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 & Innovation Office, Faculty of Health & Life Sciences, 3.35 Edith Murphy Building, Tel: 0116 250 6122 / 0116 257 7891, email hlsfro@dmu.ac.uk

Projects Requiring Ethical Review

The University requires that ethical approval is obtained by members of staff and 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

2. Research involving the collection, storage and/or analysis of human tissue biopsies and/or biofluids.

3. Using archived data in which individuals are identifiable.

4. Supporting innovation that might impact on human behaviour, e.g. Behavioural Studies.

5. The reuse of primary data.

6. Sensitive research – If the study is researching in any of the following areas:
    - Research into illegal activities, including the collection of source data, e.g. crime statistics;
    - 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 proscribed by the UK Government;
    - Research into extremism and radicalisation.

    The researcher should refer to the DMU policy and guidelines available at;
    http://www.dmu.ac.uk/research/ethics-and-governance/sensitive-research.aspx
    It is not envisaged that UG or PGT students would normally undertake such research. However, it is not inconceivable and thus supervisors must take car to ensure students are well advised of the relevant policies.

Literature and systematic reviews and those using publicly available data do not require ethical approval.

Literature and systematic reviews are library based studies that only use public/published literature or reports with no collection of data. Publicly available data includes such things as Unistats, Office of National Statistics data/reports, crime statistics, health statistics, hospital waiting times etc.

The Application Process

Undergraduate and Taught Masters Students

- HLS FREC Forms must always be used.
- Applications from students on undergraduate courses or taught Masters programmes must be supported **and electronically approved** by a suitably qualified supervisor.
- Students should electronically submit applications and supporting documents to their supervisor/programme leader **ensuring the FREC Electronic Submission Requirements have been followed** (Appendix 2: HLS FREC Electronic Submission Requirements).
- The applications must be reviewed by at least two academic members of staff independently, or a subject-based ethics committee using the FREC Reviewer Form (one form per application may be used but all reviewers must be named on the form). Those reviewing applications should not be directly involved in the supervision of the proposed research.
- The reviewers or committee decide whether the proposed project is low, medium or high risk (Appendix 1 Category Guidelines for Taught Programme Student Projects).
- If judged to be acceptable the reviewers sign the review proforma.

If the proposed project has been identified as low or medium risk:

- Students should be informed at a local level that their application has been approved and that data collection can commence.
- The reviewers or subject committee chair submits the students' applications with the signed review forms to the Faculty Research Ethics Committee (FREC). **Applications should be submitted in batches and not as individual student submission.**
- The FREC will then send confirmation of receipt to the programme leader and programme administrator.
- **Note:** Any projects requiring HRA/IRAS approval where DMU is the intended sponsor should be notified to the HLS FREC Chair before an application is submitted via IRAS.

If the proposed project has been identified as high risk:

- The reviewers or subject committee chair submits the students' applications with the signed review forms to the Faculty Research Ethics Committee (FREC). **Applications should be submitted in batches and not as individual student submission.**
- The application will then be sent for approval by the Chair of the Faculty Research Ethics Committee and ratified by the Faculty Research Ethics Committee (FREC).
- Students must not commence data collection until the programme leader receives notification that the application has been approved. To do otherwise is a disciplinary offence.

All approvals granted are then ratified at the subsequent FREC meeting.

At several points in the academic year all submitted applications will be subject to audit by sample.

Staff and Postgraduate Research Students

Applications from students undertaking postgraduate research (for example, that involving PhD, MPhil, or DHSci degrees) 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).

Completed applications should be submitted electronically to hlsfro@dmu.ac.uk (please refer to appendix 2).

It is expected that applications will be reviewed within three working weeks of submission, although this may take longer during university holidays. Please note any amendments submitted by the applicant will restart the three working week timeline.

The Ethics Application Form

There is one FREC Application Form, which is used for research involving humans or human tissue. In addition to 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, where they are recruited from, exactly what they are expected to do, and what are the potential risks to both participants and researchers, etc. 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 – Are there any Human Tissue Act considerations that you should review?
Drug or products formulation details – If relevant.

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, however, 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 the study at any time without giving a reason (such participation is always ***voluntary***).

The Consent Form
An example consent form is provided for researchers to use. However, not all the statements on the example will be relevant to your study. Please retain statements which are relevant to your study, and delete those which are irrelevant. Adapt statements if necessary. Participants are required to initial each statement instead of ticking a box, since ticks can easily be forged. Completed consent forms should be stored securely in accordance with the current Data Protection legislation and DMU data retention policy. The consent form must have a date and version number (please refer to the embedded document below).

When consent is taken using hardcopy forms, a signed copy of the consent form should be retained by the researcher. A signed copy of the consent form and a copy of the participant information sheet should be given to the participant giving their consent.

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

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

Some participants are considered to be vulnerable, such as those with a learning disability or who may be dependent in some manner upon the researchers conducting the study. In these cases, it is important that additional measures are considered when taking consent from vulnerable participants - for example, 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 therefore 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 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 means of gaining meaningful informed consent should be considered.

The Participant Information Sheet

Researchers are required to give potential participants information about the study concerned so that they can make an informed decision regarding whether or not 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 one in which written consent is being obtained, information will be presented in the form of a participant information sheet (PIS). An example of a participant information sheet is provided on the HLS FREC website for researchers to adapt according to their requirements. 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 a 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 purchase a 'pay as you go' phone/sim. The participant information sheet must have a date and version number on it.

Recruitment

Researchers must ensure that recruitment to the study is fair, not subject to duress, and complies with data protection legislation. It is not sufficient to state, 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 deemed necessary. Researchers must be careful that participants do not feel pressurised into taking part in studies. Indeed, this is especially relevant to situations 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 Legislation. Instead, researchers can give invitations, flyers or information sheets to the host organisation to distribute, or alternatively request them to recruit on their behalf.

Withdrawal of Data

It must be made clear to potential participants whether or not it is possible to withdraw their data if they elect to withdraw from the study. Where data is collected by anonymous survey, it is clearly not possible to withdraw data. There may be other occasions on which the withdrawal of data may not be possible, e.g. some qualitative investigation methodologies. In such cases, the potential participants must be informed that if they withdraw from the study, data provided up to that point in time may still be included in the study.

Data Collection Tools (for example questionnaires or interview schedules)
Researchers are required to submit a copy of the data collection tool along with the ethics application. However, a draft version may suffice in some cases since 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 as much as possible. Potential participants for focus group studies should be reminded that confidentiality and anonymity cannot be guaranteed, since participants are not necessarily bound by a code of conduct. Similar warnings should be included for participants in 'small world' studies, in which there are only a small number of people in a population that fit a certain profile.

If researchers become aware of risk of harm, they have a responsibility to take appropriate action, especially if this includes risks 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 demonstrate to the review panel that you do not intend to place yourself in a difficult position.

Personal information must be stored and processed in accordance with data protection legislation.

For anonymous surveys completed online (for example using Survey Monkey or Qualtrics), consent may not always be required (see Consent section). Survey tools often give the option to not record I.P address for anonymity purposes.

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 retention policy]. If a study is funded, sponsored or conducted within an organisation which has more extensive data storage requirements, then the researcher must comply with these specifications. Participants must also ensure that all their record keeping remains compliant with the data protection legislation that pertains at that time.

Access to Data

Access to data should be controlled in order to prevent unauthorised use. The research proposal, participant information sheet and consent form should all 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. However, there have been several cases where researchers have successfully refused external requests for data in view of access statements in participant information sheets or consent forms.

Data Protection

All research performed 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 Legislation. Therefore, researchers must obtain permission from the host organisation in order to access data. For organisations external to DMU, this may involve contacting the Head of a School or Department, the associated 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 histories 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 Legislation can be found here GDPR Policy

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 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 follow the DMU policies HERE when researching illegal activities such as gangs, terrorism or crime.

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 of the findings 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 conducted 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, provide 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 currently 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 and FAQs from the Human Tissue Authority can be found HERE. Further guidance is also available on the HLS FREC website.

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 Innovation Office to determine if your proposed study will be covered by DMU's existing insurance policy, and also if there are any additional financial costs to the research team. One example of a 'high risk' study is one in which 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 Legislation. 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/docs/CodeofEthics.pdf

The following links may provide useful additional information;

- Health Research Authority www.hra.nhs.uk/
- UK Policy Framework for Health and Social Care Research https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- 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 2018 https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
- 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/publications/working-together-to-safeguard-children

Appendix 1 Category Guidelines for Taught Programme Student Projects

Introduction

HLS FREC processes need to be managed effectively in order to ensure appropriate levels of scrutiny of application for research ethics approval. This is to ensure that the University is compliant with its obligations under law and to its insurers. In order to do this, a risk based approach is adopted which applies a level of review appropriate to the risk presented by certain categories of studies. The aim is to enable responsible ethical review of studies which do not to unnecessarily delay the commencement of research projects for taught programme students. A separate process is in place for research students and staff research.

It is recognised that there are a significant number of studies undertaken at the University which involve human participants, but which have minimal risks attached. In cases of low and medium risk studies, and also in order to assist in the management of approvals in a timely fashion, the HLS FREC has agreed the use of a "light touch" review.

High risk

These are the type of studies that are required by our insurers to have this additional approval level and/or that the University Research Ethics Committee considers are of a nature that this additional review is necessary before the research can commence. The HLS FREC (or the chair or delegated person) may at its sole discretion escalate a matter to a higher level of review (for example University Research Ethics Committee).

The studies that will fit into this category are those that involve one or more of the following:

- Administration of medicinal products (including placebos)
- Investigations of medical devices and studies that use a device on the participant that is not yet CE marked or licensed for its intended use
- Ingesting food or drink or other products (including vitamin supplements, nutritional studies etc.) which exceed normal recommended consumption levels, are outside any market authorisation, or where there is product warning and the participants are likely to be covered by that product warning
- That involve treating, preventing or diagnosing disease, assisting or altering the process of conception or investigating methods of contraception
- Studies into sensitive subjects such as pornography, illegal acts, terrorism, the dark web, etc.
- That involve treating, preventing or diagnosing disease, assisting or altering the process of conception, or investigating methods of contraception
- Induce physical discomfort and/or pain beyond which that they may routinely encounter in their everyday life
- Expose the participants to visual, auditory or other stimuli beyond that which would normally be experienced in everyday life
- Inhalation of gases
- Eliciting information from participants that could render them liable to criminal proceedings (e.g. drug abuse or child abuse)
- Alter the participants' normal patterns of sleeping, eating or drinking

- Participants who are:
    - Pregnant or a breastfeeding mother
    - Detained in lawful custody (in a prison, remand centre, young offender institution, secure training centre or attendance centre, or under the powers of the Immigration and Asylum Act 1999)
    - Is under the supervision of the probation services

- Individuals who do NOT;
    - Have the capacity to give consent in accordance with the Mental Capacity Act 2005
    - Have the capacity, or appear not, to give free and informed consent for any reason (including under the influence of drugs or alcohol, being coerced, confused etc.)

Medium risk studies

All research/studies which do not fall within the above high risk category review criteria will be considered as requiring a medium risk review unless it is agreed that the low risk criteria is met.

- Studies which recruit individuals external to DMU
- Studies conducted outside the confines of the DMU campus
- Studies which use Opt-Out consent
- Studies which involve NHS Staff or facilities and/or which may use anonymised patient/NHS data
- Collection of and/or research using human tissues
- Studies involving invasive techniques of any kind (including taking blood samples, ultrasound scans, medical resonance imaging or similar approaches)
- Studies that require ethics approval from an independent external ethics committee (e.g., a Health Research Authority)
- Induce anxiety, stress or other harmful psychological states on a momentary basis
- Studies which recruit participants under 18 years old
- Studies recruiting the homeless, or those living in sheltered accommodation
- Studies recruiting those deemed vulnerable adults.

NB. Opt out consent should only be used in exceptional circumstances where the FREC considers the risks are adequately mitigated, and clear instructions are provided to participants regarding their right and how to withdraw consent.

Low risk studies

Without being prescriptive, the types of research anticipated as possibly falling within this category are the following;

- Conducted within the confines of the DMU campus (excluding halls of residence) and recruit DMU staff or students using:
  - Anonymous questionnaires, provided that these do not touch on sensitive topics
  - Face-to-face or focus group interviews
  - Market or opinion research
  - Customer satisfaction type surveys
  - Previously collected anonymous data held by the university which cannot be traced back to the individuals who provided them by any of the study team
  - Performance of verbal/paper & pencil/computer-based tasks,
  - Service evaluation/audit/needs assessments
  - Observation of performances/behaviour

Appendix 2: HLS FREC Electronic Submission Requirements

Undergraduate and Taught Masters Students

Ethics applications will now **only** be accepted electronically. Failure to adhere may result in an application being rejected or hard copies being requested.

Student	**Step 1: Student** emails completed application with all supporting documentation to their **Supervisor/Programme Leader /Module Leader** as instructed. This must be sent from an official DMU student email account. All documents must be version controlled, including the version number (V1, V2, V3 etc) and date in the document title and footer.
Supervisor	**Step 2: Supervisor** approval and confirmation they have reviewed and approved the application for submission should be provided as an attached email from an official DMU email account. *Please consider an appropriate accompanying email to include; project title, student name, supervisor name, programme/module, school, etc.*
Programme Leader/Admin and Reviewers	**Step 3: Supervisor/Programme Leader/Module Leader** should then coordinate an appropriate review in line with Taught Student FREC requirements (see Page 4). **Step 4: Reviewers** email their completed FREC reviewer forms to whoever is coordinating the application review (**Supervisor/Programme Leader/Module Leader**) **Step 5:** Once approved, a 'Taught Student Proforma' should be completed electronically listing each student and the outcome of the reviews. Where multiple student applications are being submitted, each application including supporting documentation and the two reviewer forms must be compiled into a single zip file per student. Please rename zip files appropriately with student names and date e.g. *'Albert Einstein - 190617'*. **Step 6:** Batches of zipped applications should then be emailed by **Programme Leader/Module Leader/Admin** to hlsfro@dmu.ac.uk with an accompanying 'Taught Student Proforma'. Please title your email appropriately so it is picked up by the right team e.g. *'Student Ethics – Module'*

Attachments and supporting documentation
This list is non-exhaustive but attachments may include;

- Ethics Application Form (compulsory)
- Consent form
- Data collection tools (e.g. draft interview schedule, survey questionnaire)
- Recruitment flyer or advertisement
- 2 x completed reviewer forms (compulsory) – *Programme Leader responsibility*
- Research Proposal (compulsory)
- Participant information sheet (PIS)
- Permission from external organisation
- Human Tissue Information
- Email support from Supervisor
- Participant response slip

Accepted file formats: word.doc / word.docx / adobe.pdf / windows.zip / outlook.msg

To create a zip file - Select the files or folder that you want to zip. Right-click and select 'Send to', and then select Compressed (zipped) folder. A new zipped folder with the same name is created in the same location.

All documents, example tools and processes referred to can be found on the HLS FREC Website;
http://www.dmu.ac.uk/research/ethics-and-governance/faculty-specific-procedures/health-and-life-sciences-ethics-procedures.aspx

Staff and Postgraduate Research Students (PhD, DHSci, MRES)

Ethics applications will now be accepted electronically. Providing these guidelines are followed there will be no requirement for signed hard copies; Failure to adhere may result in an application being rejected or hard copies being requested.

All documents must be version controlled, including the version number (V1, V2, V3 etc) and date in the document title and footer.

Email requirements and signatures

Completed application and all supporting documentation should be submitted electronically via email to hlsfro@dmu.ac.uk from an official DMU email account.

Research Students may either submit their application personally from their student email or via their DMU supervisor. If submitted personally, please attach supervisor confirmation they have reviewed and approved the application for submission – this can be done with an attached email or with an electronic signature on the FREC application form.

Please consider an appropriate accompanying email for both the initial application and the supervisor approval to include; project title, area of research, member of staff/PhD student, supervisor name etc.

Attachments and supporting documentation

This list is non-exhaustive but attachments may include;

- Ethics Application Form (compulsory)
- Consent form
- Data collection tools (e.g. draft interview schedule, survey questionnaire)
- Recruitment flyer or advertisement
- Participant response slip
- Research Proposal (compulsory)
- Participant information sheet (PIS)
- Permission from external organisation
- Human Tissue Information
- Email support from supervisor

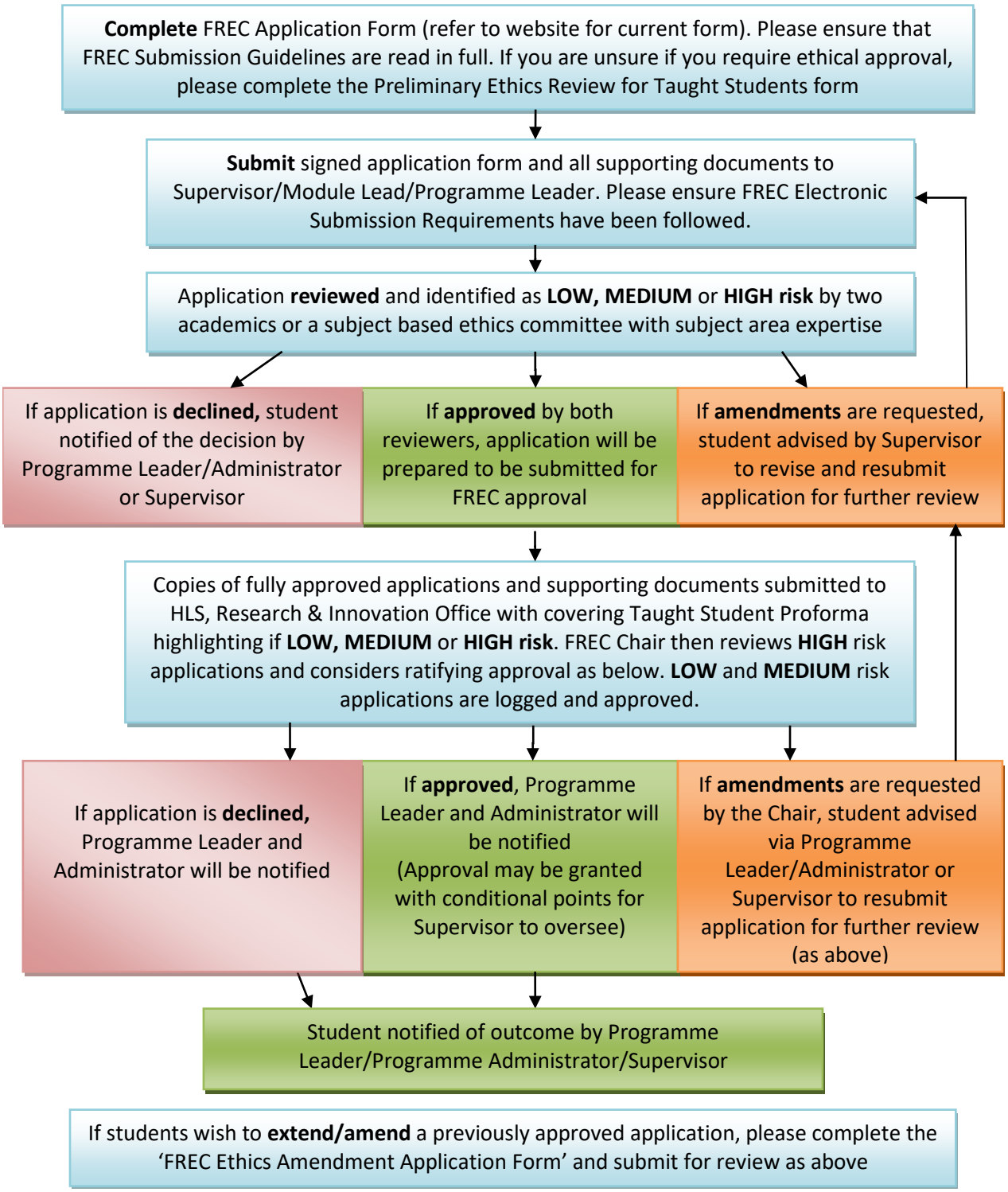
Please consider naming and numbering documents appropriately to assist reviewers and the FREC.

Accepted file formats: word.doc / word.docx / adobe.pdf / windows.zip / outlook.msg

All documents, example tools and processes referred to can be found on the HLS FREC Website; http://www.dmu.ac.uk/research/ethics-and-governance/faculty-specific-procedures/health-and-life-sciences-ethics-procedures.aspx

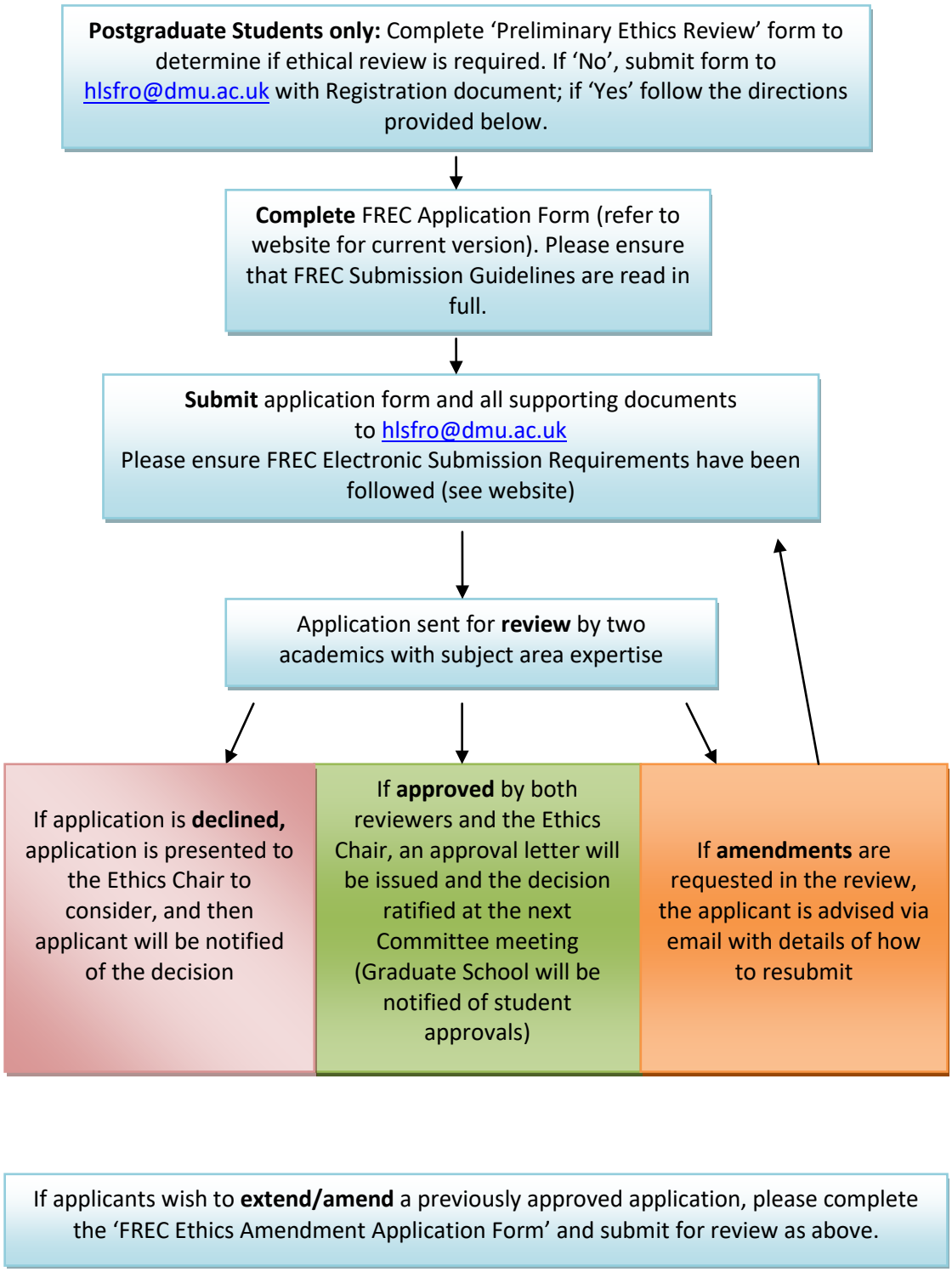
Ethics Application Process
Taught Undergraduate and Postgraduate Students

For all documentation referred to, please see http://www.dmu.ac.uk/research/ethics-and-governance/faculty-specific-procedures/health-and-life-sciences-ethics-procedures.aspx



Ethics Application Process
Staff Research and Postgraduate Research Degree Students (PhD, DHSci, MRES)

For all documentation referred to, please see http://www.dmu.ac.uk/research/ethics-and-governance/faculty-specific-procedures/health-and-life-sciences-ethics-procedures.aspx



If applicants wish to **extend/amend** a previously approved application, please complete the 'FREC Ethics Amendment Application Form' and submit for review as above.