Kingston University London

Ethics Guidance and Procedures for Undertaking Research Involving Human Participants

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Contents

Guidance

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 participants and emphasises the need to work within professional codes of conduct and legal statutes.

Section 2: Guiding Principles

2.1 Research involving human participants 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 wellbeing, 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. “Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects” (WMA 2013).

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 human rights legislation (e.g. 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 wellbeing 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 reviewers and 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 given that the 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 those ordinarily encountered in daily life. In 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 wellbeing 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 necessitate abandoning data collection.

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

- Non-discriminatory selection of participants based on inclusion criteria which allow 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 made at the time that the informed consent was obtained from participants.
- Adherence by researchers to research protocols agreed by the University and any Committees concerned with research ethics.
- Amendments to protocols should be submitted for review.

- 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 the 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. 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 Typically, consent should be obtained in writing, although verbal consent is acceptable in certain circumstances. Written consent is recommended for studies involving any 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 circumstances and methodological approaches where consent may not be obtained for justifiable reasons. Guidelines are available from professional bodies concerning such research approaches, and should be followed. The University Research Ethics Committee and the nominated Faculty Research Ethics Leads can provide further guidance on this matter. Covert research and deception is also addressed in 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. Limited autonomy 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. If you intend to interview school children and access will be facilitated via the school, you need to seek permission from the Head Teacher and secure a letter of agreement.

Pregnancy

- CIOMS/WHO[1] guidelines advise that “Research designed to obtain knowledge relevant to the health needs of the pregnant and breastfeeding woman must be promoted”. (WHO CIOMS 2016) For more information about special considerations in relation to research with pregnant or breastfeeding women, see Guideline 19 within these WHO/CIOMS guidelines.

[1] Council for International Organisation of Medical Sciences/World Health Organisation.

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 (2007) guidelines covering non-therapeutic and therapeutic research offer clear direction to researchers. It should be emphasised that proposals relating to hospitalised individuals should be submitted through the NHS research ethics review processes (advice on how to do this can be obtained from colleagues with relevant experience, please speak to your Faculty Research Ethics Lead). UREC requires that a favourable ethical opinion from an NHS committee must be lodged with our online review system.

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**

All research should conform with legislation related to data protection, specifically the UK General Data Protection Regulation (2018) the Data Protection Act (2018). Researchers should make clear to participants the nature of any promises regarding confidentiality or restrictions on the use of data. Unless agreed to the contrary in advance, information about participants is confidential.

Section 4: Safeguarding

4.1 Staff and students must at all times abide by and act in accordance with the university Safeguarding Policy. Full details of all safeguarding related information can be found on the university's Safeguarding page, and the StaffSpace Safeguarding page (internal for staff only).

4.2 Kingston University is committed to the safety and wellbeing of all students, staff, and visitors and has a legal duty to safeguard children, young people, and adults at risk. As lead of a research project you must ensure provision of a safe environment beneficial to work, study for everyone involved within your study, including collaborators, students, employees, and participants. That includes any research undertaken off-site, for which you should provide a risk-assessment, ensure travel is booked through the University travel agent and covered by our insurance and consider whether any risk is appropriate and has appropriate mitigations. At one end of the spectrum that may include ensuring that people do not travel alone, and

they have equipment to contact others if in difficulty, or, at the other extreme, rearranging fieldwork venues to avoid war zones. Safeguarding includes all risks e.g. sexual harassment and bullying as well as physical, discriminatory, mental and/or financial abuse. Staff and students must always abide by and act in accordance with the university Safeguarding Policy. Full details of all safeguarding related information can be found on the university's Safeguarding page.

4.3 Researchers should ensure that everyone involved is appropriately supported and directed to the Safeguarding Policy, including how to report safeguarding concerns. This must also be reflected within your research design and will be considered during the research ethics review process.

Section 5: Funding Agencies

5.1 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.

5.2 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[2]
- 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.
- 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.

[2] Normally the Faculty Deputy Dean.

Procedures

Section 6: Which Studies Require Ethical Review?

6.1 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.

6.2 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 human participants is required and this may be subject to audit.

6.3 Ethical review should be proportionate to the degree of risk involved. The ethical review process must be sufficiently rigorous to scrutinise any projects which have obvious ethical implications, whilst sufficiently flexible to allow for the quick processing of projects which employ low risk routine methodologies. Some projects that might be deemed to be evaluations of the kind that might be considered a normal part of the university's business may not need ethical review (e.g. assessing some teaching-related interventions); speak to your Faculty Research Ethics Lead for advice if you are uncertain. If in doubt, email KUREOS@kingston.ac.uk with your query. The University uses an online research ethics system called KUREOS (Kingston University Research Ethics Online System) through which research ethics applications are considered and reviewed at the appropriate level of scrutiny.

6.4 The pre-application checklist **below** should be used to determine whether ethical review is required:

- Is your work a *research* project?
- Will your research involve living human participants?
- Will your research involve data on humans?
- Will your research involve human biological material?

If your answer to the first question **and** to any of the other questions is YES, then a research ethics application must be submitted to KUREOS and a favourable ethical opinion received before the research project is conducted. Please refer to section 7.3 for details of how to deal with research conducted by taught students

6.5 Studies using human participants 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.

6.6 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 participants are not involved but there are still ethical concerns to be addressed, please contact your Faculty Research Ethics Lead in the first instance.

Projects reviewed by other institutions

6.7 For projects which have already been reviewed and received a favourable ethical opinion (FEO) by ethics committees outside of Kingston University (e.g. the NHS), the researcher still has a responsibility to log the FEO in KUREOS. A full application is not required, but the whole ethics application and supporting documentation must be uploaded.

Projects involving the NHS

6.8 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 review by an NHS Research Ethics Committee (REC) prior to commencement. For full details are available on the NHS HRA Research Ethics Service webpage. Applications to the National Research Ethics Service are made using the Integrated Research Application System (IRAS).

6.9 For Health Research Authority (HRA) guidance and decision tools please refer to Appendix 5: Health Research Authority (HRA) Guidance and Decision Tools.

User-testing of software

6.10 User-testing of software is not normally considered research and therefore does not require ethical approval. The user can be 'consulted' as part of practice evaluation. However, if it is the case that researchers want to collect the user testing data as the basis for a research study and/or a research paper (or part of) then ethical approval should be sought in advance. Please keep in mind that staff and students who invite people to engage in user testing, whether as research or otherwise should adhere principles of ethical practice.

Ethics queries

6.11 If after reading these guidelines together with those of any relevant professional or society bodies, any uncertainty exists about the need for ethical review, advice should be sought from your Faculty's Research Ethics Lead (FREL) for staff and students should ask their research supervisor.

Section 7: The Ethical Review and Feedback Processes

7.1 The pre-application checklist should be used to determine whether ethical review is required – see Section 6. Please allow sufficient time before you intend to commence your research project to submit your ethics application. It may take up to 20 working days for you to receive an initial response. You may then need to make a number of amendments and / or provide further information before you receive a Favourable Ethical Opinion.

7.2 **PGR Students and Staff**: For staff researchers and postgraduate research students, individual applications must be submitted via KUREOS. The review of all projects will be managed via KUREOS. 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).

7.3 **Students on UGT and PGT Programmes**: There are three potential routes for the ethical review of research projects by taught students (e.g. dissertations). They are:

A) Taught Module Route (non dissertation via KUREOS)
B) Dissertation Module Route
C) Independent Ethics Applications (high risk applications)

Module Leaders should follow the procedure outlined in Figure 1, with the first step being emailing KUREOS@Kingston.ac.uk the module guide / descriptor or equivalent information.

7.3.1 Route A – Taught Module Route

Route A applies only in very specific circumstances. More commonly, route B will be appropriate (see below). Route A is intended for the delegated review of low-risk research activities which use standard routine methodologies, typically for groups of students conducting common or very similar research activities as part of their studies. Taught Module Route (TMR) favourable ethical opinion is valid for up to five years. This means that any future projects which fall within the agreed parameters will not require an application from the module leader (unless specifically requested) and responsibility for ethical review will lie with the TMR holder. Projects which fall outside of the agreed parameters will require separate review. Projects may be audited to check that they do fall within the agreed parameters.

7.3.2 Route B –Dissertation Module Route (DMR)

Route B has been designed to meet the need of faculties to manage applications by taught students who conduct research dissertations. Such proposals are typically reviewed by supervisors and often require several re-drafts, a process that is not currently supported in KUREOS. To deal with these type of research applications, we have created a Word version of the KUREOS application called the Dissertation Module Route Form (DMRF) that students can complete and email directly to their supervisor for review. Favourable ethical opinion is granted by the module leader or supervisor. All student ethics documentation must be uploaded by the module leader/supervisor to a Sharepoint folder provided by a KUREOS Administrators.

7.3.3 **Route C – Independent Ethics Application**
This option will be used for ethics applications from taught students for research projects that are high risk or unusual and that require independent ethical review. This is the same route used by staff and postgraduate research students, i.e. it represents the "standard" KUREOS application process. This is likely to be exceptional for students on taught programmes, but where it is deemed necessary, students should apply by indicating their status on KUREOS: undergraduate student application; postgraduate taught student application; or postgraduate research student application.

7.4 **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 occur; for example, sometimes a funding body may require a provisional review before it will consider an application for funding. An application for a provisional favourable ethical opinion can be made via KUREOS. If the award is granted, then a full application is still necessary. 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 review is required, as this can be a lengthy process.

7.5 **Legal Responsibilities and Indemnity**: Attention is drawn to Appendix 1 Legal Responsibilities and paragraph 1.4 concerning indemnity.

7.6 **Local Research Ethics Review Meetings**: With the introduction of KUREOS, faculty-level meetings will only be held in exceptional circumstances for the purposes of the ethical review of particular high risk applications. Applicants may be asked to attend.

7.7 **Specialist Advice:** The advice of appropriate specialists may be sought in circumstances where the Faculty Research Ethics Lead or their nominee deems this necessary, but these individuals will not be involved in making the final decision.

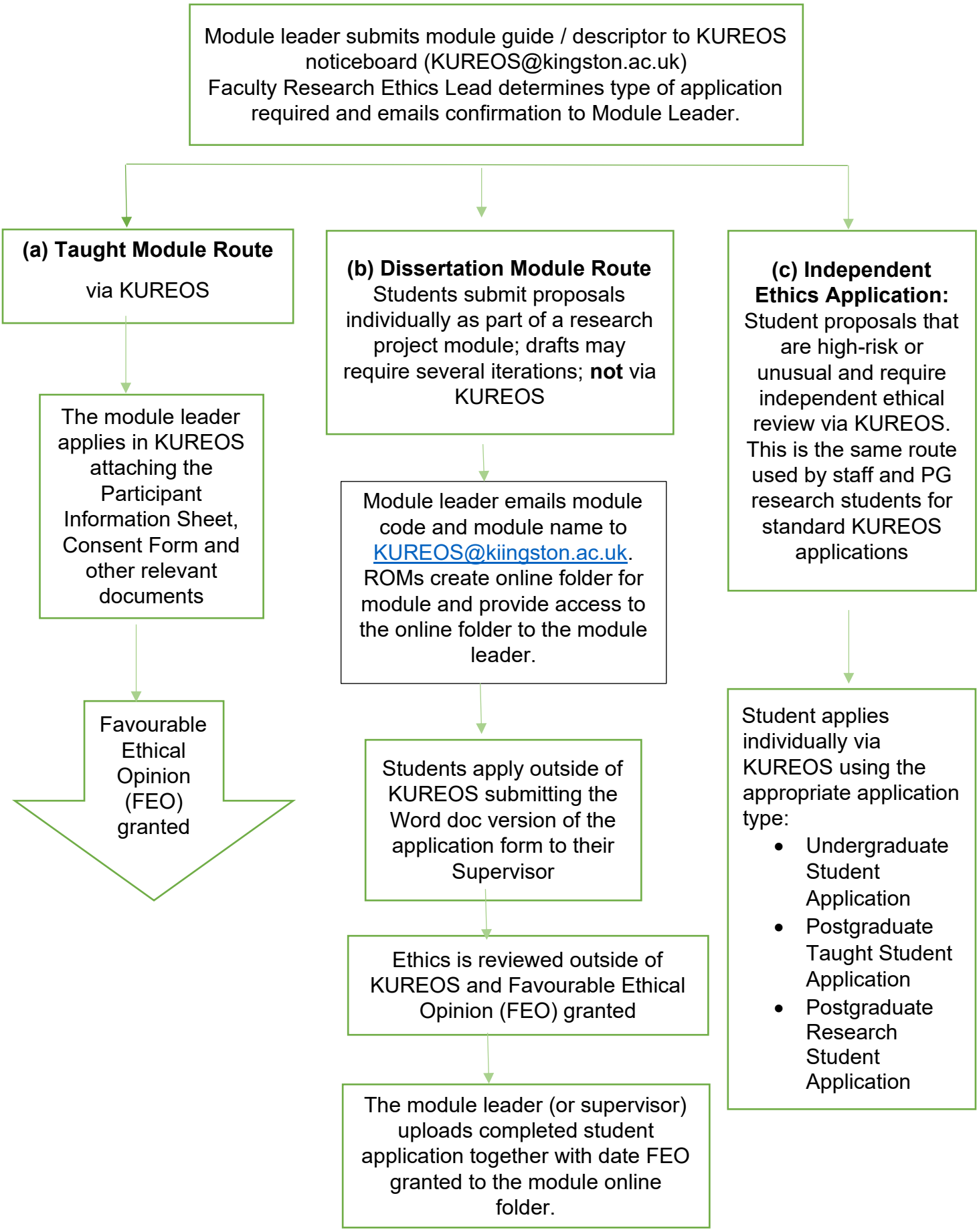
7.8 **Conditions and Resubmissions**: Applications submitted in KUREOS may receive a favourable ethical opinion or be rejected or require amendments. It may be necessary to defer a decision, in order to obtain a specific clarification, or to seek further advice about a proposal. Please note that if you are asked to make revisions to your KUREOS application, you have a maximum of three months to do so. After this period, the application will be termed 'out of time' and you will not be able to progress it further.

7.9 **Recording and Notification**: KUREOS is a paperless information management system for the completion, submission and storage of ethics applications. All relevant documentation is managed and stored within KUREOS so that a full audit trail is in place. In cases where a proposal does not receive a favourable ethical opinion, the applicant will be informed about their right to appeal.

7.10 **Appeals**: Applicants may appeal against a decision not to grant a favourable ethical opinion. Applicants should log onto KUREOS to log their appeal. Any queries regarding appeals should be emailed to KUREOS@kingston.ac.uk.

7.11 **Monitoring**: Following receipt of a favourable ethical opinion for a proposal, no changes should be made to the protocol or membership of the research team without submitting these changes for ethical review. 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 Faculty Research Ethics Lead to discuss whatever actions may be necessary to safeguard the welfare and interests of participants and/or researchers.

Figure 1: Flowchart of research ethics review processes for taught students



Section 8: Education and Training in Research Ethics: Opportunities for Staff and Students

8.1 Education and Training: Research Ethics

- **Research Supervisors**
  Research supervisor training is provided by the Graduate Research School and covers new and experienced supervisors. Such training includes updates on ethics policy and practice.

- **Academic Staff**
  Research ethics training is provided to new staff at Research Induction and at regular follow-up sessions that cover policy and procedures at Kingston University. All research-active staff are required to have attended research ethics training. This is now available online via the University's Epigeum suite of research training courses; two specific modules must be completed by those who intend to submit proposals (and by new reviewers): "Becoming an Ethical Researcher" and "Research Ethics in Practice", both part of the "Ethical Research" course, available via StaffSpace. Additionally, Faculty-level training is often available in order to address and disseminate discipline-specific issues relating to research ethics.

- **Undergraduate/ Postgraduate/ Research 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 Research School provides an introduction to ethics for research students as part of its generic research student training. PGR students are expected to complete the online training courses described above (accessible via MyKingston).

Appendices

Appendix 1: Legal Responsibilities for Research involving Human Subjects

1.1 There is no overriding legislative framework which specifically covers research work involving human participants. 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. research ethics reviewers 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 research ethics reviewers 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. Research ethics reviewers 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 their 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, Faculty Ethics Leads should be diligent in exercising a duty of care with regard to their decision-making processes.

1.3 The University's Clinical Trials insurance covers negligent conduct by researchers employed by the University, acting within their permitted remit, providing the research has been formally notified.

1.4 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 Clerk.

1.5 **Potential Criminal Liability for your Treatment of your Human Participant**

- 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 participant, whatever the purpose of the administration, informed consent should be obtained prior to carrying out the tests. Failure to do so could potentially be a criminal offence.

- Experiments involving nudity are best undertaken only within view of those involved with the project and with an understand of what it involves.

- Publication of an article which could be considered depraved or corrupt (e.g. pornographic) may be an offence under the Obscene Publications Act (1959).

- Ensure you have authorisation from a subject's computer database before accessing files. Failure not to may be a criminal offence 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.

1.6 Civil Law Duties Owed to our Human Participant

- The researcher owes a **duty of care** to his or her human participant. The legal expectation is that your conduct is consistent with that of other researchers operating in the same, or a field. You should therefore ensure that your methods are compliant with standards laid down by your peers. This duty of care continues beyond the end of a research project and applies to any conduct which could affect the participant.

- If you are asked to provide advice on a professional basis in relation to your research findings to a third party, you could be personally liable if the advice you give is incorrect, and leads to damage or injury. University insurance will not cover this situation.

- The publication of research findings may be defamatory if they contain untrue statements that could potentially damage the reputation of an individual or organisation.

- The **processing of data** is subject to the UK General Data Protection Regulations (2018) and the Data Protection Act (2018). 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. Researchers should complete data protection compliance training and follow university guidance on data protection (Staff and students).

1.7 The substantial or wholesale reproduction, adaptation or translation of works belonging to your subject without proper authorisation could be in breach of copyright law. Copyright works are not registrable if the work is original and it is an “artistic, literary, musical or dramatic” work, it would be protected. A researcher publishing works containing the works of others must ensure they have consent to do so.

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.

1.8 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 queries should be directly to the appropriate Faculty Research Ethics Lead.

Appendix 2: Education Research

1.1 Kingston University has authorisation for the use of student data for research purposes under its privacy notification

Under 'How we use your data' it states:

To manage the academic experience

- the provision of teaching, learning and research services (for example, registration, assessment, engaging with learning resources, managing progress, academic misconduct investigations and certification);
- maintaining student records;
- learning analytics including attendance;
- assessing your eligibility for bursaries, scholarships, and similar awards;
- **research (for example, academic research, evaluation research, student surveys and market research);**
- providing library, IT, and information services.

Therefore:

Academic staff can evaluate teaching provision using available student data as part of research or as practice/service evaluation, provided all data is anonymous/anonymised immediately post-download and no additional data is collected directly from students (in which case ethics approval must be sought as usual). Therefore, it is not a requirement that research ethics approval is needed to undertake education research. If you are adding an innovative component to the education delivery as part of research activity, the GDPR (General Data Protection Regulation) KU (Kingston University) team would recommend that you provide a specific privacy notice in CANVAS, stating how the information will be used, the lawful basis, any data sharing arrangement and how long data will be retained.

1.2 If you wish to publish education research using Kingston University student data, journals may well require ethics approval. The Chair of UREC (University Research Ethics Committee) can issue a letter saying research ethics approval is not required for this type of research as Kingston University has authorisation for the use of student data for research purposes under its privacy notification. You should obtain this letter prior to conducting the research.

This letter can only be written on the basis that:

- the data used for analysis and publication is completely anonymous;
- it is not possible to identify participants from any resulting report;
- use of the data will not cause substantial damage and distress.

1.3 If you wish to publish the university's identity there should be agreement from the Deputy Dean to do so if reputationally sensitive findings are to be shared.

1.4 You should check with the journal where you intend to publish your work as some journals may require explicit ethical scrutiny of your work to be published prior to your research being conducted. In addition, you may wish to obtain research ethics approval to ensure you are best placed to publish in the future. In these two cases you may submit for ethics approval and a review will be undertaken.

1.5 The BERA guidelines can be helpful for best practice in education research

Appendix 3: Using social media data in research

Recommended guidance can be found at UCL and University of York

Appendix 4: Autoethnographic Research

Recommended guidance can be found at Ryerson University, Canada and University of Arts, London (UAL).

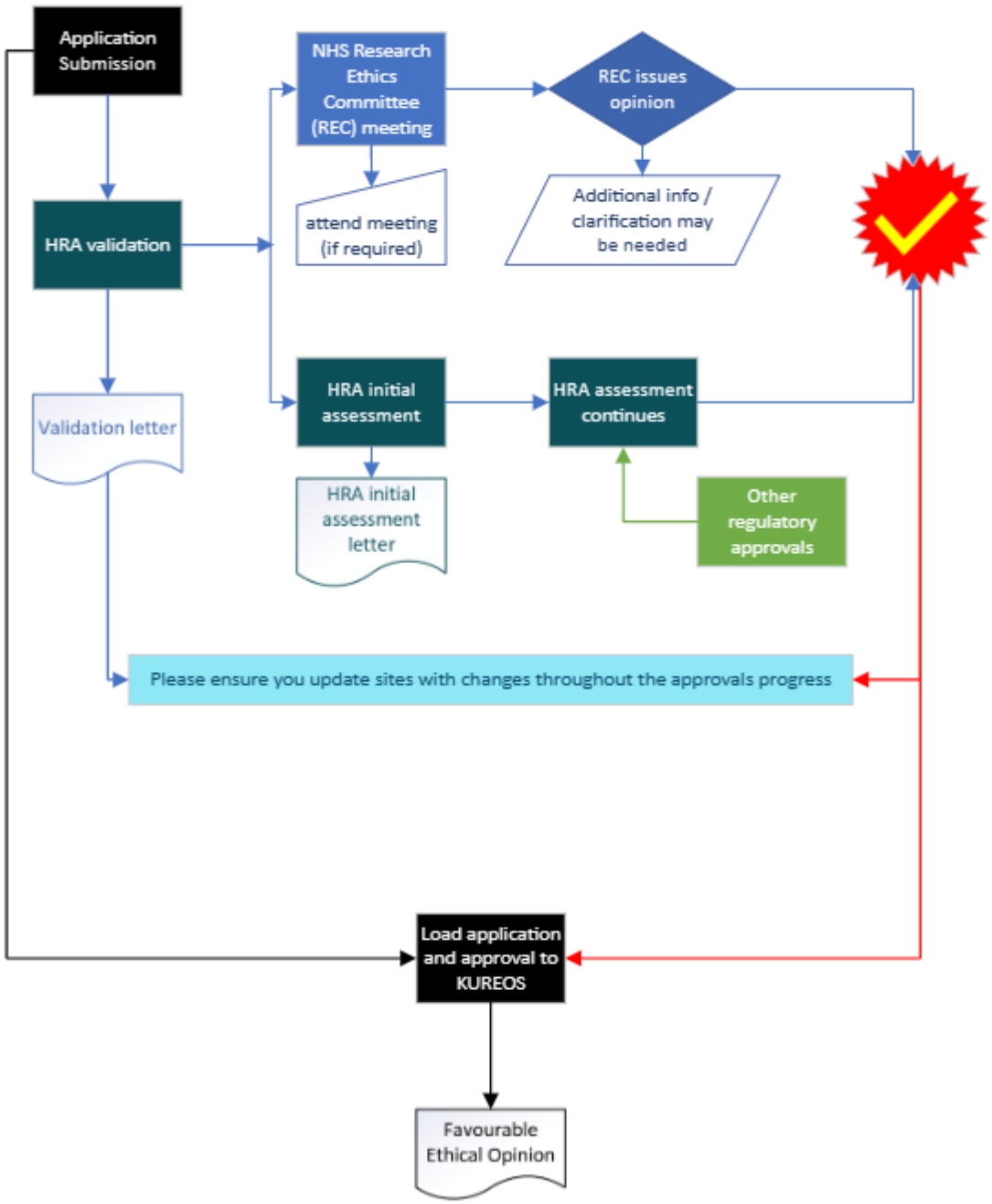
Appendix 5: Health Research Authority (HRA) Guidance and Decision Tools

Which Ethics committee to apply to

		Researcher	
		University Students	**University Staff**
Participant or Data	University Students	KUREOS	KUREOS may not be needed (see Appendix 2)
	University Staff	KUREOS	KUREOS
	NHS Trust Staff	HRA & KUREOS	HRA & KUREOS
	NHS Trust Patients	HRA & NHS REC	HRA & NHS REC
	Other Organisation	KUREOS & other Organisation's Process	KUREOS & other Organisation's Process

Please email KUREOS@kingston.ac.uk if you have any queries regarding your NHS research.

HRA / REC Approval



HRA Links

HRA decision tree - Is my study research?

Do I need NHS REC review?

Does my project require review by a Research Ethics Committee (REC)?

Student Guidance

Student research toolkit

Information to help you plan your student project

Appendix 6: Further References and Background

References

CIOMS (2022) International ethical guidelines for biomedical research involving human subjects. Geneva: Council for International Organizations of Medical Sciences.

Data Protection Act (2018)

General Data Protection Regulation (2018)

Health Research Authority (HRA) (2025) Research Ethics Committee – Standard Operating Procedures

NHS Health Research Authority (2021) Student Research

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Royal College of Physicians (2007) Guidelines on the practice of ethics committees in medical research involving human subjects, 4th edition

World Medical Association Declaration of Helsinki (2022) ethical principles for medical research involving human subjects.

Bibliography

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

The British Educational Research Association (2024), Ethical Guidelines for Educational Research, 5th Edition.

British Psychological Society, (2021) Code of Ethics and Conduct

British Sociological Association, BSA Statement of Ethical Practice 2017

The Health Research Authority (HERA), (2025), Research Ethics Committee – Standard Operating Procedures

Council of Europe (1997). CETs No. 164. Convention for the protection of human rights and dignity of the human being with regards to the application of biology and medicine. Oviedo: COE.

Department of Health (2003) The NHS confidentiality code of practice

Department of Health (2025), UK Policy Framework for Health and Social Care Research

Research Using Human Subjects, NIH (National Institute of Allergy and Infectious Diseases)

NHS Health Research Authority, Student Research, 2021

Royal College of Nursing Research Society (2004) Research ethics: RCN guidance for nurses. (Royal College of Nursing).

UKRI Policy on the Governance of Good Research Practice (GRP), March 2022

Useful websites

Association of the British Pharmaceutical Industry (abpi)

Association of Clinical Research Organizations (ACRO)

Biotechnology and Biological Sciences Research Council (BBSRC)

British Association of Social Workers (BASW)

British Psychological Society

British Sociological Association (BSA)

The Chartered Society of Physiotherapy

Council of Europe Treaty Office

Economic and Social Research Council (ESRC)

Engineering and Physical Research Sciences Research Council (EPSRC)

Health & Safety Executive (HSE)

International Conference for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)

Medical Research Council (MRC)

Nuffield Council on Bioethics

Royal College of Nursing, Research and Innovation

Social Research Association (SRA)

UK Data Archive

World Health Organisation (WHO)

Document History

Author	Research Operations Manager
Authorised	
Dissemination routes	Faculty Research Ethics Leads and Faculty Research, Business and Innovation Committees