Faculty of Technology

Faculty Research Ethics Committee (FREC)

**Standard Operating Procedure**

**Title: Application for Ethical Approval of a Research Project**

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# Purpose

This standard operating procedure (SOP) describes the processes by which all staff and students (taught and research) apply for ethical approval of research projects and the principles according to which such applications are processed and approved.

# Responsibility

The Faculty Research Ethics Committee (FREC) Chair, members and Graduate School Office are responsible for disseminating and implementing the SOP.

# General Principles

Every member of the Faculty of Technology (FoT) partaking in research activity is required to consider the ethical and safety implications of their work and, where necessary, apply for ethical clearance from within the Faculty and from external bodies, as appropriate. This will normally mean that ethical approval is sought for every research project undertaken in the Faculty.

The aims of the research ethics review procedure are to:

* + protect research participants;
	+ ensure appropriate behaviour by researchers;
	+ avoid legal liability for researchers and the university arising from insufficient attention to ethical and other issues related to research governance;
	+ comply with legal regulations and requirements of funding bodies;
	+ avoid reputation risks to the university.

# Process

## Principles of the FREC

1. All research projects (student and staff) must undergo research ethics (RE) review.
2. The FREC members meet at least twice per year.
3. All procedures shall be made publicly available and strictly observed. Procedures, policies and application forms are made available on the faculty’s RE website. All discussions shall take place in confidential formal meetings, and the reasons for its decisions shall be recorded in full and in writing.

## General guidance

General guidance and required documentation, including the appropriate application form for Ethical Approval of a Research Project, is available on the Faculty RE website (<http://www.dmu.ac.uk/research/ethics-and-governance/pg-and-research/human-research-ethics/technology/human-research-ethics.aspx>).

### Duties of the researcher

All researchers (staff or students) wishing to obtain ethical approval for their research should complete the appropriate form and submit it for authorisation. Ethical approval is a standard aspect of a research project which should form part of its planning and review. All applications usually need to be signed and authorised by two individuals in addition to the researcher. In simple cases (where the outcome of the review is 1), see below section. 4.2.3), authorisation by one individual may suffice. The applicant’s supervisor / line manager / head of research centre supports the application which is then authorised by an independent assessor who is not involved in the project in most situations. The differences in the processes between different categories of faculty members are explained below (see 4.3).

### Accompanying documents

The application should be accompanied by the relevant documents that will allow an independent assessor to come to an understanding of the nature of the project and possible ethical issues. Such documents often include:

* + the project proposal / terms of reference / student registration form;
	+ all of the documentation which will be provided to any human participant to ensure the clarity of information provided;
	+ the consent form;
	+ the survey instrument(s) to be utilised;
	+ the interview guide;
	+ the information about the selection and recruitment of volunteers;
	+ other appropriate ethical committee permissions (internal or external) or supporting documentation;
	+ a statement of the researcher's competence to carry out this research (students only) or a brief one page curriculum vitae for each applicant, including recent publications (staff only).

### Outcomes of the review

The independent assessor considering the application will decide which outcome best describes the ethical status of the project and the proposed ways of addressing possible issues. These are:

1) 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. If the project is in category 1) or 2), the project can be authorised using the signatory process as describe in section 4.2.1 and the researcher can proceed with the project.

**Guidance on choice of outcomes:**

* Outcome 1: only possible if no interaction with human beings is planned and no identifiable data of individuals is used.
* Outcome 2: outcome where researchers / students interview individuals, carry out surveys, observe, and participate with adults who understand the research and realise they can withdraw their participation at any time. Supervisors must ensure that the appropriate boxes on page 2 are ticked and that the student actually knows how to address the ethical concerns.
* Outcome 3: research with vulnerable people, people who may not understand the research and their role (eg children, hospital patients, people with mental health issues, subordinates in power relationships, etc). Also applies to research into illegal activities or research that could produce a risk or injury. The student / researcher must find ways to address these problems and the supervisor must be confident that they have been addressed satisfactorily.
* Outcome 4: ethically problematic research where the problems could not be addressed in a satisfactory way.

### Conditional authorisation

It is possible to give **conditional authorisation** to a project. This means that the project will be considered as authorised once specific conditions have been met. These will often refer to required documents, eg a consent form or project outline for subjects. It is the researcher's responsibility to inform the independent assessor that the conditions have been met. Final authorisation will then be granted. Full authorisation will be given by the independent assessor or an equally qualified individual (eg FREC Chair or member).

If the project is in category 4), then no approval can be given, research fieldwork cannot begin, and ethical issues need to be addressed before the application is resubmitted.

## Processes for different categories of faculty members

Depending on the category of faculty member, the volume and ethical severity of projects differ greatly. It was therefore decided to treat different types of projects in different ways in order to ensure maximum coverage of RE processes whilst avoiding bottlenecks.

### Taught students

Undergraduate (eg HND, BSc) and postgraduate taught students (eg MSc) often undertake projects which have an aspect of field research involving human participants. This will often be the case for final year or Masters’ projects. Occasionally taught course assignments also have a research element that requires HRE clearance. In all cases, taught students should adhere to the following processes:

1. The student fills in the form and discusses the likely outcome with the project supervisor.
2. The **project supervisor** should sign the ethical review form for those projects which fall under the first two outcomes. The form should then be **authorised by the second supervisor (or module leader where no second supervisor exists)**. The project supervisor (or module leader) should then record the outcome of the ethical review in the appropriate way, eg on the Projects Database via Blackboard. The completed form, duly signed, should be kept by the student. The student must give a copy of the form to the project supervisor who should keep it for reference. A copy of the form must be included in the project report when it is submitted for assessment.
3. Projects which fall under outcome 3 should be signed by the project supervisor and a copy of the review form sent for information to the FREC. The completed form, duly signed, should be kept by the student. The student may start work on the project immediately.
4. Projects which fall under outcome 4 should be signed by the project supervisor and a copy of the review form submitted to the FREC for resolution. Ethically relevant research elements of these projects cannot commence until the matter is resolved.

### Research students

1. Research students include MSc / MA by Research, MPhil and PhD students.
2. The research student’s **first supervisor should sign** the ethical review form.
3. A copy of the signed form should be submitted to the FREC Administrator who will log it on the FREC database and forward it to the Chair for approval. It should be accompanied by a copy of the ‘Application to Register for a Higher Degree’ form. This applies to all research students, independent of the outcome indicated by the first supervisor.
4. The Chair or designated FREC member checks the form and accompanying information to ensure they comply with requirements. If the application raises no ethical issues, the Chair can approve the application immediately - this approval is not reviewed by the FREC.
5. If the application potentially raises ethical issues, the form is forwarded to two suitable FREC members (other than the Chair) who will assess it. If both assessors conclude that the project raises minor ethical issues and addresses them appropriately (outcome 2), then the application is subject to expedited review. Upon receipt of the assessment by the two FREC members, the Chair can formally approve the application. This approval is not reviewed by the committee.
6. If the application raises major ethical issues but these appear to have been addressed, then, following receipt of the assessment by two FREC members, the Chair can provisionally approve the application. In this case the application will go to the FREC for full review. Past projects in the FoT which fitted into this category include:
	1. involvement of children or minors;
	2. collection of sensitive personal data (eg religion, sexual orientation, etc);
	3. involvement of physical interventions (eg drawing of blood);

Where the FREC members are uncertain, they should opt for the higher value, i.e. sending the application to the full committee.

1. The form is then **authorised** by the FREC at its next meeting or by Chair's action (or a FREC member). The final outcome will be communicated to the applicant and copied to the Graduate School Office via the FREC Administrator.
2. Since registration takes place at an early stage in the research, conditional or provisional approval may be appropriate. In such cases, it will be necessary to revisit the question of RE before pilot testing begins (and if there is material change after pilot testing, again before the main fieldwork).

### Staff

1. All staff members who plan a research project, regardless of the funding source, must obtain ethical approval.
2. The form, accompanied by a project proposal, needs to be signed by their **line manager** or **head of research centre**.
3. The proposal is then forwarded to the **FREC Administrator for authorisation** either by the Chair, independent assessor or FREC.
4. Staff applications follow the same process as research student applications, with the major difference being that all staff applications with outcome 2) or 3) are reviewed by the FREC.

### Contract research and consultancy

If a project involving contract research and consultancy work raises ethical issues by involving human participants or impacting on human society, it is subject to the ethics reviw processes described here. Processing of applications by the FREC

All applications forwarded to the FREC (i.e. taught students deemed to be in categories 3) or 4) and all projects by research students or staff) will be dealt with in the following way:

1. All communication with the FREC needs to go through the FREC Administrator.
2. The application is logged into the RE database by the Administrator or a nominated representative. The database is located in an appropriate and sufficiently secure location and it is also accessible by the FREC members.
3. The application is submitted to the FREC for consideration.
4. If the project requires it, the application can be approved by Chair's action and put to the FREC for ratification. In the absence of the FREC Chair, the following members of the Committee can assume the position: Faculty Dean, Faculty Head of Research, FREC Deputy Chair.
5. The FREC Chair, or representative, will determine which applications need to be viewed by the Committee in full, following the guidance provided above.
6. Applicants are informed by email or other appropriate means of communication of the outcome of the approval process. Where required, the FREC can send formal letters to applicants.
7. If the application refers to a research student project (MPhil or PhD registration), the outcome of the approval process is communicated to the Graduate School by the Administrator to the Committee or a nominated representative.

## Specific issues and topics

The majority of applications in the Faculty raise no or minor ethical issues. There are, however, cases where projects are complex and touch on issues that go beyond the capacities of the FREC. In such cases the Committee will seek guidance from other places, including the FRECs of other DMU Faculties.

### Research involving human tissue

Research involving human tissue is governed by the Human Tissue Act 2004. If a Faculty member intends to undertake such research, they are advised to seek early guidance from subject specialists in the Faculty of Health and Life Sciences (HLS). The following processes will be followed.

1. The researcher needs to fill in the HTA application form, which is also available on the FREC web site and on the University intranet.
2. The initial supporting signature must be given by the line manager / head of research centre.
3. The application is submitted to the FREC and logged according to general guidelines.
4. The application is forwarded to the FREC of HLS with a request to provide recommendations on how to evaluate it.
5. Upon receipt of the recommendation, the FREC makes a decision on approval of the application, which will normally follow the recommendation.

### Medical or related research

Research touching on medical issues will normally be carried out in collaboration with the NHS, and therefore requires NHS ethical clearance. The FREC will normally authorise research that has gained ethical approval by the NHS.

In cases where NHS authorisation is not required or University authorisation is needed as a precondition of NHS ethics approval, the following process will be followed:

1. The researcher needs to fill in the HRE application form.
2. The initial supporting signature must be given by the line manager / head of research centre.
3. The application is submitted to the FREC and logged according to general guidelines.
4. The application is forwarded to the FREC of HLS with a request to provide recommendations on how to evaluate it.
5. Upon receipt of the recommendation, the FREC makes a decision on approval of the application, which will normally follow the recommendation.

## Sensitive research

There are three broad research areas which would usually cause the research to be classified as ‘sensitive’:

1. Research into illegal activities, including the collection of source data, e.g. crime statistics;
2. Research which requires access to web sites normally prohibited on university servers; including, but not limited to; pornography, or the sites of any of the [organisations](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/472956/Proscription-update-20151030.pdf) proscribed by the UK Government. See section 10 of this policy for more details;
3. Research into extremism and radicalisation.

Such research is dealt with according to the Policy on Conducting Sensitive Research. Any research falling in this category will need to have the project details registered with the servicing officer for the UREC.

# Appeal against FREC decisions

An appeal against the decision of the FREC is possible. Such an appeal will have to be submitted to the Chair of the University REC.

# Review of SOP

These standard operating procedures will be reviewed annually (normally in conjunction with the review of the FREC Terms of Reference) to ensure they remain appropriate and applicable.

# References

FREC Terms of Reference

UREC Terms of Reference

Faculty RE web pages