The Centre for Occupational and Environmental Health Guidance Notes

The Centre for Occupational and Environmental Health (COEH) has delegated authority from the University Research Ethics Committee to give favourable ethical opinions to student research projects (at PGT level) that fall within defined ethical boundaries (referred to as the 'template' for ethical approval).

It is expected that supervisors will fully engage with the ethics review process to assess which form of documentation is required and ensuring that disciplinary norms are adhered to in all instances. The supervisor is responsible for assessing the level of ethical risk with the student and signing off on the submitted documentation.

The COEH Ethics Screening Panel has been established to ensure that student research projects receive a review proportionate to risks presented by the ethical issues raised by the research proposal. It is the responsibility of this Panel to assess projects against the University approved ethical template and to engage with, and advise students, on the most appropriate study procedures to ensure mitigation of ethical risks.

Where ethical risks are 'low' and fall within the approved template boundaries then the COEH Ethics Screening Panel assume the delegated authority and give a favourable ethical opinion on behalf of the University.

Route of Ethical Review

Questions A5 Section 1 of the Ethics Application form define the 'Route of ethical review'.

There are a number of projects which, being considered 'high' ethical risk, will fall outside the approved template boundaries and which will need to be reviewed by the University Research Ethics Committee or by an NHS Research Ethics Committee. It is important that these projects are recognised as a failure to do so could result in SIGNIFICANT delays to the review process.

NHS REC approval

This should have been considered when answering Questions A2 and A3. It is necessary where -

- NHS Governance requires ethical approval by an NHS REC. This includes all research involving participant identification through the health service as well as NHS patients and/or their data.

- There is a statutory requirement for ethical approval from an approved (i.e. NHS) REC. This would include, for example, all research involving the use of human tissue (which itself includes blood and urine samples).

Where this approval is required then you will need to complete an IRAS application form.

UREC approval

The University considers the following as 'high' risk. If any of these criteria apply, then you should select **UREC Review on Question A5** and proceed directly to the UREC application form.

- The research is being conducted in a location outside of the UK, which is NOT a workplace where you have a contract or sub-contract with the employer. [COEH ref G5]

- The research is being conducted outside the European Union, in a country on the Foreign and Commonwealth Office warning list or on NHS premises?

- The research involves the use of **identifiable** personal, sensitive data as defined by the Data Protection Act (e.g. medical, religious, labour union affiliation, political preference, etc.)? [COEH ref G8]

- A part of the research will be conducted by a commercial or external organisation (e.g. data collection through a market research or contract research organisation) **and** will be using personal, identifiable data?

- The research addresses themes or issues in respect of a participant's personal experience that may be of a sensitive nature or could create any degree of discomfort, anxiety or psychological distress in participants?

- The research involves participants from vulnerable groups. This includes participants who have a particularly dependent relationship with the researcher. [COEH ref G19]

- The research involves invasive procedures, physical testing or psychological 'intervention'.

- The research has the potential to cause physical risk or serious inconvenience to participants? [COEH ref G13]

- Research findings have the possibility of revealing any health or clinically diagnostic relevancies for the individual participants? [COEH ref G14]

- The research involves consent and/or withdrawal procedures that are not consistent with accepted practices (including observational studies in which participants are in what they feel are private settings and are observed without consent)?

- The research involves a necessary deception of research participants in which the deception is not revealed and explained during the debriefing and/or may cause distress?

Students: When these criteria do **NOT** apply then you should select **Division/School Review on Question A5 as well as 'Centre for Occupational and Environmental Health' for Question D5.2**. The subsequent questions then allow the COEH Ethics Screening Panel to confirm that the project meets the University defined ethical criteria of 'low' risk and, where

further ethical issues are identified, advise on how these could be mitigated to allow them to assume delegated authority and give a favourable ethical opinion.

There will always remain a possibility that ethical issues identified by the COEH Ethics Screening Panel are such that they would be unable to give a favourable opinion and that the project would require a full UREC review. This would require the student to return to the application form and select Option B on Question A5.

If you are a member of **staff**, please select **UREC Review for Question A5** to proceed to the UREC application form.

If you have any queries about your project, please contact: PGT-COEH@manchester.ac.uk