

Human Research Ethics

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What is ethics?

- good / bad right / wrong
- provides practical guidance
- allows reflection and justification of right / wrong
- is as old as humanity
- has an academic history of at least 2500 years
- builds on different, sometimes contradictory sources
 - intuition
 - ethical theories
 - religion





What is the role of ethics in research?

Intention

Improve the world through research

Product

Consequences of research (positive or negative)

Conduct

- Authorship, intellectual property, plagiarism
- Correctness, fabrication, negligence

Process

- Conduct of research, governance, compliance, reputation
- Treatment of humans as sources of data (HRE)





Why is HRE relevant in DMU research?

- 1. Gathering information from human beings through: Interviewing, Surveying, Questionnaires, Observation of human behaviour
- 2. Using archived data in which individuals are identifiable
- 3. Researching into illegal activities, activities at the margins of the law or activities that have a risk of injury
- 4. Supporting innovation that might impact on human behaviour

Attention:

Different regulations apply when you undertake research involving human tissue.

An application for HTA-related approval is available on the website.





Human Research Ethics, Basics

- "It is university policy that any scholarly activity involving interaction with and observation of human subjects must be subjected to a human research ethics review."
- This includes undergraduate and postgraduate and staff research projects.
- Researcher (student) fills in the form
- Supervisor suggests outcome
- Research student and staff proposals are all authorised by FHREC
- Possible outcomes
 - no ethical issues
 - 2. minor ethical issues which have been addressed and concerns resolved
 - 3. major ethical issues which have been addressed and concerns resolved
 - 4. ethical issues that have not been resolved

The approved ethics review form should be included as an appendix to the project report.





Differences taught students, research students, staff

- All must undergo ethics review
- Taught students are reviewed by 1st / 2nd supervisor
 - outcome should be included in appendix
 - submission to FHREC only if outcome is 3 or 4
- All research students must fill in form, signed by supervisor, authorised by FHREC
- All staff projects must be reviewed, signed by line manager, authorised by FHREC.
- This is a university requirement, not optional





The Form

Staff/Student Name

Programme (if relevant)

Title of Research Project

Brief description of proposed activity and its objectives:

Ethical issues identified: How these will be addressed:

To which ethical codes of conduct have you referred? These are specific to each Faculty

and if you have a query please ask your supervisor or Faculty REC for advice.





Detailed requirements

- 1 Respondents' co-operation in a research project is entirely **voluntary** at all stages. They must not be misled when being asked for co-operation.
- 2 Respondents' **anonymity** must be strictly preserved. If the Respondent on request from the Researcher has given permission for data to be passed on in a form which allows that Respondent to be identified personally:
 - the Respondent must first have been told to whom the information would be supplied and the purpose for which it will be used, and also
 - the Researcher must ensure that the information will not be used for any non-research purpose and that the recipient of the information has agreed to conform to the requirements of the Code.





Detailed requirements

- The Researcher must take all reasonable precautions to ensure that Respondents are in no way **directly harmed or adversely affected** as a result of their participation in a research project.
- 4 The Researcher must take special care when interviewing **children and young people**. The Faculty HREC will give advice on gaining consent for studies involving children or young people.
- Respondents must be told (normally at the beginning of the interview) if **observation techniques or recording equipment** are used, except where these are used in a public place. If a respondent so wishes, the record or relevant section of it must be destroyed or deleted. Respondents' anonymity must not be infringed by the use of such methods.
- 6 Respondents must be enabled to check without difficulty the **identity** and bona fides of the Researcher.





List of accompanying documentation to support the application:

- (1) A copy of the research proposal (Terms of Reference, Registration Form)
- (2) The details of arrangements for participation of human subjects (including recruitment, consent and confidentiality procedures and documentation as appropriate)
- (3) A copy of all the documentation provided to the volunteer to ensure the clarity of information provided
- (4) Copies of appropriate other ethical committee permissions (internal or external) or supporting documentation
- (5) If appropriate: a list of proprietary drugs or commercial drugs to be used in the proposed investigation including formulation, dosage and route of administration and known adverse side effects
- (6) A statement of your competence to carry out this research as a student or a brief one page curriculum vitae for each applicant, including recent publications (staff only)
- (7) Other documentation as advised necessary:





Further information

http://www.dmu.ac.uk/research/ethics-andgovernance/pg-and-research/humanresearch-ethics/technology/humanresearch-ethics.aspx