University of Cambridge – University Research Ethics Committee (UREC)
Interim research ethics review flowchart

Before beginning research, all researchers are expected to consider what, if any, ethical risks or issues arise from the research they intend to undertake and take all reasonable steps to ensure that ethical conduct of research involving human participants or their personal data.

Most research projects carried out at the University of Cambridge will involve no ethical issues or raise only minimal ethical risk, whereas some research will raise significant ethical questions. The University's ethical review framework is designed to provide a rigorous and independent ethical review process that is proportionate to the perceived risks.

As such, all researchers embarking on research involving human participants or personal data as the subject of research should 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.

Not all research conducted by researchers within the University requires independent ethical review by a University ethics committee. As appropriate, particularly in cases of doubt, the lead researcher should seek further advice in making this decision. Where more than minimal ethical risk[1] is identified, reasonable independent ethical review (which may be light-touch ethical review where appropriate) must be carried out prior to research work commencing.

Ethical issues raised by research and the understanding of research ethics vary considerably across cross disciplines. Schools will necessarily have differing approaches to ethical review and the framing of ethical guidance. Given this, subject specific guidance should be obtained by researchers from their Department, Faculty or School to ensure ethical conduct of their research where further advice is required.

This interim flowchart should be used in conjunction with the University's Ethics Policy, UREC Research Ethics handbook, Good Research Practice Guidelines and the University Research Integrity Statement and any local research ethics guidance. It will be replaced by a new ethics review flowchart in due course following the completion of the ongoing UREC review of University Ethics Policy.

This interim flowchart is intended to supplement local ethics guidance provided by Departments/Faculties and Schools and the lead researcher undertaking research involving human participants or personal data should familiarise themselves with any local exemptions or requirements.

In this document, you will find information and guidance to support you to:

- Recognise the type of research may require independent ethical review
- Consider the ethical risks raised by your research and seek ethical review as appropriate
- Understand when and how to seek ethical review from a university or external

[1] **Minimal ethical risk** Minimal ethical risk (see p.19-20 and p.38, handbook) is 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 participants 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.

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Question	Actions
1. Which of following best describes your role? a) an undergraduate or postgraduate research student (or their research supervisor) b) University employee c) visitor or any other person conducting research on University premises	If student, **Q2.A** If University employee, **Q2.B** If visitor, **Q2.C**
2.A In the first instance, your project should be submitted to your supervisor or mentor for advice. Should you wish to continue with checklist for information, please go to the **Q3.**	Continue, **Q3**
2.B. Do you intend to undertake (or, as relevant, supervise a research student intending to undertake) the proposed research within the course of your employment at the University of Cambridge and/or College? (**Note:** This extends to proposed research to be conducted outside the University or overseas by university employees and students where this work is to be undertaken within the course of employment or studies)	If yes, **Q4** If no, **Outcome 1**
2.C If intending to work on a research project led by a University employee, visitors should seek clarification from the lead researcher whether the project requires formal ethical review, and as appropriate, has received appropriate ethical approval/favourable opinion (or an amendment] prior to the visitor commencing work on the project. For more information on the University ethical framework, continue to Q4.	Continue, **Q4**
3. For supervisors of research students, does the research student you are supervising intend to undertake the proposed research within the course of their studies at the University of Cambridge?	If yes, **Q4** If no, **Outcome 1**
4. Does the proposed research involve **human participants** and/or **personal data** as the subject of research?	If no, **Q7** If yes, **Q5**
5. Does the proposed research involve any procedure or the new collection of personal data from **human participants**? (e.g., interview, observation, original survey) that raises more than minimal ethical risk?	If yes, **Outcome 2** If no, **Q6** If unsure, **section 2**
6. Does the proposed research project involve the analysis of **secondary data** that raises more than minimal ethical risk?	If yes, **Outcome3** If no, **Q8** If unsure, **section 2**
7. Does the proposed research project involve the analysis of any **secondary data from the NHS** (irrespective of the ethical risk)?	If yes, **outcome 4** If no, **Q8** If unsure, **section 2**
8. Does the proposed research involve working with **human tissue**, organs or human bodies and identifying information derived from it?	If yes, **outcome 5** If no, Q**9** If unsure, refer to HTA guidance
9. Does the proposed research involve **animals** in experimental or other scientific procedures, including field-based research?	If yes, **Outcome 6** If no, Q**10**
10. Does the research require review by an external body, such as the HRA or MoDREC? (**Note:** if undertaking overseas research, please refer to REG#3 and check whether you require ethical review from an overseas REC)	If yes, seek this approval. If unsure, **section 2** If no, **outcome 7**

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Outcomes

Outcome 1 [seek bespoke advice]	Please seek project-specific advice from the Head of Department, local ethics committee or ethics contact, as appropriate. This tool provides generalisable information that applies across the University. As such, local contextualisation should be sought to understand whether ethical review can be sought in light of project-specific matters to ensure ethical conduct of research.
Outcome 2 [appropriate University review is required]	Research that involves any procedure with human participants or collection of new data from human participants will normally require appropriate ethical review unless local ethics guidance indicates otherwise. For further University guidance on research that raises more that minimal ethical risk, please refer to local ethics guidance. Light-touch ethical review, where available locally, might provide an appropriate level of review (pp.17-21, handbook). Higher risk research typically requires full ethical review. If ethical review is not possible at a local level, such proposals should be referred to the relevant School-level REC in accordance with local ethical review procedures or referred to an external body where external ethical review is required (e.g., HRA)
Outcome 3 [appropriate University review may be required]	Secondary use of data collected from human participants **may** require ethical review from a University REC or an external body depending on the source and nature of the data and the rules of the relevant University ethics committee. The lead researcher (or the research supervisor, as appropriate) should refer to local guidance and/or contact their Local Ethics contact or local REC for advice where further information is required and, if needed, seek appropriate ethical review from the Lead Researcher's local REC prior to commencing the research. For further University guidance on research that raises more that minimal ethical risk, please refer to local ethics guidance. If ethical review is not possible at a local level, such proposals should be referred to the relevant School-level REC in accordance with local ethical review procedures. Further central guidance on secondary use of data is provided in the research ethics guidance note on the re-use of existing data in research (pp. 25-31, handbook).
Outcome 4 [external review may be required]	Ethical review from an NHS REC and/or HRA governance approval may be required. The lead researcher should refer to the HRA Student Toolkit (applicable to non-student projects – see section 2 below and/or contact the Clinical School Research Governance team for further advice.
Outcome 5 [HTA approvals	Research involving human tissues from NHS patients requires NHS ethics approval.

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may be required]	In all other cases, research using human tissues is subject to the Human Tissues Act 2004 and requires ethical review from the appropriate University REC. Some exceptions exist (e.g., anonymised donated samples from the National Blood Service, human material classed as non-relevant material or anything that falls under the local Clinical School exemption). If the human tissue is "relevant material" and you are storing tissue in a facility that is not covered by the University's Human Tissue licence, you will legally be required to get ethics approval from the Human Research Authority (HRA) or register the new facilities under the Act. For further guidance, see the Safety Office website.
Outcome 6 [animal ethics policy applies]	The Animals Scientific Procedures Act 1986 (as Amended 2012) ASPA regulates procedures that are carried out on 'protected animals' (any living vertebrate, other than man, and any living cephalopod for scientific or educational purposes that may cause pain, suffering, distress or lasting harm. Please contact UBS HO Licencing ubsHOLicencing@admin.cam.ac.uk and the Named Animal Care Welfare Officer in the animal unit in which you wish to work. In the case of Clinical Veterinary Research the Veterinary Clinical Research Ethics Committee will consider these applications and will advise the University Establishment Licence Holder. The University of Cambridge Animal Welfare Policy, the Working with animals in the UK, EU and overseas Policy and Overseeing animal research University of Cambridge are stipulated.
Outcome 7 [University ethical review is not required]	Such proposals will **not** normally require ethical review by a University REC unless otherwise required in accordance with local REC procedures. If you are still concerned, ethical review may still be requested if there are any other significant issues identified by the Lead Researcher. If you are unsure or need further advice, please contact your local REC in the first instance.

Section 2 – Further Guidance

This section provides additional information regarding external tools to help determine whether the proposed project requires external ethical review where you have indicated 'unsure' in response to one of the questions in the flowchart above.

If you are able to clarify your understanding to answer yes/no in the flowchart based on information in this section, please return to the relevant question in the flowchart and continue with the flowchart. Otherwise, please seek further advice as appropriate.

HRA Research Toolkit
The HRA decision toolkit provides access to five different decision tools to help you understand what approvals are required for your research project:

a) is your study defined as research under the UK Policy Framework for Health and Social Care Research?
b) If yes, is your research taking place in the NHS and will need NHS approval?
c) If yes, do you need a favourable opinion from an NHS REC via the HRA?
d) If yes, do you need Full or Proportionate NHS/Social Care REC review?
e) Once the above approvals have been identified, is your student eligible to carry out their research under the student research eligibility criteria (Students and supervisors of students).

The toolkit contains links to existing HRA decision tools as well as some new ones developed especially for students to help students understand what approvals are required and whether they are eligible to carry out their research in the UK. Unless otherwise specified above, the decision tool is relevant for all research projects that fall under the remit of the HRA.

You should go through each decision tool until the final outcome is provided for that decision tool and, as appropriate, move onto the next decision tree. Further guidance is available from the HRA's website.

If a favourable ethical opinion from an NHS REC is required, then you do not usually need to also seek ethical review from a University REC. If not required, please check with your local ethics review processes whether University ethical review is required.

If further advice is required regarding NHS ethical review, please contact the Clinical School research governance team.

MoDREC Guidance (JSP 536)
The Ministry of Defence REC (MoDREC) JSP 536 Part 2: Guidance provides detailed guidance to support researchers to decide whether their research requires ethical review from the MoD.

In the first instance, it is advised you refer to 'Annex 1A: Does my protocol need to be submitted for Scientific and Ethics Review?' in the JSP 536 Part 2

If the answer to ALL three questions below (taken from Annex 1A) is yes, MODREC ethical review is required:

a) Is your project funded by the MOD, or does it involve MOD-employed staff or participants?
b) Is your project 'research'?
c) Are human participants involved?

If yes or unsure, please refer to 'Annex 1C The process for scientific and ethics review' in JSP 536 Part 2. As set out in the MODREC guidance, Annex 1A must be read in conjunction with Parts 1 and 2 of the MODREC documents. Full direction on research that is within scope and needs review may be found in JSP 536 Part 1, Chapter 1 paragraphs 6-14.]