

3. Research Ethics

The University has established two Committees which oversee research programmes (including undergraduate projects) with regard to research ethics.

The first is titled the “University Ethical Review and Animal Welfare Committee” and its creation was required by legislation.

The second is called the “University Human Research Ethics Committee” and deals with the protection of individuals who are the subjects of research (including undergraduate projects).

All students must complete the Ethical Review form designated by their associated Faculty as part of their Registration process and when required, ethical approval must be obtained before commencement of the work to which it pertains.

3.1 The University Ethical Review and Animal Welfare Committee

De Montfort University Research Degree Regulations stipulate that where research involves animals an application for approval must be made to the *University Ethical Review and Animal Welfare Committee*. Without the formal approval of this committee and confirmation of relevant personal and project licence approval from the Home Office, the research must **not** proceed.

3.1.1 Procedures

Any member of staff intending to work, or having responsibility for a student intending to work, in these areas should contact the Office of the Pro Vice Chancellor (Research) for advice and guidance upon procedures concerning the University Ethical Review and Animal Welfare Committee.

The review process will be undertaken by the Committee which meets at least twice yearly and also oversees the general management of animal research work in the University. This Committee would then set up small working parties, involving individuals with statistical, pharmacological, surgical or experimental design expertise etc, when necessary, to consider new proposals for, or amendments to, Project Licences.

It is particularly recognised that whilst ethical and managerial considerations must be both adaptable to a changing workload in the future, it is important that the work of the Committee in a central university activity that reports directly to the University Executive Group. Consequently, the convenor of this committee will be a senior member of this latter group.

3.1.2 Collaborative Work Overseas

In respect of collaborative work overseas, researchers must still submit details to the University Ethical Review and Animal Welfare Committee and in addition:

- a) researchers must apply the principles of protecting animal welfare in the course of their research, especially those of refinement, reduction and replacement;
- b) they must conform with local laws;
- c) they must not undertake procedures that could jeopardise the chances of work being published in journals or presented at international conferences.

3.2 The Human Research Ethics Committee

3.2.1 Description of Role

Where research involves the collection of data directly from people, or where it involves the collection of data about individuals whose identity can be detected from the data, an application for approval must be made to the Faculty Human Research Committee which reports to the *University Human Research Ethics Committee*. Without the formal approval of this committee, the research must not proceed. All research involving human tissues is governed by the Human Tissue Act (2004) and is regulated by the University in accordance with the Act. All such work must proceed following established guidelines.

The collection of data directly from people includes research activities such as:

- i) interviewing
- ii) surveying
- iii) questionnaires
- iv) observation of human behaviour
- v) taking human tissue/fluids
- vi) experimentation involving interference with normal physiological and/or psychological processes

The collection of data about individuals whose identity can be detected from the data includes the use of archived data in which individuals are identifiable (such as patient records).

3.2.2 Ethical Issues in Human Research

3.2.2.1 Codes of research ethics relating to research on humans normally identify the following basic principles:

no harm; people participating in the research should be no worse off as a consequence of their participation. People should endure no physical or mental suffering during or after the research as a consequence of their participation.

informed consent; participants should be given information about the nature and purpose of the inquiry and about what their involvement entails. They should have the capacity to understand such information. They should provide the researcher with explicit consent to their participation. Participants can withdraw their consent at any time.

no deception; researchers should be as open and honest as possible in their dealings with participants.

avoid undue intrusion; researchers should respect the private lives of participants and cause as little disruption as possible in the process of data collection.

confidentiality; information collected by researchers should be treated in confidence and not disclosed to third parties.

anonymity; the identity of participants should not be revealed without their explicit consent.

security; data collected should be stored securely and measures should be taken to prevent loss of, or unauthorized access to, the research data.

3.2.2.2 Depending on the nature of the research, it might not be possible or desirable to adhere strictly to the basic principles outlined above. For example, psychological experiments might require some initial deception of participants as a necessary part of the research design. In some observational research, as another example, it might not be feasible to obtain formal written consent from participants. Where research does not adhere to the basic principles, researchers should provide an appropriate justification of their approach.

3.2.3 Procedures

All research degree students must complete and submit the appropriate ethical review application form to their Faculty Ethical Review Committee before

applying to the relevant Research Degrees Committee Faculty Review Panel's for registration of their degree.

For postgraduate research degree students, the application should normally be made to the Faculty's designated Human Research Ethics Officer; further information is available on the website.

The above requirements and procedures must be upheld by DMU staff and their students for collaborative work overseas involving the activities of Regulation 4.1.2.

3.3 Reporting Lines

The Human Research Ethics Committee produces a report of its activities annually to the Academic Board.