Navigating ethical and other permissions: guidance for MST Med Ed students

Note: you should not plan a study that involves patients or is conducted in a clinical environment.

Permissions required

All students require

- formal ethical approval for any study involving human subjects
- written 'gatekeeper' permissions
- supervisor 'review' of ethics applications before submission

You may also require

- approval from the appropriate research governance committee

Gaining permissions through a University of Cambridge Research Ethics Committee

For those **projects that aren't better reviewed elsewhere** (see below) this should be through a Cambridge University REC. The two best suited are: ICE Research Ethics Committee (ICE REC) and Psychology Research Ethics Committee (Psychology REC.)

1. ICE REC considers research involving human participants or personal data carried out by ICE students. This committee is well placed to review proposals for studies focussed on the experiences of students and/or staff in Higher Education settings.
2. Psychology REC Terms of Reference[1] states it considers '*the ethics of research projects with human participants referred to it by members of the staff of University departments, colleges and MRC Units, and their collaborators*.' This is the ethics committee you are likely to go to if your study participants are doctors /dentists in training or their faculty. PREC will consider all projects by MSt Med Ed students, apart from studies involving patients attending NHS clinics or users of any of the services for which UK Health Departments are responsible. Full information is on their website, including a helpful checklist for documents required as part of the submission (e.g. an insurance letter). Please indicate in your cover letter to PREC that you are submitting a Clinical Education research project, so that they can direct your application to the appropriate sub-committee. Note that applications to PREC are considered by circulation on a rolling basis, but review can take between 6 and 10 weeks.

Projects better reviewed elsewhere

3. If your study is taking place in your usual (University) work setting **within the UK**, we would suggest you are best placed to seek ethical permissions through the relevant (local) organisational ethical committee.

4. If you are conducting research in your **usual work setting but it is outside the UK**, you should seek ethical review in your own institution (where that is available) **and seek**

[1] Psychology REC Terms of Reference in full: https://www.bio.cam.ac.uk/psyres/termsofreference

confirmation from Cambridge Psychology REC that the ethical review is of similar rigour to that they would conduct. This is explained below

"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)."

To do this, you should contact the Clinical School Research Governance Office (Manager Carolyn Read cad50@medschl.cam.ac.uk) sharing a copy of the ethics application you will be submitting (or have submitted) for a decision on whether dual ethics is needed. For overseas research please contact the international research manager, Jane Gaffa, jg788@medschl.cam.ac.uk.

Notes on research governance

5. If you are employed by the University of Cambridge School of Clinical Medicine, your study should be reviewed by the Clinical School's Research and Information Governance Office. There is additional 'getting started' information on their website, along with a research governance checklist[2]. This includes arranging insurance cover for your research (see also insurance application information).
6. Where you are conducting research about postgraduate medical training in the UK, there is a research governance process for HEE that you should follow (in addition to seeking ethical review by the Cambridge Psychology REC).
7. If you are conducting research in an NHS workplace, you should also speak to your local R & D office about the permissions they require. See, for example, requirements for studies taking part in CUH Trust.
8. HRA review is needed 'for studies involving patients attending NHS clinics or users of any of the services for which UK Health Departments are responsible'. However, there is further guidance available on studies that are primarily for the purpose of obtaining an educational qualification here: Student research - Health Research Authority (hra.nhs.uk).
9. If you are seeking ethical permissions in your own institution (as point 3) you should also establish and comply with local requirements for research and information governance.

[2] https://researchgovernance.medschl.cam.ac.uk/undertaking-health-research-in-the-united-kingdom/