**Faculty of Health & Life Sciences**

**Faculty Research Ethics Committee**

**Application Guidelines**

All students or staff who wish to undertake research activities must apply for ethical approval **before** commencing their research. This document provides information on applying for ethical approval within the Faculty of Health and Life Sciences. All forms are available on the Faculty Ethics website at <http://www.dmu.ac.uk/research/ethics-and-governance/faculty-specific-procedures/health-and-life-sciences-ethics-procedures.aspx> . For additional information please contact The Research & Commercial Office, Faculty of Health & Life Sciences, 1.25 Edith Murphy Building, Tel: 0116 250 6122 / 0116 257 7891, email [hlsfro@dmu.ac.uk](mailto:hlsfro@dmu.ac.uk)

Issues to consider as part of the application process Page

Projects Requiring Ethical Review 2

The Application Process 2

The Ethics Application Form 3

The Proposal (or Protocol) 3

Consent 4

The Consenting Process - timeline 4

The Consent Form 4

Taking Consent from Vulnerable People 4

The Participant Information Sheet 5

Recruitment 5

Data Collection Tools 5

Confidentiality and Anonymity 5

Data Storage 6

Access to Data 6

Data Protection 6

Internet Mediated Research 7

Researching Illegal Activities 7

Feeding Back to Participants 7

Permission from Host Organisations (including NHS requirements) 7

Ensuring the Safety of Researchers 7

Human Tissue Act 8

Insurance Cover 8

Ethical Codes and Further Reading 8

**Projects Requiring Ethical Review**

The University requires that ethical approval is obtained by members of staff of the University and by students of the University who wish to engage in research. Research activities include:

1. Gathering information about human beings (or organisations) through:

* interviewing
* surveying
* questionnaires
* observation of human behaviour
* modifying/disturbing human behaviour
* interfering in normal physiological and/or psychological processes

1. Research involving the collection, storage and/or analysis of human tissue biopsies and/or biofluids.
2. Using archived data in which individuals are identifiable.
3. Researching into illegal activities, activities at the margin of the law or activities that have a risk of personal injury. (It should be noted that in regard to research into illegal activities there are no exclusions or blanket permissions and the University Insurance cover may not apply if the research activity has not been cleared by the University or, in certain cases with delegated authority by the appropriate Faculty Committee).
4. Supporting innovation that might impact on human behaviour e.g. Behavioural Studies.
5. Reuse of primary data.

Literature reviews and systematic reviews do not require ethical approval.

**The Application Process**

Undergraduate and Taught Masters Students

Applications from students on undergraduate courses or taught Masters programmes are reviewed within each school by Programme Management Board (PMB) panels. Students should submit one paper copy of the application and supporting documents to their supervisor/programme leader. This must be reviewed by two academic members of staff using the FREC Reviewer Form and then submitted to the relevant PMB Chair with a covering PMB Proforma for consideration, provisional approval and signature. Once signed this is then submitted to FREC for consideration and approval by the FREC Chair. Confirmation of approval will be sent to the Programme Leader and Programme Administrator, who should notify the student. All approvals granted are then ratified at the subsequent FREC meeting.

Staff and Postgraduate Research Students

Applications from students undertaking post graduate research (for example, PhD, MPhil, or DHSci) or staff are reviewed by two members of the Faculty Research Ethics Review Panel, approved by the Chair of the Faculty Research Ethics Committee and ratified by the Faculty Research Ethics Committee (FREC).

To submit completed applications, send one electronic copy to [hlsfro@dmu.ac.uk](mailto:hlsfro@dmu.ac.uk) **and** two signed paper copies of application forms and all supporting documentation to the FREC, Research & Commercial Office, 1.25 Edith Murphy House, The Gateway, Leicester, LE1 9BH. Please ensure forms are signed. It is expected that applications will be reviewed within three working weeks of submission, though this may be longer during university holidays.

**The Ethics Application Form**

There is one FREC Application Form, which is used for research involving humans or human tissue. As well as the application form, a proposal (protocol) must be submitted along with the appropriate supporting documents listed on the application form. Suggested information to include in the proposal is listed in the following section.

**The Proposal (or Protocol)**

The purpose of the proposal is to provide the reviewers with sufficient information about your proposed study. The review panel are interested in the practical aspects of your study, such as how many participants will be recruited, and from where. The study proposal should include the following sections:

Background – Short summary of the background or rationale for your proposed study in around one paragraph.

Research aims / objectives – List your research aims and objectives.

Research question – List your main research question or questions.

Study design – Brief overview of design.

Sample details – Who or what is the sample population. For example, all patients who had cardiac surgery at Glenfield hospital between January and June 2012

Sample size – State your intended sample size and rationale for choosing this sample size. Include statistical power calculations if appropriate.

Sampling method – How will you sample your population, for example ‘the first 20 DMU students to respond to an advert on the student notice board’.

Recruitment method – For example, letters sent out to all 1st year Pharmacy students with reply slips or flyers with contact details.

Data collection method -Where relevant, for example, biofluid and/or tissue biopsy collection protocol, interviews, questionnaires, surveys.

Data collection tool - For example, information about questionnaire or interview schedule

Analysis - Proposed statistical methods, tests or qualitative methods to be employed, e.g. thematic content analysis

Ethical issues - Including risks to study participants and researchers

Human Tissue issues

Drug formulation details

**Consent**

Participants must give consent before they take part in a study. Obtaining informed consent is one of the more complicated aspects of empirical research, with several issues to consider.

The Consenting Process - Timeline

Where possible, written information about the study should be given to applicants in advance of obtaining consent so that the applicant has time to seek advice and consider whether to participate. If written consent is required, this should be obtained in person by a member of the research team who is familiar with the study. If there is a long delay between obtaining consent and the participant taking part in the study, then the researcher must re-confirm the participant’s willingness to take part. Having given consent, a participant can still withdraw from a study at any time without giving a reason.

The Consent Form

An example consent form is provided for researchers to use. Not all the statements on the example will be relevant to your study. Keep statements which are relevant to your study and delete statements which are irrelevant. Adapt statements if necessary. Participants are required to initial each statement instead of ticking a box as ticks can easily be forged. Completed consent forms should be stored securely in accordance with the Data Protection Act. The consent form must have a date and version number. See embedded document below.

NOTE: not all studies require written consent from participants. For example, with anonymous postal surveys consent is implied by the participant completing and returning the survey form.



Taking Consent from Vulnerable People, Young People or People in Difficult Situations

Some participants are considered to be vulnerable; such as people with a learning disability or people who may be dependent in some way upon the researchers conducting the study. It is important that additional measures are considered when taking consent from vulnerable people, for instance this may include having a carer or advocate present. In some studies involving children, consent must be obtained from parents or guardians, and permission (assent) must be obtained from the child. There are some studies where it can be argued that the child is competent to judge whether they wish to take part and parental permission is not required. You may need to consult professional ethical codes, such as the British Psychological Association, when deciding whether parental consent is required. You may also need to consider DBS (formerly CRB) checks, safeguarding issues and vulnerable adults’ policy. Some participants may be protected by the Mental Capacity Act. In this case researchers should seek expert advice. Where obtaining written consent may be difficult because of literacy, language, age, formality, or marginalisation it may be possible to omit written consent and other ways of gaining meaningful informed consent should be considered.

**The Participant Information Sheet**

Researchers are required to give potential participants information about the study so they can make an informed decision whether to participate. Participant information sheets are not required for simple studies such as short anonymous surveys. Instead the key information can be given at the top of the survey sheet. For a more complicated study or a study where written consent is being obtained, information will be presented in the form of a participant information sheet. An example of a participant information sheet is provided below for researchers to adapt. The information sheet **MUST** describe exactly what taking part in the study will involve for the participant. For example, ‘participants will take part in a one hour interview with the researcher’. This document must be written in language which is appropriate and easy to understand. For your own safety, do not list your personal contact details on this form. Use your university email address and if you wish to provide a mobile telephone contact number you are advised to buy a ‘pay as you go’ phone which can be obtained for as little as £5. The participant information sheet must have a date and version number.



**Recruitment**

Researchers must ensure recruitment to the study is fair, not subject to duress, and complies with data protection legislation. It is not sufficient to say, for example, that four children out of a class of 30 will be selected to participate. Applicants must describe the selection process, providing inclusion or exclusion criteria where necessary. Researchers must be careful that participants do not feel pressurised into taking part in studies. This is especially relevant where participants are in dependent relationships with researchers, for example employers and employees, students and lecturers, or patients and clinical staff.

The organisation where the research is being carried out must not provide researchers with names or contact details of potential participants, unless these are already publicly available. This would breach the Data Protection Act. Instead, researchers can give invitations, flyers or information sheets to the host organisation to distribute or ask them to recruit on their behalf.

**Data Collection Tools** (for example questionnaire or interview schedule)

Researchers are required to submit a copy of the data collection tool along with the ethics application. A draft version may suffice in some cases as it is acknowledged that the final version of the questionnaire or interview schedule may be generated or refined during the study.

**Confidentiality and Anonymity**

Researchers must ensure the confidentiality and anonymity of participants and their data. Personal information must be stored and processed in accordance with data protection legislation.

**Data Storage**

Data must be stored securely to protect participants and researchers. Hard copy records should be stored in locked rooms, in locked filing cabinets. Electronic records should be password protected and backed up. Encryption software may be advised for some electronic data. Great care should be taken if using memory sticks or laptops. Organisations and funding bodies have varying requirements regarding the duration of data storage. DMU requires that raw and analysed data from all studies (completed questionnaires, audio / video recordings, diaries, observational recordings, laboratory notebooks and emails) should be kept for five years after the completion of the project. Data generated from projects that may have a secondary use for further research should be kept for the life of the project plus ten years. [[DMU data storage policy](http://www.dmu.ac.uk/documents/about-dmu-documents/quality-management-and-policy/records-management/research-records-retention-policy.pdf)]. If a study is funded, sponsored or conducted within an organisation which has more extensive data storage requirements, then the researcher must comply with the more extensive requirements. Participants must ensure that all their record keeping remains compliant with the data protection legislation that pertains at the time.

**Access to Data**

Access to data should be controlled to prevent unauthorised use. The proposal, participant information sheet and consent form should identify who has access to the data. Usually access is restricted to named members of the research team, or the research student and their supervisor. There have been several cases where researchers have successfully refused external requests for data because of access statements in information sheets or consent forms.

**Data Protection**

All research carried out by staff or students at DMU must comply with data protection legislation. This covers issues relating to accessing, obtaining and storing data. Several key issues are relevant to research projects. Researchers who wish to access personal data held by an organisation such as a hospital or a school must have explicit permission to do so. Researchers may have access to patients’ notes or students’ files because they are employed, or on a placement, within the organisation where they will conduct the research. However this does allow them to access data for their own research projects. Accessing personal data for research purposes without permission contravenes the Data Protection Act 1998. Researchers must obtain permission from the host organisation to access data. For organisations external to DMU this may mean contacting the Head of a School or Department, the Research and Development Office, the Clinical Audit Department or the Data Protection Officer.

Only personal data which is relevant to the research project should be collected. For example, do not ask for participants’ names or medical history unless this is fundamental to the study. Personal data must be processed in accordance with the Data Protection Act. Data must be held securely and access should be limited to researchers specified in the research protocol / proposal, participant information sheet or consent form. More information on the Data Protection Act can be found [here](http://www.legislation.gov.uk/ukpga/1998/29/contents).

**Internet Mediated Research**

Using the internet to conduct your research raises additional concerns. For example, participants can be identifiable or anonymous; they can explicitly consent to participate, or they can be invisibly observed without their knowledge. The key issues inherent when researching online are discussed [here](http://www.bps.org.uk/sites/default/files/documents/conducting_research_on_the_internet-guidelines_for_ethical_practice_in_psychological_research_online.pdf). These include: verifying identity; public/private space; informed consent; levels of control; withdrawal; debriefing; deception; monitoring; protection of participants and researchers; and data

protection.

**Researching Illegal Activities**

Researchers must be careful when researching illegal activities such as gangs, terrorism or crime. If researchers become aware of risk of harm they have a responsibility to take appropriate action, especially if this includes risk to children or vulnerable adults. Action may include informing the police or other authority. This action may supersede confidentiality. Including a copy of your interview schedule or questionnaire with your ethics application should show the review panel that you do not intend to place yourself in a difficult position.

**Feeding Back to Participants**

Informing participants of your findings is encouraged as part of your dissemination strategy. This might involve sending participants a short summary report at the end of the study.

**Permission from Host Organisations (including NHS requirements)**

If research is being conducted in an organisation outside DMU, such as a school, you must obtain permission from the host. If researchers are accessing data held by the host organisation then explicit written permission from the host organisation must be obtained to do this. Specific procedures must be followed if the host organisation is the NHS.

If the project is going to be carried out within the NHS and the project is considered by the NHS to be research (as opposed to audit or service evaluation), then approval from the relevant NHS Research Ethics Committee and the relevant NHS Research and Development (R&D) department must be obtained. If a project involves NHS staff only and there are no ethical concerns then the project might only require NHS R&D permission and not NHS Research Ethics approval. The NHS R&D department will advise on this. Researchers are still expected to obtain ethical approval from the DMU FREC before seeking approval from NHS Research Ethics. The Chair of the FREC will sign NHS Research Ethics applications and will provide a letter of sponsorship upon request.

**Ensuring the Safety of Researchers**

Researchers must minimise personal risks to themselves. Where possible, data collection should be conducted on DMU premises, a host organisation’s premises or in a public place. If data has to be collected in a private area such as a participant’s home, then researchers should carry a mobile phone, give details of their whereabouts to a colleague and contact the colleague after data collection is complete to confirm their safety. DMU’s Lone Worker Policy (available from POD/HR or via your Supervisor/Programme Leader) provides more information. Researchers must refrain from giving out personal contact details, especially in recruitment material. This includes personal email addresses and personal mobile phone numbers.

**Human Tissue Act**

If you are conducting research on biological samples collected from humans this is governed by the Human Tissue Act which serves to regulate the removal, storage and further utilisation of such human-derived specimens (tissue biopsies and biofluids). DMU does not hold a licence to store human tissue; however this does not mean that you cannot conduct research on human tissue at DMU. Research on human tissue can be conducted if ;

* project specific ethical approval has been sought from NRES
* the human tissue is obtained from an NRES approved human tissue bank and stored at the human tissue bank
* tissue is anonymised and has come from an NRES approved human tissue bank
* tissue is rendered acellular

The key points of the Human Tissue Act can be found [here](http://www.legislation.gov.uk/ukpga/2004/30/contents) and more detailed information can be found [here](http://www.legislation.gov.uk/ukpga/2004/30/contents).

**Insurance Cover**

DMU students and staff are covered by DMU’s public liability and professional indemnity insurance policies to undertake laboratory work, interviews, questionnaires and observations on or off campus. This includes cover for experimental studies which are considered by DMU to have a low risk of injury to participants or research staff. Risk assessment forms can be obtained from your Faculty Risk Assessor or via your Supervisor/Programme Leader. If you wish to undertake a clinical trial or a study where there is a high risk of injury to participants or research staff you must contact the Research and Commercial Office to find out if your proposed study will be covered by DMU’s existing insurance policy and if there are any additional financial costs to the research team. An example of a high risk study is a study where participants are asked to undertake exercise tests which might result in cardiac problems.

**Ethical Codes and Further Reading**

All research studies must comply with the Declaration of Helsinki and the Data Protection Act 1998. Additional codes may also be relevant such as the NHS Research Governance Framework for all studies involving NHS patients or staff. Other codes include:

* Nursing and Midwifery Professional Code of Conduct <http://www.nmc-uk.org/Publications/Standards/The-code/Introduction/>
* British Psychological Society - <http://www.bps.org.uk/>
* British Educational Research Association <http://www.bera.ac.uk/>
* British Sociological Association Ethics - <http://www.britsoc.co.uk/>
* British Society of Criminology <http://www.britsoccrim.org/codeofethics.htm>

The following links may provide useful additional information;

* National Research Ethics Service <http://www.nres.nhs.uk/>
* Research Governance Framework for Health and Social Care <https://www.gov.uk/government/publications/research-governance-framework-for-health-and-social-care-second-edition>
* Medical Research Council <http://www.mrc.ac.uk/index.htm>
* International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Guidelines for Good Clinical Practice <http://www.ich.org/>
* World Medical Association Declaration of Helsinki 2008 <http://www.wma.net/en/30publications/10policies/b3/>
* Department of Health Mental Capacity Act <https://www.gov.uk/government/publications/mental-capacity-act-deprivation-of-liberty-safeguards>
* Department of Health Adult Safeguarding <https://www.gov.uk/government/publications/adult-safeguarding-statement-of-government-policy-10-may-2013>
* Department of Health Safeguarding Children <https://www.gov.uk/government/organisations/department-for-education/series/safeguarding-children>