RESEARCH ETHICS HANDBOOK FOR RESEARCH ETHICS COMMITTEES

UNIVERSITY RESEARCH ETHICS COMMITTEE

UNIVERSITY OF CAMBRIDGE

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UNIVERSITY RESEARCH ETHICS COMMITTEE

UNIVERSITY RESEARCH ETHICS COMMITTEE

The University Research Ethics Committee (UREC) is the overarching Committee at the University of Cambridge for the consideration of ethical issues arising from research that involves human participants and personal data.

The remit of the UREC includes:

- Devising and implementing University policy as regards the ethics of research involving human participants or personal data, including the establishment of specialist sub-committees, where appropriate, to cover specific areas
- Overseeing and reviewing the work of School and Departmental-level research ethics committees
- Acting as a reviewing committee for especially complex ethical cases and hearing appeals against local committee decisions
- Reporting annually to the General Board on matters within its remit

For queries, please contact the research governance and integrity team at researchethics@admin.cam.ac.uk

Full details of the remit and membership of UREC can be found here:
https://www.research-integrity.admin.cam.ac.uk/university-research-ethics-committee

UNIVERSITY POLICY ON THE ETHICS OF RESEARCH INVOLVING HUMAN PARTICIPANTS AND PERSONAL DATA

POLICY ON THE ETHICS OF RESEARCH INVOLVING HUMAN PARTICIPANTS AND PERSONAL DATA

1. Policy Statement

1.1 The University is fully committed to the advancement of high quality academic research and to ensuring that all activities undertaken by University employees, or on University premises, involving human participants and/or personal data as the subject of research are undertaken in a way that safeguards the dignity, rights, health, safety, freedom of expression and privacy of those involved. This commitment extends to participants, researchers, students and third parties.

1.2 The University expects its employees, or any other person conducting research on University premises, to abide by the University's normal expectations of good practice in research and to take all reasonable steps to ensure that ethical conduct of research involving human participants and personal data is observed at all times. This includes research undertaken outside the University and overseas by University employees and students when conducted within the course of their employment and/or studies at the University of Cambridge. To facilitate this, the University will:

a) Foster a research culture that embraces the principles set out in this Policy as well as all obligations set out in relevant legislation governing the protection of the dignity, rights, safety, freedom of expression and privacy of those involved in research

b**)** Provide clear and easily accessible guidance on best ethical practice and regulatory requirements;

c) Offer support and training to staff and students and any others engaged in University research projects to maintain awareness and high ethical standards;

d) Maintain an ethical review process that enables research projects to be subject to a level of scrutiny in proportion to the ethical risk;

e) Maintain an oversight of the policies and practices of Department, Faculty, School or equivalent-level Ethics Committees and to take appropriate action where there is evidence that the University's policy is not being followed.

1.3 This policy should be read in conjunction with the University's Good Research Practice Guidelines and the University Research Integrity Statement.

2. Guiding Principles

2.1 The University recognises that ethical issues raised by research and the understanding of research ethics varies considerably across disciplines and that Schools will necessarily have differing approaches to ethical review and the framing of ethical guidance. Set out below are the broad principles that the University generally expects its researchers to abide by. Given this, subject specific guidance should be obtained by researchers from their Department, Faculty or School.

a) **Risk of harm to research participants must be minimised** in line with department guidance. Participants should be warned in advance about any potential risks of harm. Where the risk of harm to research participant is considered by the researcher to be warranted (e.g. as result of disclosure of criminal activity or public corruption) researchers should seek advice.

b) Any non-harmful burdens to participants (e.g. travel expenses, inconvenient study site, invasive questions/ procedures, a lengthy study duration etc.) involved in research should be minimised. If a less burdensome means of conducting research is not feasible, the participants should be appropriately informed of the burdens involved.

c) **Researchers are required to consider the ethical risk of any procedure within a research project which involves human participants or personal data**, consulting relevant Faculty, Department, School and University policies and, if necessary, personnel before any work is undertaken. Advice should be sought in case of doubt.

d) Where more than minimal ethical risk is identified, reasonable independent ethical review (which may be expedited review where appropriate) must be carried out prior to research work commencing.

e) **Significant risks that become apparent during research should be communicated** to the appropriate person which may include the Chair of the relevant Research Ethics Committee and/or other relevant personnel. Advice should be sought as necessary.

f) **Researchers must respect a participant's right to withdraw from active** participation in research without adverse consequences to the participant. In some circumstances, for instance where the participant opts to withdraw after the data has been aggregated and can no longer be related to the individual, retaining the data will be unavoidable.

g) In general, i**nformed consent must be obtained from any participants in research** at an appropriate point in the research process. Projects in which informed consent is impracticable due to the nature of the research or participants must undergo the appropriate ethical review process. Participants and research staff should be informed of the purpose, methods and intended use of the research.

h) Research must be designed, reviewed and undertaken in a way that maintains academic **independence, integrity and quality.**

i) Research methods and the process of ethical review should be **open, independent and transparent.**

j) Research should be carried out consistently with all relevant principles set out within current UK law.

k) **University sponsored research carried out overseas must uphold the University's ethical standards**. Research must adhere to local expectations, practices and laws, without compromising University standards.

l) **Confidentiality of information given by participants, and the anonymity of participants, must be respected** at all times and documentation protected accordingly except where participants have agreed otherwise or disclosure is required by law.

m) While anonymisation of stored research data is encouraged, it should be recognised that this does not guarantee privacy and consequently every effort should be made to ensure **effective protection of stored data which is private and confidential.**

n) Research involving participants **under the age of 18, vulnerable groups and those lacking the capacity or opportunity to consent requires specifically considered protection**, including appropriate ethical review. Research involving vulnerable participants should only be undertaken when a project cannot reasonably be carried out with non-vulnerable participants or where the research has the potential to benefit that vulnerable group. **Researchers undertaking such research should also be aware of and abide by the University's** Children and Vulnerable Adults Safeguarding Policy and the Mental Capacity Act. In cases where a vulnerable participant over the age of 18 lacks the capacity to consent, researchers must seek review from the Health Research Authority (HRA).

3. University Ethical Review Process

3.1 The University is committed to providing a rigorous and independent ethical review process that is proportionate to the potential risk.

3.2 The University recognises that in many cases independent ethical review will not be necessary. However, it expects all researchers embarking on research involving human participants or personal data as the subject of research to consider the ethical risks of their work consulting, where necessary, with their Supervisor, Faculty and/or Departmental policies and/or the Departmental/Faculty staff member identified as responsible for research ethics.

3.3 Any project that is identified at the outset (by the researcher, supervisor, Faculty or Department) as raising significant ethical risks should be referred to the appropriate local Research Ethics Committee in the first instance. Where local review is not available or insufficient, review should be sought at a School level.

3.4 Research that requires review by an external body, such as the HRA, should be identified and referred to that body as early as possible in the review process. The Clinical School Research Governance team will provide up-to-date guidance to assist this process.

3.5 Local and School-level Research Ethics Committees may review, and give favourable opinion to projects through 'light-touch' expedited review (e.g. by the chair), checklist review or through full Committee review. Ethical review

need not be exhaustive, but it should be reasonable and proportionate to any perceived risk. Committees should ensure timely review and provide applicants with clear guidance on the likely timetable for review. Any agreed timetable should allow for flexibility where this is required to ensure the quality of the review

3.6 In accordance with good practice, Research Ethics Committees should consult with Committees operating in cognate areas, and also refer projects that are beyond their expertise to a more appropriate ethical review group.

3.7 All applicants intending to carry out research using human bodies, organs and/or tissue and identifying information derived from it, whose work does not come under the remit the HRA, **must** seek ethical approval in proportion to the level of risk and comply with the Human Tissue Act (2004).

3.8 Where local Research Ethics Committees consider that they are unable to provide the level of necessary review they will normally be expected, in the first instance, to refer the case to the relevant School-level Research Ethics Committee. Where circumstances make it impossible for a School-level Committee to review a project, typically when the project is beyond the expertise of the Committee members, this case should normally be referred immediately to the Secretary of the University Research Ethics Committee. The University Research Ethics Committee expects such occurrences to be rare and will expect that School-level Committees, in their constitution and procedures, meet the standards necessary to enable them to provide ethical opinion for all forms of research in their field.

3.9 A researcher may appeal the decision of any local and/or School-level Research Ethics Committee on any of the following grounds:

a) That there existed material circumstances relating directly to the case of which the reviewing committee was not aware;
b) That procedural irregularities occurred in the review process, which were of such a nature as to cause reasonable doubt as to whether the Committee would have reached the same conclusion had the irregularities not occurred; and
c) That there is demonstrable evidence of prejudice, bias, inadequate review or review which does not comport with the standards of proportionality and reasonableness required by this Policy.

Under any of these circumstances, an appeal may be made to the University Research Ethics Committee within the time limit and arrangements set out on the University Research Ethics Committee website or available from the Committee Secretary. If the University Research Ethics Committee are of the view that a complaint does not fall within any of the grounds specified above, they will dismiss the complaint and inform the complainant accordingly. Dissatisfaction with the decision of a local or School-level Research Ethics Committee alone is not sufficient grounds for appeal.

3.10 The University Research Ethics Committee may also review the decisions of a local or School-level Research Ethics Committee without referral or appeal where there are grounds for reasonable doubt concerning the appropriateness or correctness of a decision made by a Research Ethics Committee. This might, for example, be where subsequent information becomes available, either through documentary evidence or through a whistle-blower.

3.11 Complaints, or expressions of concern about research ethics at the University, can also be made to the University Research Ethics Committee, which will refer cases to the University's Misconduct Procedures when appropriate. The Committee welcomes approaches from whistleblowers with information concerning research ethics at the University. Staff are protected under the University's 'Whistleblowing' Policy.

3.12 To ensure a consistency of standard and approach, the University Research Ethics Committee will monitor the ethical review system through receipt of annual reports from all University Research Ethics Committees.

3.13 Serious cases of a failure to apply for ethical review where required or the breach of the approved terms of a project may be addressed through the University's established misconduct procedures.

4. Areas of responsibility for ethical review

4.1 Both the individual researcher and the University have responsibilities in ensuring the ethical conduct of research.

4.2 Individual researchers must take personal responsibility for the conduct of their research. The University expects researchers to familiarise themselves with this policy and accompanying guidance, as well as any subject specific material. Researchers undertaking a project that involves human participation or personal data that requires ethical review must not begin their research project until favourable review has been obtained. Advice should be sought where necessary.

4.3 It is the responsibility of supervisors of students or Principal Investigators (as appropriate) undertaking research to ensure that their students become familiar with this policy and accompanying online guidance.

4.4 It is the responsibility of Heads of Department and Chairmen of Faculty Boards to ensure that members of staff and students, and other researchers with privileged access to the Department's premises and facilities, are aware of this policy and also for ensuring the effective implementation of the ethical process in their academic institution.

4.5 Local and School-level Research Ethics Committees are responsible for ensuring that proposals referred to them receive valid, sufficiently comprehensive, independent and timely ethical review. Research Ethics Committees may also advise, where appropriate, on the wider ethical issues raised by research projects and their potential outcomes (for example dissemination, data use and archiving).

4.6 The University Research Ethics Committee has overall responsibility for the implementation of this policy. It will also offer advice on best practice in research ethics training. The Committee will report to the General Board annually and will recommend any changes that are considered necessary in the light of experience.

5. Application of the policy

5.1 This policy will apply to all members of staff and students at the University involved in:

a) Research within the course of their employment and/or studies at the University of Cambridge;
b) University-led research studies whether or not the research is conducted on the University premises or using the University's facilities;
c) Research studies which are led by other institutions except where there is a collaboration agreement that researchers will adhere to the lead institution's policies and these policies are sufficiently robust to meet the University's standards and expectations

5.2 The policy will also apply to other persons engaged in a University-led research project who, as a condition of being granted access to University facilities or premises, have agreed in writing that this policy will apply to them.

Policy review

6.1 As part of the University's commitment to ethical research, this policy will be reviewed every 3 years, or more frequently in the event of a major policy change by a significant stake-holder or the identification of a significant

weakness in the policy as it stands.

Policy Owner: Secretary of the University Research Ethics Committee
Date Last Reviewed: July 2020
Date of Next Review: July 2023

RESEARCH ETHICS REVIEW APPEALS PROCEDURE

UNIVERSITY OF CAMBRIDGE RESEARCH ETHICS REVIEW APPEALS PROCEDURE

A. Background

i. The University is committed to advancing high quality academic research and ensuring that any research activities which involve human participation or personal data are undertaken in such a way that the dignity, rights, health, safety, and privacy of those involved are safeguarded. As part of this commitment, the University has established a procedure to allow appeal against the decisions of local and School-level Ethics Committees.

ii. This procedure applies to all University staff and students engaged in a research project to which the University's Policy on the Ethical Conduct of Research Involving Human Participants and Personal Data applies, and to other persons engaged in a University-led research project who, as a condition of being granted access to University facilities or premises, have agreed in writing that the policy will apply to them.

iii. A researcher may appeal the decision of any local and/or School-level Research Ethics Committee on any of the following grounds:

a) That there existed material circumstances relating directly to the case of which the reviewing committee was not aware;
b) That procedural irregularities occurred in the review process, which were of such a nature as to cause reasonable doubt as to whether the Committee would have reached the same conclusion had the irregularities not occurred;

c) That there is demonstrable evidence of prejudice, bias, or inadequate review.

iv. If the University Research Ethics Committee are of the view that a complaint does not fall within any of the grounds specified above, they shall dismiss the complaint and shall inform the complainant accordingly. Dissatisfaction with the decision of a local or School level Research Ethics Committee alone is not sufficient grounds for appeal.

B. Appeal procedure

i. If a researcher wishes to appeal the decision of a Research Ethics Committee, he or she should notify the Secretary of the University Research Ethics Committee within ten working days of being notified of that decision. The appeal should be sent to the address given on the University's Research and Research Ethics websites. If significant new information concerning the project comes to light after this date, the researcher should approach the initial reviewing REC in the first instance.

ii. An appeal should be submitted in writing and must include:

- The title of the research proposal, and name of the supervisor, if appropriate
- The name of the Research Ethics Committee to which it was submitted and the date of the decision to be appealed
- The reason for the appeal
- Any documentary evidence to support the appeal.

iii. The University Research Ethics Committee Chairman will decide on a case by case basis whether the appeal will be dealt with electronically or in person.

iv. The Committee will co-opt experts if deemed necessary.

v. The Secretary shall obtain all relevant information from the Secretary of the Committee(s) that made the initial decision and circulate it to all University Research Ethics Committee members. The researcher and the Committee(s) that made the initial decision will also be required to provide any additional information relevant to the case for consideration by the University Research Ethics Committee. Up to fifteen working days from receipt of the appeal will be allowed for the gathering of this information.

vi. The Secretary shall ensure that any institutional obligations and/or relevant contractual obligations to research funding bodies and partner institutions are met, which may include notifying them of the appeal and its outcome.

vii. In any case that involves allegations of misconduct, in accordance with the University's established procedures, the Secretary shall ensure that the Academic Secretary is fully aware of the appeal.

viii. The University Research Ethics Committee will deal with requests for appeal with all reasonable expedition. The Secretary shall set a deadline for the completion of the appeal process and, where appropriate, provide a date for the Appeal hearing, and inform the appellant accordingly. ix. Both the researcher and the secretary of the Research Ethics Committee involved will be notified of the result in writing.

x. Those making an appeal to the University Research Ethics Committee are protected by University policies on victimisation and harassment: http://www.admin.cam.ac.uk/offices/hr/policy/dignity/procedure.html .

Approved October 2012
Date of next review: n/a

Version 1.0

GUIDANCE ON ETHICAL REVIEW PROCEDURES

GUIDANCE ON ETHICAL REVIEW PROCEDURES

1. Overview

1.1 The University of Cambridge expects all researchers to consider any ethical implications imposed by their research.

1.2 Research involving human participants and personal data will in many cases require more formal ethical review, either through a research ethics committee or an agreed 'light-touch' review process.

1.3 It is the responsibility of departments, faculties and schools to decide within their own ethical review processes which types of human participant or personal data research will require full ethical review and which will be subject to a light-touch process.

1.4 Departments/ethics committees should also decide which formats[1] of ethical review can be provided within the department/faculty depending on local needs and capacity.

1.5 The ultimate responsibility for ethical decision-making and the management of a research project rests with the lead researcher. Any researcher who is unsure whether their proposed research requires ethical review should seek further advice.

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[1] In doing so, ethics committees may wish to consider whether studies involving re-use of data collected from human participants (see Research Ethics Guidance 2) and/or substantial amendments can be handled by light-touch ethical process.

1.6 Student researchers should initially discuss their proposal with their supervisor. Principal Investigators and supervisors should, in the first instance, check the ethical review procedures of the relevant ethics committee and, as needed, seek advice. The lead researcher, or supervisor in the case of student research, has the responsibility for seeking the appropriate level of ethical review in light of the ethical considerations raised by their research.

1.7 Although this document has been prepared by the University Research Ethics Committee as guidance/advice for local Cambridge research ethics committees on the types of ethical review, enacting this guidance is not a requirement for compliance with the University Policy on the Ethics of Research Involving Human Participants and Personal Data. The UREC does not expect ethics committees to offer any additional types of ethical review.

1.8 As such, it is recommended that researchers consult local guidance and procedures to understand the type of ethical review that is conducted within their Department or Faculty.

2. Research that does not normally require formal ethical review

2.1 The following types of projects involving human participants and personal data will not normally require ethical review, unless otherwise specified by departments and faculties or by requirements of funders or other external stakeholders:

- **Activities that are not classed as 'research**'[2], for example routine audit or service evaluation (see section 7 for further discussion), and development of teaching materials that do not embody original research.
- **Research involving information that is already public in nature including evaluation and opinions based on this.**
- **Non-relevant human material**[3]. Research using acellular human samples that are not classed as 'relevant material' under Human Tissue Act does not require ethical review.

2.2 Deciding whether information is 'public' is not straightforward and requires careful thought. Some information, including some personal data, may be clearly public, for example information published in books, journals or newspapers. Other information, for example personal data collected by the researcher through a questionnaire, is clearly not public.

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[2] As set out in the UUK *Concordat to Support Research Integrity*, 'research' is here defined as "a process of investigation leading to new insights, effectively shared".

[3] For instance, acellular materials include human serum, platelet-free plasma, DNA/RNA and cell lines.

2.3 In some cases, however, the status of a particular set of data may not be clear. This is particularly true of personal data posted on a social media platform. Such data may formally be public (i.e. can be accessed without restriction), but the data subjects themselves may consider that data to be private and have reasonable and overriding expectations that it would not be used in research.

2.4 Where the 'public' nature of information is in doubt at least light-touch ethical review may be required. The responsibility for undertaking ethical research remains with the lead researcher and, as such, they should seek ethical advice when in doubt to ensure that ethical review is sought as appropriate.

2.5 Further exemptions[4] may be agreed by departments, faculties and Schools, provided compliance with the University Policy on the Ethics of Research Involving Human Participants and Personal Data is maintained. Departments, Faculties and Schools may also require ethical review for the types of project listed under 2.1 above where appropriate.

3. Light-touch ethical review

3.1 Unless subject to an exemption, such as those set out in 2.1, or agreed by the relevant Department, Faculty or School, it is normally expected that research involving human participants or personal data will be subject to at least light-touch ethical review.

3.2 Light-touch ethical review is a type of ethical review that may be used by some departments and ethics committees to facilitate the ethical review of projects that pose minimal ethical risk[5].

3.3 Light-touch ethical review is designed to:

- provide proportionate and timely consideration of research projects that pose minimal ethical risk
- identify any research that poses more than **minimal ethical risk** (which would normally be escalated for full ethical review – see section 5)

3.4 Departments/ethics committees may use their own judgement and prepare bespoke rules to establish what type of research can be reviewed by their light-touch mechanism.

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[4]] For instance, the School of Clinical Medicine has approved two exemptions from University ethical review for research that fulfils specific criteria and undergoes an appropriate governance check

[5] Minimal ethical risk is a risk no greater than the level of risk research participants are likely to encounter in their normal lives (see 3.11-3.12 for a further discussion).

3.5 As a guide, the University Research Ethics Committee recommends that research that involves any of the matters listed below are not appropriate for light-touch ethical review and should be subject to full review (see section 5):

a) Vulnerable participants (including participants under 16 years old).
b) Research for which the permission of a gatekeeper is required for access to participants.
c) Intrusive interventions or data collection methods, including use of bodily materials, medical imaging, DNA/RNA analysis or the administration of drugs, placebos or food.
d) Research involving the questioning of participants about intimate topics.
e) Research that has the potential to cause physical or psychological stress or discomfort or cause harm or negative consequences beyond the risks encountered in normal life.
f) Research conducted without a participant's valid and informed consent (unless subject to 2.1b) above). This includes any research that involves deception of participants (as informed consent cannot be obtained for such studies).
g) Participation of members of the public in the collection of research data (i.e. members of the public acting as researchers).
h) Sharing of private datasets beyond the default conditions of use (set by, for example, the initial consent given).
i) Research that may expose participants to a risk of legal or disciplinary action.
j) Research for which participants are provided with significant incentives to encourage participation.

3.6 Light-touch review can take a variety of forms, for example, self-assessment review, supervisor review and expedited review.

3.7 **Self-assessment review**[7] is a written self-assessment by the lead researcher. This may use an agreed form providing a set checklist of questions to assess the level of risk, signing an agreed declaration that a project meets the agreed local definition/description of a minimal ethical risk project, or a less formal process Self-assessment review inevitably places the responsibility of deciding whether a project poses more than minimal risk with the lead researcher.

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[7] It is not necessary for a research ethics committee or department to undertake detailed checking of the decision making of lead researchers, although some form of occasional audit may be beneficial

3.8 In the case of student research posing no or minimal ethical risk it may be appropriate for review to be carried out by the supervisor (**supervisor review**). Local research ethics committees or departments may wish to produce guidance for supervisors undertaking such review.

3.9 **Expedited review** is the review of research posing no or minimal ethical risk by a single member of the ethics committee, sometimes, but not necessarily, the Chair. In clearly justified circumstances (for example when there are external drivers beyond the control of the researcher that require faster review), expedited review may also be used to review research that poses more than minimal ethical risk.

3.10 The UREC notes that some ethics committees may undertake the majority or all of their reviews through expedited review (on the basis that the majority or all of their applications pose no or minimal risk). Such committee should, however, ensure that they have a process for handling projects that pose more than minimal ethical risk (either internally by the committee or through referral to another committee).

3.11 To meet the standard of 'minimal ethical risk' a project should generally pose no greater ethical risk to research participants (if any) than they would likely encounter in their normal lives. Risk is generally judged by the potential seriousness of the foreseeable harm to participants posed by the project and the likelihood of that harm materialising.

3.12 The level of ethical risk that a participant would encounter in their normal lives will, of course, vary according to the participants involved. The following illustrative examples are provided to highlight research that raises minimal ethical risk.

Example 1: A research study proposing to interview and publicly criticise politicians about their policies is likely to be judged as of minimal ethical risk since politicians might encounter public criticism on a regular basis. However, if the research proposed to publicly expose a member of the public to similar scrutiny in a way that they would not normally encounter then this would not normally be considered minimal ethical risk.

Example 2: A student research project proposing to interview individuals about their careers might be considered minimal ethical risk as these would be the sorts of questions they might encounter in everyday life, but if the interview also included questions pertaining to their sexuality or political beliefs the project would not normally be considered minimal ethical risk. Please note that if participants are recruited from the NHS, the project will require HRA approval even if it is minimal risk.

4. REC-approved procedure

4.1 Ethics committees may also develop REC-approved procedures[8] for certain forms of commonly occurring research involving more than minimal ethical risk.

4.2 A 'REC-approved procedure' will set out procedures designed to minimise the risk of a particular, commonly encountered, type of research. It is designed to avoid the need for full ethical approval of projects for which there are 'standard' procedures that can be adopted in most cases.

4.3 REC-approved procedures are only suitable for types of research project for which the risk of which can be appropriately minimised through the use of standard procedures (for example non-invasive research with children in mainstream school settings). There should be clear criteria for when a protocol can be used.

4.4 The requirements of a REC-approved procedure will vary according to the research concerned, but may include: training of research staff, set recruitment methods, procedures for informed consent, actions required to minimise risk to participants and researchers and monitoring and reporting of adverse events.

4.5 To be covered by a REC-approved procedure, researchers must be able to implement the procedures set out within in full and without variation. Where a researcher is able to follow the standards set by a REC-approved procedure a light-touch review (i.e. by self-assessment, chair's action or supervisor review) may be appropriate. The light-touch review should include confirmation of which REC-approved procedure is to be followed.

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[8] REC-approved may be designed by the research ethics committee (see, for example, the following following approved procedures in use at the University of Oxford) or committees may adopt guidance documents developed by externally, for example guidance or codes developed by professional bodies.

4.6 REC-approved procedures may be developed or adopted independently by departmental and school-level research ethics committees (there is no requirement to submit protocols to the UREC for approval). The UREC will maintain oversight of protocols by requiring that all protocols used by departmental and school-level research ethics committees are submitted as part of annual reports to the UREC.

5. Full Ethical Review

5.1 Where a project poses more than minimal ethical risk[9], full and proportionate ethical review by an appropriate ethics committee will normally be required before research work can commence (unless subject to the exceptions set out in 2.1 above or handled by a REC-approved procedure as set out in section 4)

5.2 As noted in section 3.4, departments/ethics committees should develop their own approach for deciding which projects can be reviewed by light-touch processes and which require full review. As a guide, however, the University Research Ethics Committee expects that justification would be needed for not requiring full ethical review of research involving the following (unless covered by an appropriate REC-approved procedure (see section 4):

a) Vulnerable participants (including participants under 16 years old).
b) Research for which the permission of a gatekeeper is required for access to participants.
c) Intrusive interventions or data collection methods, including use of bodily materials, medical imaging, DNA/RNA analysis or the administration of drugs, placebos or food.
d) Research involving the questioning of participants about intimate topics.
e) Research that has the potential to cause physical or psychological stress or discomfort or cause harm or negative consequences beyond the risks encountered in normal life.
f) Research conducted without a participant's valid and informed consent (unless subject to 2.1b) above). This includes any research that involves deception of participants (as informed consent cannot be obtained for such studies).
g) Participation of members of the public in the collection of research data (i.e. members of the public acting as researchers).
h) Sharing of private datasets beyond the default conditions of use (set by, for example, the initial consent given).

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[9] To meet the standard of 'minimal ethical risk' a project should generally pose no greater ethical risk to research participants (if any) than they would likely encounter in their normal lives. See 3.12 for illustrative examples.

i) Research that may expose participants to a risk of legal or disciplinary action.

j) Research for which participants are provided with significant incentives to encourage participation.

5.3 This list is not exhaustive and departments/ethics committees may require other types of research to be referred for full review.

6. External Ethical Review for Research Involving Human Participants

6.1 In some cases, ethical review must be sought from an external research ethics committees.

NHS Research Ethics Committee

6.2 Research involving recruitment of patients through the NHS, use of NHS data, premises and/or equipment, and intrusive research involving participants aged over 16 who are unable to give informed consent will require review by an NHS Research Ethics Committee.[11]

6.3 Some other forms of research will also require NHS REC review see: http://www.research-integrity.admin.cam.ac.uk/research-ethics/guidance/nres-review.

6.4 Research involving human tissue samples, including blood, will also require full review and storage of such material will require a licence under the Human Tissue Act or NHS REC ethical approval, see: http://www.safety.admin.cam.ac.uk/subjects/biologicals/human-tissue-act. Please note: use of 'non-relevant material' does not, in itself, require NHS or University ethical review.

The Ministry of Defence Research Ethics Committee

6.4 The Ministry of Defence Research Ethics Committee (MoDREC) ensures that all research involving human participants either undertaken, funded or sponsored by the MoD meets nationally and internationally accepted ethical standards. For further information, please see the MoDREC webpage here.

Overseas Research Ethics Committees

6.5 As appropriate, University sponsored research carried out overseas may require ethical review from an ethics committee in the country in which the research is to take place and/or review from an University of Cambridge research ethics committee (REG3).

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[11] The HRA defines 'intrusive research' as research that "if a person taking part had capacity, the researcher would need to get consent to involve them".

7. Non-research activities

7.1 Please note that audit and service evaluation are activities designed and conducted solely to define, assess or judge an existing service and are designed for internal use (i.e. they are not "effectively shared"). These are likely to be activities designed to improve or monitor University services or activities (e.g. reviews of teaching or research impact activities).

7.2 Where the aim of the work is to derive generalisable new knowledge for publication this would be classed as research (e.g. a project intended to identify particular characteristics of a service or assess a new intervention in a service, the results of which would be shared with external practitioners with the aim of improving their knowledge of that type of service or the usefulness of the new intervention would be classed as research).

7.3 Please note that this definition differs from that provided by the NHS – the University's definition takes precedence for University research.

8. Non-ethical matters

8.1 Finally, the lead researcher should be aware of, and comply with, any relevant governance requirements. As these matters are handled through separate process, it is not expected that Ethics Committees should review such documentation or make a decision as to whether or not they are required. However, it is recognised that in some instances, e.g. university insurance, that committees may wish to seek confirmation from the lead researcher that the appropriate arrangements are in place where needed.

8.2 Depending on project-specific matters or funder expectations, this may include some of the following considerations:

- University insurance;
- Material Transfer Agreement or Data Transfer Agreement;
- Export Control Licence;
- External research permits;
- Collaboration agreements;
- Research data management plan;

9. Resources

In addition to this guidance from UREC, ethics committees may also wish to consider the following external guidance regarding ethical review:

- UKRIO and ARMA (2020) – Research Ethics Support and Review in Research Organisations. Research Ethics Support and Review in Research Organisations.
- ESRC (2022) – Research organisations and research ethics committees. Criteria for research ethics committee review.

Date last reviewed: March 2023
Date of next review: March 2026

Version 2.0

GUIDANCE ON THE RE-USE OF EXISTING DATA IN RESEARCH

GUIDANCE ON THE RE-USE OF EXISTING DATA IN RESEARCH ('SECONDARY DATA')

1. Overview

1.1 Research data may have significant value beyond its usage in the original research. However, the secondary use of such data may raise ethical issues that require further consideration by the researcher and potentially an ethics committee.

1.2 This guidance applies to the secondary use of data collected from living human participants who provided informed consent[1] for the original use of the data that is to be used for further research purposes.

1.3 Within this guidance, re-use of existing data in research (or 'secondary use') is defined as any use of existing data that was previously collected from human participants beyond those purposes for which they were originally collected. Secondary use includes:

- reuse of data by the original collector of the data for a purpose different to that for which they were collected and
- reuse by other researchers (unless these uses are specifically encompassed in the original consent)

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[1]The University recognises that use of research data does not always require informed consent, particularly where seeking consent is not possible or there are strong ethical reasons why using the data without consent is acceptable, this will be particularly relevant in the context of historical and political research.

1.4 For guidance, see University guidance on academic research involving personal data and ICO guidance. In particular, researchers should check that the research participants whose personal data they intend to re-use have been adequately informed about this possibility, or that a relevant exemption applies.

2. University ethical review of research involving the secondary use of data

2.1 Whilst the University recognises that the secondary use of many datasets will be uncontroversial, researchers are expected to give careful consideration to the ethical risk[2] of any research that involves the reuse of data collected from human participants and seek advice in the case of doubt.

2.2 Secondary use of data collected from human participants may require University or external ethical review (see Research Ethics Guidance 1; REG1) depending on the source and nature of the data and the rules of the relevant ethics committee.

2.3 Ethics committees in Schools and Departments/Faculties may have stricter rules[2] on when ethical review must be sought than outlined in this document, which seeks to establish shared minimum standards of good practice.

2.4 The following types of projects involving secondary use of data will not normally require ethical review, unless otherwise specified by departments and faculties or by requirements of funders:

- The re-use of data which are already in the public domain (i.e. published in books, journals etc. – see REG1 for further information);
- The re-use of a researchers' own primary dataset for which consent for reuse for research purposes beyond which the data was originally gathered was provided by the participants;
- The re-use of a third party's dataset for which consent for reuse for research purposes beyond which the data was originally gathered was provided by the participants and for which all data have been robustly anonymised

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[2] Please refer to Research Ethics Guidance #1 for a definition of 'minimal ethical risk'

[3] Some ethics committees will require researchers to complete a light-touch review (see REG1) even in the cases mentioned above. For instance, the Humanities and Social Sciences Research Ethics Committee requires researchers in Departments or Faculties which use their Committee to refer any project reusing personal data (even in an anonymised form) directly to the HSS REC. These projects will be dealt with by Chair's action (unless issues requiring full review are identified).

2.5 Any researcher who is unsure whether a planned use of data falls under one of the exemptions noted in 2.4 must seek further advice. Student researchers should initially discuss their proposal with their supervisor. Principal Investigators and supervisors should, in the first instance, check the ethical review procedures of the relevant local ethics committee and approach the ethics committee for further guidance as needed.

2.6 It should be noted, however, that ethical review of a project may be needed for other reasons. Researchers should seek ethical advice where a proposed reuse of data (even in an anonymised form) raises additional ethical considerations such as:

- The data provider requires ethical review of the proposed research;
- The use of research methods risk re-identification of individuals (e.g. artificial intelligence tools or triangulation of several datasets);
- The researcher has concerns regarding the provenance of the data or the original participant's consent for future use of the data etc.

3. NHS ethical review of patient and service user secondary data

3.1 The reuse of data which were collected from participants identified from, or because of, their past or present use of services for which the UK Health Departments are responsible, including participants recruited through these services as healthy controls and those who have died within the last 100 years, requires NHS Research Ethics Committee review.

3.2 If the data has been anonymised such research will normally qualify for the NHS Proportionate Review Service. If the data is anonymised and is properly in the public domain (e.g. statistics published by a government agency) this will not require review.

3.3 Subject to any overriding legal concerns, NHS Research Ethics Committee review is not required for research limited to the secondary use of information previously collected in the course of normal care (without an intention to use it for research at the time of collection), provided that the patients or service users are not identifiable to the research team in carrying out the research. Nonetheless, R&D approval must be sought and a DTA put in place. Please note that in some cases, R&D approval may require ethical review.

3.4 The use of anonymised patient or service user data from an ethically approved research database may not need separate ethics approval. Whether separate HRA ethics approval is required will normally be made clear in the terms and conditions of access.

3.5 For more guidance on information governance in the Clinical School see: http://www.medschl.cam.ac.uk/research/information-governance/

4. Ethical considerations of primary research – consent for future use

4.1 All researchers are encouraged to consider the possibility of secondary research and data sharing at the outset. Many public funders of research and journals have adopted research data sharing policies and mandate or encourage researchers to share data and outputs.

4.2 As such, researchers should build the long-term use of data into the informed consent process by including details of this in the information given to potential participants and an appropriate section on the consent form.

4.3 Consent forms and information sheets should be written in a manner that provides for reasonable additional uses of the data and provides participants with sufficient explanation of how research data will be stored, preserved, and used in future, as well as how confidentiality, where promised, will be maintained.

4.4 Information sheets should also set out the appropriate safeguards that will be put in place for assuring ethical future use of the data. This should include how the data will be anonymised, any restrictions on use, and how data will be protected.

4.5 Researchers should be aware that under the requirements of the data protection legislation personal data must not be transferred to a country or territory outside the UK unless covered by an appropriate safeguard, including:

- The country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data[1].
- An appropriate contractual arrangement (e.g. as part of a Data Transfer Agreement) is put in place in line with standard clauses.
- An appropriate 'derogation' (exception) to the prohibition on transfers outside the UK can be identified.

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[1] All European Economic Area countries are deemed adequate in this regard and further guidance is published at https://www.information-compliance.admin.cam.ac.uk/data-protection/guidance/data-sharing#heading9

5. Ethical considerations of secondary research – consent for sharing

5.1 Use of secondary data should be in accordance with the requirements of the data provider, data protection legislation and the University Policy on the Ethics of Research Involving Human Participants and Personal Data.

5.2 Researchers seeking to reuse data which they did not collect themselves, and which are not in the public domain should:

- Observe the limits placed on secondary data, including archival data, and to consider whether the proposed re-use of the data is in line with consent, if relevant.
- Check whether the re-use of data is in line with the consent originally obtained from participants (and the information sheets given to them) by seeking evidence and/or assurance from the data owner or ensure that consent for reuse for research purposes beyond which the data was originally gathered (see section 4).
- Identify the appropriate agreement that must be sought prior to accessing the secondary data, such as a data transfer agreement (DTA), and comply with the terms of the agreement. For archival research, the agreement may be the terms and conditions of the archive rather than a DTA.

6. Ethical Considerations of secondary data - anonymisation of data

6.1 Anonymisation of data allows data to be shared whilst preserving privacy of participants. Data which are completely and robustly anonymised do not contain personal data and so ethical review is not normally required (see 2.6 for possible exceptions).

6.2 Robustly anonymised data should have all identifying information removed, so that it is not possible to identify the participant from the data, directly or indirectly. Direct identifiers - such as names, NHS numbers, postcodes or pictures – must have been removed for data to be classed as anonymous. Data are not anonymous if they contain indirect identifiers that can be linked to other data within the data set or to publicly available information sources to identify an individual.

Example 1: UK hospital episode statistics (HES) data may or may not contain the postcode and date of birth of each patient. However even if these are removed, the HES ID used to link different episodes of care that relate to the same patient contains date of birth plus NHS number, or date of birth plus postcode, or postcode plus other data, depending on which system it came from. It is not anonymous and cannot be treated as such.

Example 2: A research team receives data collected by a polling organisation relating to the political affiliation and age of individuals in Cambridgeshire. The researchers publish an analysis of the political affiliation and age data and replace individuals' names with codes to ensure their anonymity. However, if the researchers also receive data on the residential post-codes of the same individuals and decide to publish it using the same codes, the individuals could be identified by combining the two datasets, particularly if only one person of a particular age lived in a particular post-code.

Example 3: Researchers should take care that data cannot be linked to further data that the participants have made publicly available on social media sites. For example, individuals might make significant amounts of information regarding their careers (start dates at an employer, education and professional qualifications, job type, etc.) available on professional networking sites. If these data can be matched with data produced by a research group, this could lead to re-identification of the participants.

6.3 Data are not anonymous if they are sufficiently rich for data subjects to be re-identified easily from context.

Example 1: It is a matter of public record that a well-known public figure had treatment for a health condition at a named hospital on a specific date. Thus, if a record of this treatment is linked to records of their other, private, treatments, then their privacy is undermined. For this reason, a copy of the HES data with the HES ID encrypted, or replaced with a pseudonym, must still be treated as sensitive personal health information.

Example 2: A researcher wishes to reuse data from an interview transcript. The real names of the participants were replaced with pseudonyms at the time of transcription. The researcher must, however, still be aware that contextual statements made by the participants have the potential to lead to identification. For example, references in an interview to particular locations, indirect identifiers such as age or occupation, and details of experiences or actions attributed to an individual may, cumulatively, allow an individual to be identified. Such data would thus not be anonymous. The researcher should also consider using new pseudonyms for any new/re-analysis as this will decrease the likelihood of linking to previously published analyses of the same data.

Example 3: Retail data (e.g. spending habits in supermarkets) can reveal a significant amount about an individual. Age, wealth, diet, alcohol consumption, family size, smoking behaviour and many other identifiers can be inferred from such data. Thus if such data are linked to other data, such as the area of residence or place of work, researcher should consider the potential for individuals to be identified.

6.4 Researchers should consider whether the data they intend to use are truly anonymous and should not rely solely on assurances from third parties.

6.5 There is a substantial literature on the difficulties of inference control, also known as statistical security. Researchers who seek to rely on anonymisation mechanisms should seek expert advice and must expect that the mechanism they use will be opened to scrutiny by the data subjects and the public. Consent cannot be meaningful if data subjects have no way of finding out how their data may be used.

6.6 Where there remains a risk that participants could be re-identified from an anonymous dataset, the data should be considered to be pseudonomised. In this case, the data would still be classed as personal data and thus is likely to require ethical review. In such instances, advice should be sought from an ethics committee.

7. Resources

7.1 Further reading on secondary use of data:

- The European Commission (2018) – Use of previously collected data ('secondary use'). Ethics and Data Protection, VII, 12-14
- UK Data Service (2022) – UK Data Service guidance on secondary analysis. Secondary data analysis.
- UK Data Service (third edition 2011), Managing and Sharing Research Data, Sage.https://ukdataservice.ac.uk/learning-hub/new-to-using-data/

7.2 For further support and guidance, please see the University of Cambridge Research Data Management website here: https://www.data.cam.ac.uk/

Date last reviewed: March 2023
Date of next review: March 2026

Version 2

ETHICAL REVIEW OF OVERSEAS RESEARCH

ETHICAL REVIEW OF OVERSEAS RESEARCH

University sponsored search carried out overseas must uphold the University's ethical standards while also being cognisant of local expectations, practices and laws. Any research that would require ethical review when carried out in the UK should similarly be subject to appropriate ethical review when carried out overseas. Such review may be sought from a University of Cambridge research ethics committee.

For projects in which the research takes place entirely overseas, researchers may seek ethical approval from a research ethics committee in the country in which the research is to take place. In such cases, full ethical review by a Cambridge research ethics committee may be unnecessary, as long as the overseas research ethics process and standards are at least as rigorous as our own.

To decide whether this is the case, researchers who wish to rely on an overseas ethical review process should seek confirmation from a Cambridge research ethics committee to confirm that the overseas process is sufficiently robust to meet the University's standards and expectations. If the committee deems the review process to be insufficiently robust, they may require ethical review under University processes to ensure that the project meets University ethical standards (potentially in addition to overseas approval).

As such, researchers should always seek advice from their local or School-level research ethics committee before seeking ethical approval for a project through an overseas ethical review process[1].

In addition, researchers should also note that:

- Projects that take place partly overseas and partly in the UK will require appropriate UK ethical approval for the research that takes place in the UK.
- Some funders may require ethical review to be carried out both in the UK and overseas, care should therefore be taken to read the relevant funder conditions before relying solely on overseas ethical review.
- Some departments/faculties may choose to require ethical approval via a University committee for all overseas research.

Date Last Reviewed: March 2023
Date of next review: March 2026

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[1] For instance, the School of Clinical Medicine has approved two exemptions from University ethical review for research that fulfils specific criteria and undergoes an appropriate governance check

GUIDANCE ON THE ETHICAL REVIEW OF AMENDMENTS

ETHICAL REVIEW OF AMENDMENTS

1. Overview

1.1 The University of Cambridge expects all researchers to consider any ethical implications imposed by their research. In some instances, changes to a research project may require a researcher to seek an amendment[1] to their research.

1.2 It is the responsibility of Departments/Faculties and Schools to decide within their own ethical review processes what type of project amendments require ethical review and, if required, whether these can be reviewed by a light-touch process in the first instance or full ethical review (types of ethical review are described in Research Ethics Guidance #1; REG1).

1.3 Although this document has been prepared by the University Research Ethics Committee as guidance/advice for local Cambridge research ethics committees on ethical review of project amendments, the ultimate responsibility for ethical decision-making and the management of a research project rests with the lead researcher. The decision to seek an amendment should be made by the Principal Investigator based on the level of ethical risk raised by the amendment.

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[1] Amendments are changes made to a research project after ethical approval or a favourable opinion has been given.

1.4 Although the judgement regarding whether an update is likely to have a potential impact on the dignity, rights, safety and well-being of the participants should be made by the lead researcher, the lead researcher is advised to contact the relevant REC should they have any queries about amending their ethics applications.

1.5 There are three levels of amendments:

- Trivial – the update does not raise any ethical risk
- Minor – the update does not raise any ethical risk
- Substantial – the update raises minimal ethical risk or more than minimal ethical risk;

2. Trivial amendments

2.1 Trivial amendments are very minor text updates that do not raise any ethical considerations e.g. correcting spelling errors or typos. The lead researcher is not expected to notify the ethics committee of any trivial amendments. Ethical review is not required.

2.2 Where the lead researcher judges another type of modification to be trivial, e.g. the addition of new team members or routine adjustments to data plans, it is unnecessary to notify the ethics committee of the amendment.

3. Minor amendments

3.1 Minor amendments, i.e. straightforward updates that do not alter or add any additional ethical considerations than those matters noted in the original application, should normally be recorded but would not require ethical review unless otherwise specified by departments/ethics committees.

3.2 Minor amendments[1] that do not normally require ethical review include:

a) a short-term extension up to one year after the original study end date;
b) change of project title (note: the project must remain the same);
c) Updating contact details in study documents to reflect changes in the research team;
d**)** Adding required transparency information to study documents used in a long-running project to comply with current data regulation requirements;
e) The addition or removal of individual research team members;
f) Any routine, everyday adjustments to data gathering plans and activities;
g) Any combination of the above changes;

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[2] This list is indicative, rather than exhaustive. As appropriate, the lead researcher may judge the points listed in 3.2 as trivial rather than minor amendments (see section 2).

3.3 Although ethical review is not normally required in these instances, it is generally expected that the lead researcher should notify the relevant REC of a minor amendment to the study to ensure that the REC can keep appropriate records. If, however, the lead researcher judges that the proposed modification is a trivial amendment, it is not necessary to notify the ethics committee (unless otherwise specified by departments/ethics committee)

3.4 If an amendment includes minor and substantial updates, ethical review is likely to be required to consider the substantial updates. This can be handled as two amendments or a single substantial amendment as deemed appropriate by the REC.

4. Substantial amendments

4.1 Substantial amendments are considered to be any updates that substantially change the information provided in the original application and, in particular, where the update modifies the ethical issues or ethical considerations associated with the project and/or adds new factors.

4.2 A 'substantial change' refers to a new research approach or method that, had it been planned at the time, would have been mentioned on the original research ethics approval application.

4.3 Departments/ethics committees should develop their own approach for deciding what type of proposed project updates constitute as a substantial amendment. As a guide, examples[3] of substantial changes may include:

a) Adding a new participant group or new research method;
b) Removing a group of participants or research method from the project;
c) Changes to procedures undertaken by participants (including instruments);
d) A different method of data gathering or seeking additional data from existing participants;
e) Applying for an extension of longer than one year;
f) Appointment of a new Principal investigator/research supervisor/lead researcher;
g) Significant changes to study documents (i.e. more significant than those set out in 3.2);
h) A change in the affiliation of the PI to another Faculty/Department within the University,
i) Any changes likely to have a significant impact on the safety or welfare of participants;
j) A different approach to obtaining consent, such as major changes in the information; given to participants or in the consent form

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[2] This list is indicative, rather than exhaustive. Any circumstances not listed here may be deemed minor by RECs and should be handled accordingly.

- 4.4 It is recognised that ethics committees handle ethics applications, including amendments, in several different ways according to local needs and preferences. It is expected that an amendment submission may take several formats including:
- A short amendment application form noting the original study ID and the changes;
- An email request from the researcher providing information to the committee;
- Submission of a revised application form and study in which the updates are highlighted in track-changes;
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- 4.5 Although ethics committees in Schools and Departments/Faculties may have stricter rules than that outlined in this document, as a shared minimum it is expected that an amendment includes the following information:
- A description of the proposed amendment(s)
- As appropriate, a justification for the proposed amendment(s)
- As appropriate, details of the ethical consideration raised by the amendment & how the resulting risks are mitigated;
- The original approval letter or application number as required for administrative purposes
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- 4.6 Where an amendment poses more than minimal ethical risk, full ethical review will normally be required (see REG1).
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- 4.7 Lead Researchers should also consider whether they need to notify the Insurance Office of their amendment.
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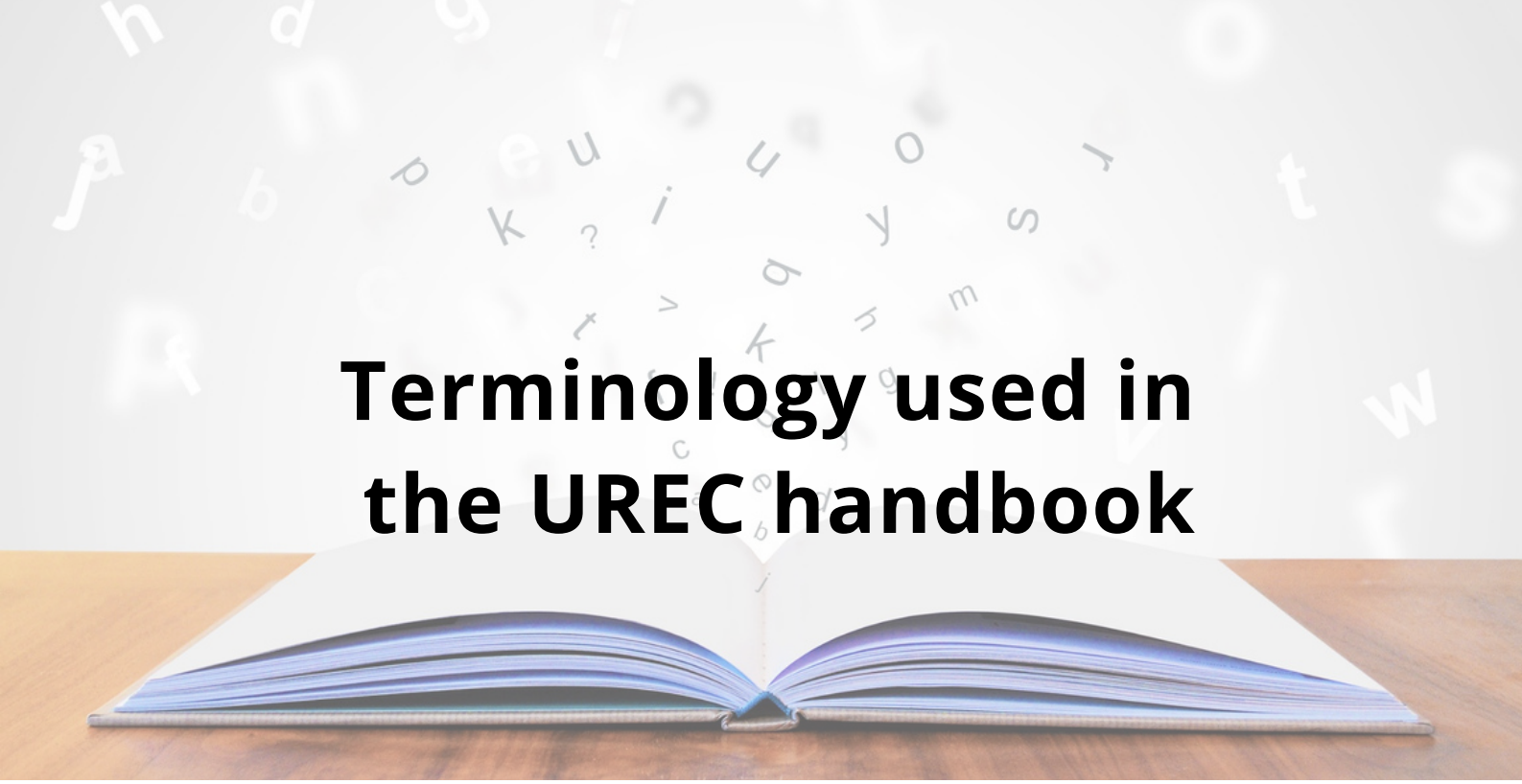
- 3.8 If a project update requires a substantial amendment, substantial amendments must be reviewed and given a favourable opinion/ethical approval before the amendment may be implemented by the researcher.

Date last reviewed: March 2023
Date of next review: March 2026
Version 1.0



Terminology used in the UREC handbook

TERMINOLOGY USED IN THE UREC HANDBOOK

Data in the public domain – Some information, including some personal data, may be clearly public, for example information published in books, journals or newspapers. Other information, for example personal data collected by the researcher through a questionnaire, is clearly not public. In some cases, however, the status of a particular set of data may not be clear. This is particularly true of personal data posted on a social media platform. Such data may formally be public (i.e. can be accessed without restriction), but the data subjects themselves may consider that data to be private and have reasonable and overriding expectations that it would not be used in research. Where the 'public' nature of information is in doubt at least light-touch ethical review may be required.

Expedited review – a type of light-touch ethical review of research in which a single member (sometimes, but not necessarily, the Chair) of the ethics committee reviews research that poses no or minimal ethical risk. In clearly justified circumstances (for example when there are external drivers beyond the control of the researcher that require faster review), expedited review may also be used to review research that poses more than minimal ethical risk.

(**Ethical) risk** –risk is generally judged by the potential seriousness of the foreseeable harm to participants posed.

Full ethical review – a type of ethical review by which an appropriate research ethics committee provides full and proportionate ethical review of research projects that pose more than **minimal ethical risk**.

Light-touch ethical review – a type of ethical review that that may be used by some departments and ethics committees to facilitate the ethical review projects that pose **minimal ethical risk**. Light-touch review is designed to provide proportionate consideration of the risks of the project and identify any research that poses more than minimal ethical risk (which would normally be escalated for **full ethical review**). Light-touch review can take a variety of forms, for example: self-assessment review, supervisor ethical review and expedited review.

Local Research Ethics Committee – one of the Research Ethics Committees (REC) at a Department, Faculty or Centre within the University of Cambridge i.e. any Cambridge research ethics committee that is not one of the 4 School-level Committees.

Minimal ethical risk – a risk no greater than the level of risk research participants are likely to encounter in their normal lives. The level of ethical risk that a participant would encounter in their normal lives will, of course, vary according to the participants involved, for example research that publicly criticised the policies of a politician or other public figure who might encounter public criticism on a regular basis is more likely to be judged as of minimal ethical risk than research that exposed a member of the public to similar scrutiny in a way that they would not normally encounter.

Principal Investigator – a staff member that is of postdoctoral or above status (or has equivalent research experience) that assumes overall responsibility for the intellectual leadership of the research project and for the overall management of the research and who is accountable for the financial, administrative, and compliance matters relating to the project.

REC-approved procedure– A procedure designed to minimise the risk of a particular, commonly encountered, type of research. It is designed to avoid the need for full ethical review of projects for which there are 'standard' procedures that can be adopted in most cases. Protocols may be designed by the research ethics committee (see this example at the University of Oxford) or committees may adopt guidance documents developed by externally, for example guidance or codes developed by professional bodies

Research - As set out in the UUK Concordat to Support Research Integrity, 'research' is defined as "a process of investigation leading to new insights, effectively shared".

Self-assessment ethical review – a type of light-touch ethical review in which the lead researcher completes a written self-assessment. This may use an agreed form providing a set checklist of questions to assess the level of risk, signing an agreed declaration that a project meets the agreed local definition/description of a minimal ethical risk project, or a less formal process.

Service evaluation – activities designed and conducted solely to define, assess or judge an existing service and are designed for internal use (i.e. they are not "effectively shared"). These are likely to be activities designed to improve or monitor University services or activities (e.g. reviews of teaching). Where the aim of the work is to derive generalisable new knowledge for publication this would be classed as research (e.g. a project intended to identify particular characteristics of a service or assess a new intervention in a service, the results of which would be shared with external practitioners with the aim of improving their knowledge of that type of service or the usefulness of the new intervention would be classed as research..

Supervisor review – a type of **light-touch ethical review** in which the research supervisor reviews student's research that poses no or minimal ethical risk. Local research ethics committees or departments may have guidance for supervisors undertaking such review.

DATA PROTECTION GUIDANCE

ADDITIONAL GUIDANCE ON DATA PROTECTION

Ethics Committees
The UREC guidance for ethics committees on data protection and ethics processes is available upon request from researchethics@admin.cam.ac.uk. When next updated, the new data protection guidance will be circulated to ethics committee contacts.

Researchers
For guidance, see University guidance on academic research involving personal data and ICO guidance

Legislation
- Data Protection Act 2018

SCHOOL-LEVEL RESEARCH ETHIC GUIDANCE

SCHOOL-LEVEL RESEARCH ETHICS GUIDANCE

The School of Clinical Medicine
The Clinical School provides the following information and guidance on the research governance website:

- Clinical School Research Governance
- Clinical School Information Governance

School of Technology
The Cambridge Working Group on Human Participants in Technology and Physical Science research has prepared extensive guidance on the conduct of technology research with human participants for Cambridge researchers.

School of Humanities and Social Sciences REC
The SHSS REC webpages notes that it draws primarily on the ESRC Framework for Research Ethics and points researchers to this guidance.

Cambridge Psychology REC
The Cambridge Psychology REC provides a detailed research ethics handbook on its webpage

UNIVERSITY RESEARCH ETHICS COMMITTEE

https://www.research-integrity.admin.cam.ac.uk/

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This handbook was approved by UREC on 10/03/2023.