committee (FREC) where necessary.

The flowchart at the end of this section can be used to determine the most appropriate pathway.

6.2 Block release
This is a mechanism for FRECs to authorize delegated approval for low risk projects which use standard routine methodologies. The module leader should submit a one-off fully completed RE4 form to the Faculty Research Ethics Committee (FREC). The form should present an exemplar project typical to the group/cohort. The FREC will consider the form and, if it is appropriate to do so, may grant a block release agreement for this group or cohort. The FREC will provide a block release letter which states the agreed parameters, applicable cohort and duration of the block release (up to five years). This means that any future projects which fall within the agreed parameters will not require an application for ethical review by the committee (unless specifically requested) and responsibility for ethical approval will lie with the block release holder. Projects which fall outside of the agreed parameters will require separate approval by the committee. Project titles covered by the block release should be reported to the FREC annually and FRECs may request further information if required. Projects may be audited to check that they do fall within the agreed parameters.

6.3 Where block release is not appropriate or possible, an RE4 form is required and this should be submitted as either a full application or a fast-track application.

6.4 Fast track applications
A fast track application may be submitted if the project is low-risk or if the project has already been approved by another suitably qualified ethics committee:

• If the project has already received ethical approval from another committee only sections A, B and D of the RE4 form should be completed. A copy of the approval letter should be attached to the form and this should be submitted to the faculty research ethics administrator as a fast-track form. A copy of the original application should be held on file in the Faculty Research Office in case of inspection.
• For all other projects, Sections A, C and D of the RE4 form must be completed. If the applicant answers NO to all questions on the Risk Assessment Questionnaire, then the form may be submitted to the faculty research ethics administrator as a fast-track application. A copy of the Participant Information Sheet should be attached.

6.5 Faculty Research Ethics Committees (FRECs) may implement their own procedures for processing fast-track applications and are encouraged to make use of delegated approval processes, provided there is a clear reporting line to FREC. If the FREC Chair (or delegate) feels that the application is not suitable for fast-track processing, he/she may request further supporting documentation from the applicant and/or require a full application for ethical approval.

6.6 **Full applications**

If the applicant answers YES to any of the questions on the Risk Assessment Questionnaire, then the full project proposal and all supporting documentation must be supplied. Committee approval is required for full applications. Applicants should obtain information regarding meeting dates/timescales from the Chair of their Faculty Research Ethics Committee (FREC).

6.7 The RE4 form contains instructions to guide researchers through the application process.

**Quick reference notes**

6.8 UG AND PGT: Ethical approval for undergraduate and taught postgraduate students should usually be covered by a block release agreement, held by the module leader. Responsibility for ethical approval is delegated to the block release holder.

6.9 PGR AND STAFF: The ethical approval process for staff and postgraduate research students will vary depending on the degree of risk involved. Typically, for low-risk projects, certain parameters will be agreed by a FREC and a block release agreement will be granted for particular cohorts or groups. An RE4 form is required for medium- to high-risk projects but this may be processed as a fast-track or full application depending on the degree of risk involved (this is determined using the risk assessment questionnaire). Some FRECs may require full applications for all projects. Ethical issues (past, present and future) should be considered as part of the ongoing monitoring of projects, particularly at key reporting stages (such as annual reporting and upgrade from MPhil to PhD).

6.10 **DELEGATED APPROVAL:** FRECs may implement delegated approval processes, provided there is a clear reporting line to FREC and UREC. Delegated approval transfers the right and responsibilities to project supervisors, or other nominated academic member of staff, to approve and monitor research projects within the agreed parameters. Delegated ethical approval should be granted by a Faculty Research Ethics Committee to module leaders/project supervisors. A record of individuals/groups with delegated responsibility should be maintained by the FREC and faculty research ethics administrator.

6.11 FUNDED RESEARCH: Normally, it is not necessary to have received ethical clearance prior to submitting a research proposal to a funding body, however, exceptions do exist. It is the responsibility of researchers to ensure that the timing of ethical clearance for their proposals meets the requirements of funders. This is especially the case where NHS approval is required, as this can be a lengthy process.

6.12 **LEGAL RESPONSIBILITIES AND INDEMNITY:** Attention is drawn to Appendix 1 Legal Responsibilities and paragraph 1.4 concerning indemnity.

6.13 **FREC MEETINGS:** Committees allow a range of different perspectives to be shared and the opportunity for debate and negotiation. Researchers (or other advocates of a proposal) are not normally required to attend meetings of an ethics committee. If necessary, the FREC may invite the applicant to attend the Committee meeting where their application is being considered for further clarification. If members of an ethics committee have a direct
involvement in a research proposal, such interests should be declared and the discussion conducted in their absence.

6.14 SPECIALIST ADVICE: The advice of appropriate specialists may be sought in circumstances where the committee deems this necessary, including guidance from an appropriate Faculty Research Ethics Committee (FREC), but these individuals will not be involved in making a decision.

6.15 CONDITIONS AND RESUBMISSIONS: A Faculty Research Ethics Committee (FREC) or nominated delegate, may approve or reject a proposal, or require amendments. It may be necessary to defer a decision to obtain clarification or further advice about a proposal. If an appropriate FREC cannot be identified for the project (e.g. certain interdisciplinary projects), an application may be submitted directly to the University Research Ethics Committee for consideration.

6.16 RECORDING AND NOTIFICATION: Decisions of an ethics committee should be formally recorded in the minutes. Applicants should be notified of the decision within 7 working days of the committee meeting and, where applicable, should be informed about their right to appeal. A copy of this correspondence and a record of any conditions should be kept on file with the application in case of query or audit. Faculties should record details of block release agreements and block release holders and ensure project details are reported annually to FREC as required.

6.17 CHAIR’S ACTION: Where a decision regarding ethical clearance of a proposal is required before the next available meeting of the committee, the chair may use discretion to make a decision after consultation with other members by circulation of papers. Any actions taken by the chair shall be reported to the next committee meeting.

6.18 APPEALS: Applicants may appeal against a decision to reject or require amendments. An appeal should be made to the chair of the committee which considered the application within 21 working days of the date of notification. The applicant should provide an explanation of the grounds for appeal, providing further evidence or information as necessary. If, after re-consideration, the committee is not able to reach an agreement, or a further appeal is made, the application may be referred up to the parent committee for decision (Faculty Research Ethics Committees report to University Research Ethics Committee which reports to University Research Committee). Committees may seek the advice of subject specialists if necessary. It is expected that most matters should be resolved without the involvement of the University Research Committee.

6.19 MONITORING: Following ethical approval of a proposal no changes should be made to the protocol or membership of the research team without the consent of the research ethics committee. If unanticipated problems which generate ethical concerns arise during the course of a study these should be notified by the researcher or supervisor (as appropriate) to the chair of the FREC to discuss whatever actions may be necessary to safeguard the welfare and interests of participants and/or researchers.

6.20 PROJECTS INVOLVING THE NHS: The National Research Ethics Service (NRES) for England works closely with the UK Health Departments to develop and maintain a common UK-wide system for ethical review of health and social care research. Certain health and social care research projects require approval by an NHS Research Ethics Committee (REC) prior to commencement. For full details see http://www.nres.nhs.uk/applications/ All to the National Research Ethics Service are made using the Integrated Research Application System (IRAS). www.myresearchproject.org.uk
Ethical approval process

Three pathways:
1. Block release application: FRECs grant a block release agreement for specified groups or cohorts on the basis of a typical application (for low risk projects which use standard routine methodologies).
2. Fast track: Only certain sections of the RE4 form are required and these may be processed by delegated approval (for low risk projects where block release is not appropriate, and for projects already approved by another qualified committee e.g. NHS).
3. Full application: A full RE4 form and additional supporting documents are required. Applications require Committee approval (for medium and high risk projects).

PRE APPLICATION CHECK (ALL PROJECTS).  Will your research involve:
- Living human participants?
- Data on humans?
- Human biological material?

Yes

No

Ethical approval is probably not required. If you are unsure, check with your FREC Chair.

Is the project low risk, using standard routine methodology? See the Ethics Guidance and Guide to Good Research Practice for further information on risk.

Yes

No

Is a block release agreement already in place? If in doubt check with your FREC Chair.

Yes

No

Is it appropriate to apply for a new block release agreement on behalf of this group/cohort?

Yes

No

A suitably qualified individual (e.g. supervisor or module leader) should submit a fully completed RE4 form to FREC. The form should present a typical project in this area. If it is appropriate to do so, the FREC will grant a block release agreement (meaning ethical oversight for typical future projects will reside with the nominated individual).

Complete Section A of the RE4 form.

Has another ethics committee already granted approval for this project?

Yes

No

Complete Section B of the RE4 form. Attach evidence of approval and ensure the original application is held on file in the Faculty Office in case of audit.

Complete section C of the RE4 form and append your Participant Information Sheet.

Have you answered 'Yes' to any questions in the risk assessment questionnaire?

Yes

No

Projects should be monitored for any changes in design which may have ethical implications. Project details should be reported to UREC via the FREC annual monitoring report.

A full ethics application is required. Complete section D and append the additional documents as outlined in the application checklist.

No

Yes

Does your project fall within the agreed parameters of the block release?

Yes

No

The project should be reported to the block release holder (e.g. supervisor or module leader). No further action is required unless specified by the block release holder.

Complete section D and submit to faculty ethics administrator as a fast-track form.

FRECs usually have delegated approval processes for fast-track forms.
7.1 Education and Training: Research Ethics

- **Research Supervisors**
  Provision of research supervisor training is addressed as part of the post-graduate certificate/diploma in teaching and learning in higher education. This is aimed primarily at new research supervisors and contains lectures on research ethics. The ethics lecture component can be accessed more widely by academic staff who wish to update their knowledge and skills. Further information can be obtained from the Academic Development Centre.

- **Undergraduate/Postgraduate Students**
  Research ethics should form part of the content of research methods courses delivered at levels 6 and 7 within undergraduate and taught postgraduate programmes. The Graduate School also offers an ethics session for research students as part of its generic research student training.

- **External Courses**
  A number of organisations hold short one/two day courses designed either to provide a training on general research ethics, or to address specialist, discipline-specific research ethics issues. Exemplars include:

  - Department of Medical Ethics and Law, Kings College, University of London
  - Professional bodies and Learned Societies listed in websites;
  - Government websites including the National Research Ethics Service (NRES)
  - Association of Research Ethics Committees (UK). This national organisation holds 3 annual meetings addressing a wide range of research ethics issues from an interdisciplinary perspective. Short training courses also available.
  - Centre for Professional Ethics, University of Keele
APPENDIX 1: LEGAL RESPONSIBILITIES FOR RESEARCH INVOLVING HUMAN SUBJECTS

1.1 There is no overriding legislative framework which specifically covers research work involving human subjects. There are, of course, statutes dealing with particular problems such as the Data Protection Act, the Mental Health Act, the Medicines Act, Human Tissue Act etc. A Research Ethics Committee (‘REC’) would be expected to abide by the requirements of these items of legislation. However, in general terms, it is the common law of negligence which would apply to the activities of a Research Ethics Committee and researchers, as it does to all activities which involve risk. There are of course legal statutes such as the Data Protection Act, the Mental Health Act, the Medicines Act and the Equality Act 2010. A Research Ethics Committee (REC) will be expected to abide by the requirements of statute law.

1.2 The general principle of negligence is deceptively simple: a person is liable for damage, injury or death caused by his or her acts or omissions the results of which should have been reasonably foreseeable. Therefore, it is essential that a person exercises the appropriate duty of care when carrying out his or her actions. However, the practical application of this legal principle is complex and is influenced by the often-ambiguous nature of the links in the chain of causation leading to particular events or results. The notion of ‘reasonable foreseeability’ can be remarkably elusive in legal argument. However, it is clear that a REC should be diligent in exercising a duty of care with regard to its proceedings and decision-making.

1.3 Liability arising out of negligence is always assessed in terms of the reasonableness of expectations as to the outcome of any act or omission and this would be measured against the procedures and preventative measures taken by the researcher, the REC (whose terms of reference and authority would be taken into consideration) and the institution – in this case the University. Since a REC is not a legal entity, liability would lie with its members jointly and severally. However, in practice, an injured party is more likely to sue the researcher whose work would be the immediate cause of injury or damage, or the institution which enables, allows or funds the research. The primary responsibility of researchers for negligent work can also be placed on students carrying out research under their supervision.

1.4 With regard to indemnity, members of the REC and researchers who are employees of Kingston University would be covered by insurance under Public Liability and Professional Negligence policies for any deleterious effects arising from their research work. This only applies where the research has been formally notified. Clearly, insurance can only protect both the University and its employees as far as material loss is concerned, it does not help with regard to the damage to the reputation of the University and the researcher which inevitably arises where negligence is attributed to a piece of research. If, during the course of research, matters arise which are likely to have reputational consequences for the University, advice should be sought from the FREC Chair and from the Director of Communications.

1.5 The following checklist should be taken only as a guide. It does not purport to replace sound legal advice. All researchers who are in doubt about their specific legal duties should make contact with the faculty committee concerned with research ethics in the first instance which may refer the matter to the University Research Ethics Committee and the University Secretary.

1.6 Potential Criminal Liability for your Treatment of your Human Subject
Where bodily contact is involved, for example, medical or health examinations are involved, the researcher must ensure that proper consent has been obtained. That consent must be informed consent, that is to say, it must be made clear to the human subject what that examination will entail. Transparency is vital. Where no consent has been obtained, the researcher could be held liable for assault, battery and/or other offences against the person.

Where medicines or foods are to be administered to the human subject, whatever the purpose of the administration, the researcher should observe that the Offences Against the Person 1861 provides that any person who unlawfully administers to or cause to be administered to or taken by any other person any poison or other destructive or noxious thing so as thereby to endanger the life of such person, or so as thereby to inflict upon such person any grievous bodily harm, commits an offence which is punishable with imprisonment. “Administer” refers to “conduct which not being the direct application of force to the [subject] nevertheless brings the noxious thing into contact with his body”. This includes the spraying of substances on a person’s face, underarms, fingernails etc. Informed consent from the subject should be obtained prior to the carrying out of any such tests but consent may not suffice where the experiment is unusual and infringes public policy, or likely to lead to serious harm.

Experiments involving nudity either of the researcher or his/her human subject should observe the provisions of the common law misdemeanor of ‘committing an act outraging public decency in public and in such a way that more than one person sees, or is at least able to see, the act. A wide definition has been applied to the term ‘public’ by the courts. It is a place where the public go, regardless of whether they have a right to be there or not. There is no need to prove any sexual motive or the intention to insult or annoy for the offence to be committed. All that needs to be established is as long as the person intended that or was reckless that the exposure might be seen by two or more persons who have not consented to see it. There is also a statutory offence of indecent exposure – section 4 of the vagrancy Act 1824 provides that “every person [who] willfully, openly, lewdly and obscenely expose[s] his person with intent to insult any female … shall be deemed a rogue and vagabond.” This offence is punishable by three months’ imprisonment or a fine. It cannot be committed by a female.

A person who publishes an obscene article whether for gain or not, or has an obscene article for publication for gain commits an offence under the Obscene Publications Act 1959. An obscene article is defined as – an article whose “effect or (where the article comprises two or more distinct items) the effect of any one of its items is, if taken as a whole, such as to tend to deprave and corrupt persons who are likely, having regard to all relevant circumstances, to read, see or hear the matter contained or embodied in it”. An ‘article’ includes any description of article containing or embodying matter to be read or looked at or both, any sound record, and any film or other record of or a picture or pictures”. An obscene publication offence is not necessarily confined to matters of ‘sexual depravity’, it could involve a publication which encourages certain sections of the community to experiment with dangerous substances (for example, particularly harmful drugs) etc. There are two known defences – the defendant had no reasonable cause to believe the article to be obscene and the publication was for the public good on the ground that it is in the interests of science, literature, art or learning, or of other objects of general concern. This is however not a carte blanche for researchers to publish ‘obscene’ articles. Opinions of experts as to the literary, artistic, scientific or other merits of an article may be required by the court and this opinion may not always support your cause. This is not an easy defence to raise, researchers beware!

Other offences involving obscene publications include:
(a) obscene libel

5 In reality, prosecutions are rare.
• A researcher should also take care when using computing systems belonging to a third party. Under the Computer Misuse Act 1990, it is an offence to gain or attempt to gain access to program or data held in a computer which is not authorized as long as the person is aware that he is so doing or attempting. This offence does not only apply to hackers but also to researchers accessing files from a subject’s computer database. Authorization must be sought. General authorisation is probably insufficient – the files you wish to access should be specified and clear authorisation (preferably in writing) should be obtained to avoid any dispute as to what was agreed and what was not between researcher and subject.

• Within the context of diversity and equality, researchers must take due care not to intentionally or unintentionally discriminate on grounds of Age, Disability, Gender Reassignment, Race, Religion or Belief, Sex, Sexual Orientation, Marriage and Civil Partnership, Pregnancy and Maternity. The University is opposed to discrimination based on human attributes and values listed above and will take appropriate disciplinary and/or legal action if discrimination occurs.

### 1.7 Civil Law Duties Owed to your Human Subject

• The researcher owes a duty of care to his or her human subject. Reasonableness is not a subjective test. This means that just because you, the researcher, think your actions are reasonable does not necessarily mean that you are, in fact and in law, acting reasonably. One good gauge of reasonableness is the norms and conventions accepted by your research fraternity or community as being reasonable. Ensure therefore that your methods are compliant with standards laid down by your peers. This duty of care applies not only during the course of your research, but continues as long as your human subject remains a ‘neighbour’. A neighbour is a person who, it is reasonably foreseeable, will suffer harm as result of your breach of duty. For example, long after you have completed your research, if the sensitive data you have collected of your subject is lost through your negligence and this causes harm or loss to him or her, you would be held liable.

• You should note that the law expects you to take your ‘victim’ as you find him or her. This is generally known as the ‘egg shell skull’ rule, that is to say, if you have breached your duty of care but given the unusual and sensitive nature of the subject’s physical or personal condition, the damage is far worse than would normally be the case, you are liable to that extent. For example, if you fail to take care when administering a test drug to your subject. Under normal circumstances, some pain would be caused, as a result, to the subject. However, your subject is particularly sensitive to the drug and suffers very severe pain. You are liable for that pain even though another subject might only suffer minor pain.

• As a researcher, especially if you are in the professions, it is not unlikely that your research findings might be sought after by a third party as professional or expert advice. The law imposes a duty on advisors or persons holding themselves out as advisors liable for the advice they give. If the following conditions are met, you could be liable for negligent misstatements:
  - your advice is sought for a purpose (this does not need to be direct face-to-face consultation – if, for example, you have a web site offering ‘advice’ or ‘tips’ that could suffice);
  - you know that your advice is likely to be communicated to the person seeking your advice or a class of persons of which that person belongs (for example, you offer...
advice to a group who have AIDS, who are members of your web based newsgroup or a forum you are addressing);

- you know that your advice is likely to be acted upon;
- your ‘subject’ acts on your advice and suffers loss or damage;
- A researcher is however not liable for statements made in his or her published works even if they are clearly erroneous. The law only makes the advisor liable when a ‘particular transaction ’ is involved (provided the above criteria are met). In order to protect yourself, always add a disclaimer to any ‘advice’ you dispense, especially, when the advice is sought because of your expertise or professional standing but that disclaimer must be reasonable.

- The publication of research findings might run foul of the laws of **defamation**. Defamation is defined as the publication of untrue and unwarranted statements about an individual which tend to lower that person’s standing in the eyes of right thinking members of society. Not only are private individuals protected but companies or other business entities where it could be demonstrated that their trading reputation has been damaged by the false and unwarranted statement. The **processing of data** is subject to the **UK Data Protection Act 2018 (DPA 2018)**. The following are the so-called data protection principles laid down under the Act. Personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless at least one of the following conditions is met:
  - the subject has given consent to the processing;
  - the processing is necessary because;
    - it is to facilitate the performance of a contract of which the subject is a party;
    - it is to comply with any legal obligation;
    - it is to protect the vital interests of the subject;
    - it is for the administration of justice;
    - it is for the exercise of any government functions;
    - it is for the exercise of any other functions of a public nature taken for the public interest by any person;
  - the personal data obtained must refer specifically to one or more specified purposes and shall not be processed in any manner incompatible with that purpose of those purposes;
  - the personal data obtained shall not be excessive in relation to the purpose/s as specified;
  - personal data shall be accurate and where necessary, kept up to date;
  - personal data processed for purpose/s specified shall not be kept for longer than is necessary for that purpose or those purposes;
  - personal data shall be processed in accordance with the rights of the subject as provided for in the Act;
  - appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data;
  - personal data shall not be transferred to a country or territory outside the European Economic Area unless that country or territory ensures an adequate level of protection for the personal data rights and freedoms of data subjects.

There are also special rules relating to the processing of sensitive data, i.e. data which relates to the racial or ethnic origin of the subject, their disability, their sexuality, their citizenship, asylum, or refugee status, their religion or belief, their political beliefs, membership of a trade union, physical or mental health, sexual life, criminal record etc.

It is clearly outside the remit of this handbook to offer specific and detailed advice of data protection laws. Any researcher who could be potentially affected should consult the relevant individuals and committees in the university. It would also be beneficial for the researcher to have a copy of the Data Protection Act [DPA 2018] in hand. The Act can be downloaded free of charge from [www.hmso.gov.uk](http://www.hmso.gov.uk).
1.8 The substantial or wholesale reproduction, adaptation or translation of works belonging to your subject without proper authorisation could be in breach of copyright law. Do not imagine that your subject must register his or her work with some agency before he or she could claim copyright. There is no such requirement at law. As long as the work is original and it is an “artistic, literary, musical or dramatic” work, it would be protected. If the researcher is to publish in his own work, works made by his subjects or other third parties, he or she must be careful to ensure that copyright law is not being infringed. It has been held that even the mere reproduction of a photograph, albeit in a smaller size and on a different medium, could constitute a breach of copyright as long as the photograph had been taken with skill and is original. Researchers, especially those in the arts and social sciences, are known to reproduce without clear, unambiguous authorisation, materials produced by their subjects in research publication. Such a wholesale reproduction can be in breach.

**Some examples of possible breaches**
- reproduction of a picture drawn by your subject;
- translation of a Spanish poem written by your human subject;
- copying and adapting a software program written by your human subject;
- reproducing a photograph taken by your subject and placing it on your webpage as an icon without consent or licence.

1.9 As far as contractual duties are concerned, please ensure that any contract (whether express or implied, oral or in writing) you intend to make with persons associated with your research is discussed with an appropriately qualified person in the University. Make sure you understand the terms of your own contract of employment before embarking on any particular research project.

**CAVEAT: THIS IS NOT A COMPREHENSIVE LIST OF LEGAL DUTIES TO WHICH YOU ARE SUBJECT. ANY QUERY SHOULD BE DIRECTED AT THE APPROPRIATE PERSON/COMMITTEE.**
APPENDIX 2: FURTHER REFERENCES AND BACKGROUND

FURTHER REFERENCES

Professional associations’ guidelines/Government and EU publications on ethical research and research committees:


(2004) Guidelines for conduct of research involving human subjects at NIH
(1979) The Belmont Report
(1949) Nuremberg Code


Royal College of Physicians (1996) Guidelines on the practice of ethics committees in medical research


Further reading: books


and Wilkins.


**Further reading: journal articles**


**Useful websites**

Association of the British Pharmaceutical Industry
http://www.abpi.org.uk

Association of Clinical Research Organizations
http://www.acrohealth.org/

Association of Directors of Social Services Research Group
http://www.adss.org.uk/research.shtml

Biotechnology and Biological Sciences Research Council (BBSRC)
http://www.bbsrc.ac.uk
British Association of Social Workers  
http://www.basw.co.uk

British Psychological Society  
http://www.bps.org

British Sociological Association  
http://www.britsoc.org.uk

Biotechnical and Biological Sciences Research Council (BBSRC)  
http://www.bbsrc.ac.uk

British Association of Social Workers  
http://basw.org

British Psychological Society  
http://www.bps.org.uk

British Sociological Association  
http://www.britsoc.co.uk

Bulletin of Medical Ethics  
http://www.bullmedeth.info/current

The Chartered Society of Physiotherapy  
http://www.csp.org.uk

Council of Europe Treaty Office  
http://conventions.coe.int

Directgov  
http://www.direct.gov.uk

Economic and Social Research Council (ESRC)  
http://www.esrc.ac.uk

Engineering and Physical Research Sciences Research Council (EPSRC)  
http://www.esprc.ac.uk

Office of Public Sector Information  
http://www.opsi.gov.uk

Health & Safety Executive (HSE)  
http://www.hse.gov.uk

Higher Educational and Research Opportunities (HERO)  
http://www.hero.ac.uk

International Conference on Harmonisation of Technical Requirements for registration of Pharmaceuticals for Human Use (ICH).  
http://www.ich.org

The Institute for Social Research  
http://www.soc.surrey.ac.uk

Medical Research Council  
http://www.mrc.ac.uk

New Scientist  
http://www.newscientist.com

Nuffield Council on Bioethics  
http://www.nuffieldbioethics.org
Patient Information Advisory Group (PIAG)
http://www.advisorybodies.doh.gov.uk/PIAG/

Qualidata: Qualitative Data Archive Resource Centre
http://www.esds.ac.uk/qualidata

Royal College of Nursing Research and Development Co-ordinating Centre
http://www.man.ac.uk/rcn/

Scottish Office
http://www.scotland.gov.uk

The Social Research Association
http://www.the-sra.org.uk

Social Services Research Group
http://www.ssrg.org.uk

UK Data Archive
http://www.data-archive.ac.uk

World Health Organisation
http://www.who.ch