DE MONTFORT UNIVERSITY LEICESTER

Research Services

RESEARCH ETHICS CODE OF PRACTICE

CONTENTS

For enquiries relating to this document contact: ethics@dmu.ac.uk

1. INTRODUCTION

1.1 This code should be read alongside the university's policies, procedures and advice relating to ethical review, health and safety, data protection, insurance cover and research contractual issues.

Health and Safety	Health, Safety and Occupational Health (sharepoint.com)
Data Protection	GDPR Data Protection Processes and Policies (sharepoint.com)
Insurance	Insurance (sharepoint.com)
Research Ethics	Research Ethics (sharepoint.com)

It is intended to cover ethical considerations and conduct to include, but not be limited to, all research involving human participants, the processing of personal data or animal subjects carried out at DMU or under the auspices of DMU, and research integrity. Researchers should respect the rights and dignity of participants in their research and the legitimate interests of stakeholders such as funders, institutions, sponsors and society at large. Researchers should also follow the ethical codes of any relevant professional association, educational institute or other external body with which they are associated, and abide by relevant legislation.

1.2 Investigations involving human participants may be undertaken within Schools/Faculties at DMU, or indeed, in professional services as research, teaching or consultancy/ enterprise activity. The University seeks to ensure that the conduct of all its staff and students and of visiting investigators carrying out investigations under the University's aegis conform to the relevant sections of the University's Research Ethics Code of Practice (RECoP).

1.3 All researchers and research supervisors must read the RECoP prior to commencement of research. If further clarification or guidance is needed, members of the relevant Faculty Research Ethics Committees (FRECs) should be consulted.

1.4 DMU requires that all research is subject to ethical consideration. If ethical approval is needed, it must be obtained prior to the commencement of research. This includes internal ethical approval as well as external approval where necessary (e.g. external approval from the NHS Research Ethics Committee (NHS REC)).

1.5 Failure to conduct research in accordance with the RECoP may result in the loss of funding support, withdrawal, or failure of degree assessments or awards, and personal disciplinary or legal action taken against the researcher, supervisors or the University.

1.6 More information can be found on the research ethics website.

2. DEFINITIONS

2.1 '**Research**' is defined as any form of disciplined enquiry that aims to contribute to a body of knowledge or theory. According to the Frascati definition: 'Research and experimental development (R&D) comprise creative and systematic work undertaken in order to increase

the stock of knowledge – including knowledge of humankind, culture and society – and to devise new applications of available knowledge.'

2.2 To qualify as R&D, an activity must be all of the following: novel, creative, uncertain, systematic, and transferable and/or reproducible. The term 'R&D' covers three types of activity: basic research, applied research and experimental development.

2.3 The Frascati Manual lists Frascati Manual 2015: situations where certain activities are to be excluded from R&D except when carried out solely or primarily for the purposes of an R&D project. These include:

2.3.1 Routine testing and analysis of materials, components, products, processes, etc.;
2.3.2 Feasibility studies;
2.3.3 Routine software development;
2.3.4 General purpose data collection.
2.3.5 Education and training other than UG/PGT/ PhD research

2.4 The latter stages of some clinical drug trials may be more akin to routine testing, particularly in cases where the original research has been done by a drug company or other contractor. Examples of non-research income include Consultancy, PhD Studentships, and Services Rendered activity.

2.5 **'Research ethics'** refers to the moral principles guiding research from its inception through to completion and publication of results.

2.6 '**Research Ethics Committee (REC)**' refers to a multidisciplinary, independent body responsible for reviewing research proposals involving human participants to ensure that their dignity, rights and welfare are protected. The independence and competence of a REC are based upon its membership, its rules regarding conflicts of interest and on regular monitoring of and accountability for its decisions. At DMU, the Faculty Research Ethics Committee (FREC) is the body responsible for reviewing research proposals, with oversight from the University Research & Enterprise Ethics Committee (UREEC).

2.7 '**Protocol'** refers to a filed document which specifies the procedures for recruiting participants and gathering and managing data for a research project, with which all project staff agree to comply.

2.8 **'Human participant'** is defined as including; living human beings, human beings who have recently died (cadavers, human remains and body parts), embryos and foetuses, human tissue and bodily fluids and human data and records (such as but not restricted to medical, genetic, financial, personnel, criminal or administrative records and test results including scholastic achievements).

2.9 It is now common practice to refer to a person who serves as a data source for research as a 'participant'. This recognises their active role and replaces the term 'subject' which has been viewed as portraying people as passive recipients rather than active agents. While the extent of active 'participation' in the research over and above providing information will of course vary greatly from one project to another, the use of the term 'participant' also serves to acknowledge the autonomy and agency of the individual in contributing to the research, and their right to withdraw at any time without penalty.

2.10 Types of research or activities requiring ethical approval include, but are not limited to:

2.10.1 Funded research: research that is funded in whole or in part by an organisation (both internal and external funding);
2.10.2 Staff research: an agreed programme of research undertaken by a member of staff under the auspices of DMU that is not 'funded' research;
2.10.3 Research undertaken by Postgraduate Research Degree Students registered at DMU;
2.10.4 Undergraduate and Taught Postgraduate Dissertations or Projects: a research programme/project for a dissertation undertaken by an undergraduate or postgraduate taught student registered at DMU;
2.10.5 Institutional Research: any research conducted or commissioned by DMU which might include:

2.10.5.1 Basic Research: experimental and theoretical work undertaken to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view;
2.10.5.2 Strategic Research: applied research that is in a subject area which has not yet advanced to the stage where eventual applications can be clearly specified;
2.10.5.3 Applied Research: work undertaken in order to acquire new knowledge.

2.11 Research undertaken with DMU staff or students as participants (see 5.4 below).

2.12 If you are unsure if your project is considered research, consult with the Faculty Research Ethics Sub-committee or the University Research and Enterprise Ethics Committee, or your supervisor (you can also email ethics@dmu.ac.uk). For the purposes of best practice, or where there is any doubt as to whether ethical approval should be sought, it is recommended that DMU's standard ethical procedures are followed. This is especially pertinent for projects where any data of any type is collected, which researchers may wish to re-use or re-present in another format at a later date.

3. THE KEY PRINCIPLES

3.1 In addition to the scientific rigour of a project and the conduct of the researcher(s), projects should be ethical and in particular safeguard any participants and/or their data, and the researcher(s). Ethical issues are many and varied and may be quite complex, with ethical implications changing depending on the context. It is recognised that there are differences between disciplines, but all research should be guided by the principle that the risk of harm to the participants should be removed or minimised as far as reasonable, and the benefit (beneficence and non-maleficence) to the participants and/or society should be maximised as far as possible.

3.2 Research should be designed, reviewed and undertaken to ensure integrity, value and quality.

3.3 The results of research should benefit society either directly or by generally improving human knowledge and understanding.

3.4 Researchers must ensure their proposed research project follows the ethical guidelines of an appropriate professional practice recognised by their faculty where applicable. FRECs will be responsible for identifying appropriate professional practices with ethical guidelines.

3.5 Participants should be fully informed about the purpose, methods and intended possible use of the research. Where there are exceptions to this, the purpose and rationale of such research projects will be fully considered, as appropriate, before approval is given.

3.6 Researchers should respect the human participants involved in their research as persons of worth whose participation is a matter of their autonomous choice (Section 4.5.2 provides further guidance on research on participants who lack the capacity to consent). The process of securing informed consent upholds the principle of respecting autonomy. Special consideration needs to be given in circumstances where a participant is unable to fully appreciate or comprehend the implications of participating in research.

3.7 Research participants must normally participate voluntarily, free from coercion. In this regard, incentive payments could be seen as coercive, or as exerting undue influence on potential participants' decisions about whether to take part in research. Section 10.7 provides further guidance on reimbursement of research participants.

3.8 Participants also have a right to withdraw from participating as well as the right not to answer particular questions. Researchers should indicate a point at which a participant may withdraw (e.g. up to the point of anonymisation when a participant's data cannot be excluded from the study or destroyed).

3.9 Researchers must consider the physiological, psychological, social, political, economic, cultural, environmental and spiritual impact of their research on participants. Efforts must be made to protect participants as far as possible, so that no harm comes to them as a result of being involved in the study.

3.10 The confidentiality of information supplied by participants must be respected, except where the requirements of professional practice determine otherwise. Any limits to confidentiality must be explained to participants.

3.11 Issues of anonymity and anonymisation of results should be fully considered, and where personal disclosure or identification is likely, this must be discussed with the participants and their specific consent to this obtained. Pseudonyms do not always protect anonymity and researchers need to ensure other personal information is not given that could make the participant identifiable.

3.12 All research must comply with the General Data Protection Regulations (GDPR) and the seven data protection principles. All funded, contractual or collaborative research must comply with the specified requirements for data storage and retention. See DMU's Research Data Management webpages.

3.13 The health and safety of both, researchers and participants, should be considered in the design and execution of research projects.

3.14 Research outcomes should be disseminated in a manner which makes them accessible to participants.

3.15 The independence of the research outcomes must be ensured. External sources of funding and any potential conflict of interest must be declared during the ethical approval process.

3.16 Researchers should comply with guidelines on authorship of publications. The Committee on Publication Ethics (COPE) has core practices and extensive resources and guidelines that should be referred to.

3.17 Failure to comply with the terms of ethical approval for a research project, or failure to seek further approval if required, may lead to action under the University's Misconduct In Research policy.

4. Roles and Responsibilities

4.1 Responsibility for drafting and reviewing research ethics policies and procedures as set out in this document lies with the University Research and Enterprise Ethics Committee (UREEC), which acts on authority delegated to it by the University's Academic Board for oversight of matters relating to research ethics. Implementation of these policies and procedures is the responsibility of the Faculty Research Ethics Sub-committees (FRECs) and is monitored by UREEC. The key responsibilities for those involved in conducting and overseeing research is set out as below.

4.2 **University Responsibilities:** The University is responsible for creating a research environment that develops good research practice and supports a culture of research integrity and ethics. This includes supporting researchers to understand and act according to expected standards, making guidelines and policies easily available and having procedures in place to ensure that research is conducted in compliance with the Concordat to Support Research Integrity. DMU will provide comprehensive training and development on good research practice as well as have appropriate arrangements in place through which researchers can access advice and guidance on ethical, legal and professional obligations and standards. The University exercises its responsibilities largely through the University Research and Enterprise Ethics Committee (UREEC).

4.2.1 DMU will ensure that staff and students have been informed of the research ethics and integrity requirements of the University.

4.2.2 The University will promote and facilitate staff and student training and development in research ethics and integrity.

4.2.3 The University will ensure that all academic staff, supervisors and students conducting research are made aware of their obligations, including the completion of any relevant research ethics and integrity training.

4.2.4 The University may undertake monitoring of approved research projects to ensure compliance with the terms of the ethics approval.

4.2.5 UREEC is responsible for overseeing ethics policies and processes and reviewing applications which cannot be adequately dealt with, or are referred to it, by the Faculty Research Ethics Committee (FREC). It will consider the ethical implications of all research involving human participants, the processing of personal data, or animal subjects, carried out at DMU or under the auspices of DMU, including the use of DMU's name and/or logo, or facilities for research purposes, and where DMU is the data controller or processor.

4.2.6 The University's Governing Body will ensure that UREEC has external and lay membership in accordance with the terms of reference, reflecting the importance of

independent (including lay) contributions to discussions and decisions on ethical approval and ethical policy.

4.2.7 Ethical review is the responsibility of each FREC; however, UREEC has overall responsibility for ethical review and may intervene at any stage. UREEC guides, directs and monitors FRECs to consider ethical issues relating to research, receiving and reviewing regular reports from them.

4.2.8 The composition and responsibilities of UREEC and the FRECs are set out in detail in their respective terms of reference. Contact the FREC servicing officers within the appropriate faculty for access to the most recent TOR for the FREC. HLSRCO@dmu.ac.uk The chief responsibilities of UREEC and FRECs are:

4.2.8.1 Development of policy;
4.2.8.2 Development and communication of good practice;
4.2.8.3 Debate and developmental work relating to research ethics issues;
4.2.8.4 Consider specific ethical issues;
4.2.8.5 Provide developmental opportunities for UREEC and FREC members, including lay and/or external members;
4.2.8.6 Approve ethics for research proposals;
4.2.8.7 Oversee research ethics processes;
4.2.8.8 Provide guidance and recommendation on misconduct related to research ethics/integrity;
4.2.8.9 Audit of compliance with the RECoP.

4.3 **Researcher Responsibilities:** Ultimately, responsibility for ethical conduct primarily rests with the researcher. The researcher (staff or student) is responsible for the following, and *must* abide by the DMU Research Ethics Code of Practice at all times when undertaking research under the auspices of DMU.

4.3.1 *In the case of students*, ensure the project is discussed with the supervisor/ module leader prior to seeking ethical approval;
4.3.2 Complete the Ethics Checklist/ Triage questions via the online application system where ethics approval is required;
4.3.3 Ensure compliance with any other additional requirements (such as those defined by the NHS, the laws and regulations of the country within which the research is taking place, research collaborator/s, funders, or any other relevant organisation or body);
4.3.4 Obtain ethical approval **before** any data collection commences for the project;
4.3.5 Prior to commencing and during the research project, the Principal Investigator (PI)/student *must*:

4.3.5.1 Operate with integrity and with due regard to the ethical considerations and challenges relevant to the research project;
4.3.5.2 Operate within the provisions of the ethical approval granted;
4.3.5.3 Provide annual updates for high-risk research (Appendix 2)
4.3.5.4 Ensure that where the scope of the research project changes, such changes are discussed with the supervisor/ module leader to ensure the original ethical approval granted remains appropriate *(the staff/student researcher must re-submit an application for ethical approval if changes to the research project mean that previous ethical approval may no longer be valid);*
4.3.5.5 It is advisable to address publication and authorship issues at an early stage of the project, and to document agreed decisions. PIs must ensure that, where appropriate, all researchers have the opportunity to contribute to the publication process.

4.3.6 Following completion of the research project, the PI/student **must**:

4.3.6.1 Take full responsibility for ensuring **ALL** study information, including research data and participant consent forms is stored securely and retained/destroyed in accordance with the GDPR and Data Protection Act 2018. See also DMU's Data Protection Policy;

4.3.6.2 Ensure dissemination of the findings is appropriate in terms of anonymity and confidentiality;

4.3.6.3 In order to ensure a high standard of publication, PIs should, where appropriate, submit their work for peer review prior to publication.

4.3.7 The University expects anyone listed as an author on a paper to accept personal responsibility for ensuring that they are familiar with the contents of the paper. The COPE (Committee on Publication Ethics) report on "How to handle authorship disputes: a guide for new researchers can be a useful resource for all those publishing research along with the UK Research Integrity Office (UKRIO) publication UKRI good practice in research policies and standards. "Good Practice in research: Authorship" (2017);

4.3.8 Researchers should clearly acknowledge all sources used in their research and seek permission from any individuals if a significant amount of their work has been used in the publication.

4.3.9 PIs should adhere to any conditions set by funding or other bodies regarding making their research and findings open access within a specified period. They should familiarise themselves with DMU's Policy for Managing Open Access at DMU and Research Data Management Policy

4.3.10 The University and researcher should accept their duty to publish and disseminate research in a manner that reports the research and all the findings of the research accurately and without selection that could be misleading. If an error is found that diminishes the worth of the published results, the researcher should discuss the matter with the PI/supervisor and notify any co-authors. A correction should be published as soon as possible setting out the basis of the reservation. Where the findings are found to be in serious doubt, a retraction should be published speedily. Further guidance relating to journal retractions and corrections are available at Publication of UKRIO Information Note: Guidance for researchers on retractions in academic journals - UK Research Integrity Office

4.3.11 All research undertaken by staff or students must comply with the legal requirements of the UK, and/or the country of location of the research project.

4.4 **Supervisor Responsibilities:** To ensure that all research, especially that undertaken by new researchers, is in accordance with best practice, supervisors must undertake appropriate training. DMU academic colleagues who wish to act as supervisors for research degree students are required to complete the University's Certificate in Research Supervision on good practice and student monitoring.

4.4.1 Supervisors overseeing the research projects of Postgraduate Researchers (PGRs) have a responsibility to discuss research ethics with their student(s), review the student's ethics application to ensure the research project is in line with research ethics principles and

ensure the student is prepared to submit an ethics application to a FREC for approval as appropriate;

4.4.2 Supervisors overseeing the research projects of undergraduate and postgraduate taught students have a responsibility to discuss research ethics with their student(s Undergraduate and post graduate taught students should only be engaging in low risk activity. See Appendix 2 for information regarding risk) ; Supervisors should be continually aware of the activities that are being undertaken for the duration of the project, and to ensure that they are in line with the ethical clearance that was granted.

4.4.3 DMU will provide research ethics training to supervisors to ensure they have the appropriate knowledge to inform their students regarding basic research ethics principles.

4.5 **Ethics Panel Responsibilities**: It is the responsibility of Faculty Research Ethics Committees to determine whether a research project is ethically sound. As recommended by thehttps://www.ukri.org/councils/esrc/guidance-for-applicants/research-ethics-guidance/framework-for-research-ethics/ , Ethics Panels/Ethics Champions and Supervisors/Ethics Programme Teams should regard the following aspects of research to be considered as involving above minimal risk and therefore likely to require a more thorough ethical review prior to approval (Appendix 2):

4.5.1 *Research involving potentially vulnerable groups*, for example, children and/or young people, those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship. Dependent or unequal relationships can be defined as pre-existing relationships between participants and researchers or between participants and others involved in facilitating or implementing the research. These relationships may compromise the voluntary character of participants' decisions, as typically one party has or has had a position of influence or authority over the other. Examples may include relationships between:

4.5.1.1 Carers and people with chronic conditions or disabilities, including long-term hospital patients, involuntary patients or people in residential care or supported accommodation;

4.5.1.2 Health care professionals and their patients or clients;

4.5.1.3 Teachers and their students;

4.5.1.4 Prison authorities and prisoners;

4.5.1.5 Governmental authorities and refugees;

4.5.1.6 Employers or supervisors and their employees;

4.5.1.7 Service-providers (government or private) and especially vulnerable communities to whom the service is provided (e.g. homeless, rough sleeping).

4.5.2 *Research involving those who lack capacity.* All research involving those who lack capacity (as defined under the Mental Capacity Act 2005 Part 1 Section 2), or who during the research project come to lack capacity, must be approved by an 'appropriate body' operating under the Mental Capacity Act 2005. It is illegal to conduct such research without approval of an 'appropriate body'. An 'appropriate body' is a Research Ethics Committee (REC) recognised by the Secretary of State or Welsh Ministers. All NHS Research Ethics Committees (RECs) in England and Wales are recognised. RECs in Scotland and Northern Ireland are not recognised for the purposes of the Mental Capacity Act. In addition, there is a national Social Care REC (SCREC) established in 2009 under the aegis of the Social Care Institute of Excellence (SCIE), which is recognised as an 'appropriate body' under the Mental Capacity Act.

4.5.3 *Research involving sensitive topics*, including, for example, but not exclusively, participants' sexual behaviour, their illegal behaviour, their experience of violence, their abuse or exploitation, their mental health, or their gender or ethnic status and certain illnesses and/or including bereavement.

4.5.4 Research involving deceased persons, body parts or other human tissues including bodily fluids (e.g. blood, saliva).

4.5.5 *Research using administrative data or secure data*. Researchers using these data sets will need to be approved by the body supplying the data and keep data in secure areas. In most cases a review confirming that researchers have met these requirements will be sufficient. Issues however may arise when data are linked and where it may be possible to identify participants.

4.5.6 *Research involving groups where permission of a gatekeeper is normally required* for initial access to members. This includes research involving gatekeepers such as adult professionals (e.g. those working with children or the elderly), or research in communities (in the UK or overseas) where access to research participants is not possible without the permission of another adult, such as another family member (e.g. the parent or husband of the participant) or a community leader.

4.5.7 *Research involving deception, covert research or which is conducted without participants' full and informed consent* at the time the study is carried out. It is recognised that there are occasions when the use of covert research methods is necessary and justifiable and consent may need to be managed at a point beyond the completion of research fieldwork. Section 10.3 provides detailed guidance on conducting covert research.

4.5.8 *Research involving access to records of personal or sensitive confidential information*, including genetic or other biological information, concerning identifiable individuals.

4.5.9 *Research which may induce psychological stress*, anxiety or humiliation, or cause more than minimal pain. Minimal can be defined as negligible or of a minimum amount, quantity or degree.

4.5.10 *Research involving intrusive interventions or data collection methods*. This may include, for example, the administration of substances, vigorous physical exercise or techniques such as hypnosis. In particular, where participants are persuaded to reveal information which they would not otherwise disclose in the course of everyday life.

4.5.11 *Research where the safety of the researcher may be in question*, in particular those conducting field research and where research assistants are recruited locally working outside the UK.

4.5.12 *Research involving members of the public in a research capacity* in research data collection (e.g. community-based participatory research). Further guidance can be found on the National Co-ordinating Centre for Public Engagement web page regarding ethics in community-based participatory research.

4.5.13 *Research undertaken outside of the UK* where there may be issues of local practice and political sensitivities. In some cases, partnership with a research organisation in the area involved may prove helpful. It is also necessary to check the requirements for ethics review in the countries included in the research.

4.5.14 *Research involving respondents through the internet*, in particular where visual images are used, and where sensitive issues are discussed. The BPS, Ethics guidelines for internet-mediated research. should be consulted prior to the commencement of research along with DMU's Guidelines for Internet Mediated Research. The term 'internet-mediated research' (IMR), as used in this document' covers a wide range of quantitative and qualitative approaches to research involving human participants. IMR can be broadly defined as any research involving the remote acquisition of data from or about human participants using the internet and its associated technologies.

4.5.15 *Other research involving visual/vocal methods* particularly where participants or other individuals may be identifiable in the visual images used or generated.

4.5.16 *Research which may involve data sharing of confidential information beyond the initial consent given* – for example where the research topic or data gathering involves a risk of information being disclosed that would require the researchers to breach confidentiality conditions agreed with participants.

4.5.17 Research involving procedures beyond those normally experienced in everyday life – for example the administration of substances (Appendix 2).

4.6 Ethics Panels are responsible for reviewing and approving staff and PGR ethics applications, and are available for guidance and clarification on all ethical matters. Members of Ethics Panels include academic staff and lay members who have experience and expertise in providing guidance on research ethics and reviewing submissions for ethical approval.

4.7 Supervisors overseeing the research projects of PGRs have a responsibility to discuss research ethics with their student(s), review the student's ethics checklist to ensure the research project is in line with research ethics principles and ensure the student is prepared to submit an ethics application for approval as appropriate.

4.8 Supervisors overseeing the research projects of undergraduate and postgraduate taught students have a responsibility to discuss research ethics with their student(s), review the student's ethics application to ensure the research project is in line with basic research ethics principles and approve the research to commence if it involves minimal risk. Undergraduate and postgraduate taught student research that is above low-risk will be escalated to the relevant FREC and reviewed there.

5. SCOPE OF THE CODE

5.1 **Context of investigation:** All investigations involving research with human participants fall within the scope of the Code (including, but not limited to, research investigations, class teaching experiments/demonstrations, student projects, surveys and questionnaires) and should conform with the appropriate University and/or external guidelines. Researchers, whether students or staff, must ensure they submit their ethics application form to the appropriate FREC. If in doubt as to which FREC to apply to, contact ethics@dmu.ac.uk.

5.2 **Block Ethics Approval:** The Faculty Research Ethics Committee will consider applications from module convenors involving undergraduate student projects that are minimal risk, and involve protocols on a 'block' basis where it is the intention to adopt the same procedure in a number of related investigations. It will be the responsibility of the successful applicant and relevant Head of School to ensure that such individuals/students are fully competent to use the protocol before permission is given. The names of individuals/students cleared through this procedure should be appended to the list of investigators in the copies of the protocol document held by both the Department/School concerned and the FREC Secretary. FREC approval is given for a period of three years only and is subject to review and re-approval thereafter. Random audits on the projects may be carried out at any time at the discretion of the FREC, and digression from approved protocols will lead to the termination of the block ethics approval. Applications for dissertation modules are not suitable for the block ethics approval process.

5.3 **Investigations conducted off campus:** DMU staff or students who wish to carry out investigations involving human participants at premises other than those of the University will be expected to obtain approval from any collaborating organisation/owners of the premises (if not the collaborating organisation) as well as from the Faculty Research Ethics Committee. Where collaborating organisations have their own ethics committees, their approval may be accepted by DMU's FREC in lieu of a separate submission. Any pertinent risk assessments should also have been undertaken prior to research commencing. Details should be submitted to the Secretary of the FREC for confirmation. Students and staff must also view the University's Lone Working policy and refer to the Suzy Lamplugh Trust for help and advice about working alone in the field.

5.4 **Visiting investigators:** Investigators from outside the University who wish to carry out investigations involving human participants in the University will be expected to conform to the relevant sections of the University's Research Ethics Code of Practice and, as appropriate. Any research to be conducted with DMU staff or students as participants must be vetted by the University Research Ethics Committee. Only once UREEC has given formal authorisation can research be initiated.

5.5 **Ethics Approval from External Bodies:** Even where ethical approval is to be obtained from external bodies, such as an NHS Research Ethics Committee, Social Care Research Ethics Committee, etc, a separate application to the FREC will be required. If DMU is to act as sponsor, it is one of the duties of the sponsor to ensure appropriate review has taken place and taking project ethics applications through the University's internal processes ensures this oversight. Once a favourable opinion/approval has been gained from an external committee, a copy of this external approval must be provided to the relevant FREC.

5.5.1 Research requiring external review and confirmation of approval. Please note, FREC review is ALWAYS required alongside any external reviews and approvals that may be required for your work.

Some research activities will require external approvals, and this includes research activities conducted in partnership with or involving the; NHS, military or prison service. Details for the management of approvals with these organisations are set-out below. However, other organisations may also require external approvals before research can commence.

5.5.2 **Research involving the NHS**, Research with the NHS includes: Research recruiting patients, or anyone via their affiliation with the NHS including staff. Using their data, including patient records, using NHS resources or premises.

5.5.2.1 Approval from the Health Research Authority (HRA) is required for research involving the NHS. In addition, approval from one of the NHS Research Ethics Committees (RECs) is often required for studies involving patients and patient data. Further information on HRA approval review requirements can be found on the NHS HRA website, which includes a decision tool to determine if your proposed activity is considered to be research and requires HRA approval. As part of HRA approval, DMU staff and students conducting NHS research may also need approval from an NHS Research Ethics Committee (REC). REC approval is typically not required if the research involves only NHS staff (and no patients). If the project is recruiting patients, approval from an NHS REC will be required: Does my project require REC approval? When engaging in research with the NHS, notify research.nhs@dmu.ac.uk .

5.5.2.2 The Research Governance Framework for Health and Social Care (v2, 2005) provides broad principles of good research governance in health and social care. Research which falls within the scope of the Research Governance Framework requires a research Sponsor. Formal confirmation of sponsorship must be obtained prior to an application for Host Organisation (e.g. NHS Trust, Social Care) or Research Ethics Service (NHS REC). If the researcher has an associate NHS contract, the NHS Trust or third party should be approached to take the role of Sponsor, otherwise DMU may act as Sponsor.

5.5.3 **Research involving the military**

5.5.3.1 MoDREC (Ministry of Defence Research Ethics Committee) review is required when all of the following 3 criteria are met;

- The research involves human participants.
- The project is classified as research.
- The project is funded by the MOD (Ministry of Defence),
    - OR it involves MOD employed staff or participants (including reservists).

For further information see MODREC Guidance for Suppliers (publishing.service.gov.uk)

Applications to MoDREC should be made using MoDREC's own application form rather than the REC application form in IRAS.For further information, please email the MoDREC Secretariat.

5.5.4 **Research involving His Majesties Prison and Probation Service (HMPPS)**

5.5.4.1 All applications must be made using the National Research Application form HMPPS research application template or, for projects also requiring approval from health and social care bodies, through the Integrated Research Application System (IRAS). All applications should be sent to national.research@justice.gov.uk.

The application form must be accompanied by the researchers' CVs, any ethical approvals, any questionnaires/interview schedules and consent forms/information sheets that have already been devised.

For more information please see Research at HMPPS - HM Prison and Probation Service - GOV.UK (www.gov.uk)

5.6 **Retrospective Approval:** FRECs cannot give retrospective ethical approval for studies which have already been conducted or have already commenced. Please refer to the University's Misconduct in Research – Investigation Procedure Policy.

5.7 **DMU collaborations (UK)**: Where the researcher is undertaking research in the UK and collaborating with a third party and the third party is responsible for ethical approval (e.g. PI based at another institution), ethics approval documents must be sent to the relevant DMU FREC as evidence for auditing purposes.

5.8 **International research:** Researchers should be mindful of the different civil, legal, financial and cultural conditions when working overseas, or conducting research involving participants who are located overseas, and are expected to refer to international guidelines and conform to relevant local regulations and laws for the country or countries where the research is taking place. Below is the protocol for ethical review of research undertaken outside the UK:

5.8.1 Where the researcher is collaborating with a third party and the third party is responsible for the ethics (as in 5.7 above), separate DMU approval is not necessary where standard review is comparable. Approval documents, however, must be sent to the relevant FREC as evidence for auditing purposes;

5.8.2 If the DMU researcher is the project lead and the country has established ethical guidelines that must be adhered to, the country's/partner institution's ethical approval must be gained and approval documents sent to the relevant FREC as evidence for auditing purposes. DMU ethical approval is also required and the researcher should submit an ethics checklist for review. Where the country does not have established ethical guidelines, DMU ethical approval is required before any research can commence.

5.9 **Public Engagement or Research Impact:** Projects that fall under the auspices of Public Engagement or Research Impact may require ethical approval. For the purposes of best practice, or where there is any doubt as to whether ethical approval should be sought, it is recommended that DMU's standard ethical procedures are followed. This is especially pertinent for projects where any data of any type is collected, which researchers may wish to re-use or represent in another format at a later date. Consult with a member of a FREC or supervisor prior to commencement of the project and complete the Research Ethics Pre-Screening Questions (5.11) to determine if ethical approval is required. Further guidance can be found on the National Co-ordinating Centre for Public Engagement website regarding Social and ethical issues in Public Engagement | NCCPE .

5.10 **Secondary Data Analysis:** Whilst the University recognises that the secondary data analysis will often be uncontroversial, researchers are expected to give careful consideration to the ethical risk involved in the reuse of data collected from human participants and seek advice in the case of doubt.

Ethical review will not always be required for the secondary use of data collected from human participants particularly where:

- Data are already in the public domain (i.e. curated for public access, published in books, journals, etc.), or;
- The re-use of datasets for which consent for reuse for research purposes beyond which the data was originally gathered was provided by the participants, and for which all data have been robustly anonymised.

All work requires ethical consideration. To confirm whether ethical review is required for the proposed activity, complete the ethics screening checklist. Research Ethics Pre-Screening Questions V3 (dmu.ac.uk)

Regarding data collected at other institutions;

- The data will be pre-existing and therefore considered to be secondary data.
- Typically ethical review will not be required as long as consent for research purposes, beyond the original consent given, is in place. This is on the condition that the data is fully anonymous.
- If the data is NOT fully anonymised, ethical review will be required.

Anyone who is unsure whether their proposed use of secondary data requires ethical approval should discuss this with their FREC, or with the Research Governance Team. There may be additional governance requirements with some data such as data obtained from the NHS.

5.11 **Exclusions from Code:** The code does not apply to:

5.11.1 Research which involves working only from anonymous historical data and/or literary databases and documents and does not involve working with 'live' participants or experimentation and anatomical examination in human morbid anatomy. This is strictly controlled by the 1984 Anatomy Act, under licence from the Secretary of State for Social Services and therefore falls outside the scope of the Code. Staff and students are advised that it is an offence to carry out dissection or experimentation on cadavers outside the control of a Licensed Teacher of Anatomy or in unlicensed premises;

5.11.2 Patient and Public Involvement (PPI) events undertaken as part of the design of a study do not require ethical approval providing it does not involve increased risk to participants, vulnerable participants or invasive procedures.

5.11.3 Service evaluation/Audit and Operational Activities carried out in the course of the University's business (e.g. the staff surveys, module feedback from students, experiments of new operational processes etc.) do not require ethical review.

6. Considerations Relating to Specific Types of Investigation

6.1 **University class teaching experiments and demonstrations:** Undergraduate or postgraduate students may be invited to participate in experiments or studies as a normal part of their programme, provided:

6.1.1 they have the right to decline to participate in a particular procedure or, having accepted, to withdraw at any time;

6.1.2 they are assured that neither declining nor agreeing to participate in a particular procedure will affect their academic assessment in any way;

6.1.3 no coercion, actual or implied, or any financial inducement should be used to persuade students to participate.

6.2 **Research using publicly available social media posts:** This includes views and opinions expressed via social media (Facebook, Twitter etc), and any other publicly available website (such as responses to news articles, discussion forums etc.). Whilst online posts can be considered in the public domain, their use in research can be likened to observational research and therefore requires ethics review. Whilst preferable, it is recognised that it may not always be practical to obtain consent from individuals whose content is to be used. If you obtain personal data from publicly accessible sources (such as social media, the open electoral register and Companies House), you still need to provide individuals with privacy information. If you rely on the exception that providing the privacy information would be impossible, or that it would involve a disproportionate effort, you must carry out a DPIA in order to identify and mitigate the risks associated with your further use of personal data**.**For further guidance please refer to DMU's Guidance on Internet-Mediated Research. Other resources to consult include those from The British Psychological Society The British Psychological Society, The Association of Internet Researchers The Association of Internet Researchers- Ethics and the Economic and Social Research Council's (ESRC) Framework for Research Ethics. https://www.ukri.org/councils/esrc/guidance-for-applicants/research-ethics-guidance/

6.3 **Drug Studies and Experimental Medical Devices:** Drug studies on human participants, involving new chemical entities or new combinations of drugs, and/or testing of experimental medical devices, will need to be approved via the NHS Research Ethics Committees. Drug trials are strictly regulated by the MHRA and the University must have the appropriate licencing before any study of this nature can be carried out.

6.4 **Investigations involving contact with Human Body Fluids:** All proposals for investigations involving contact with human body fluids should adhere to the Health and Safety Policy on Blood Borne Viruses and the University's risk assessments covering the use of fluids.

6.5 **Investigations involving Human Tissue Act Relevant Material:** The University does not hold a Human Tissue Authority (HTA) licence and 'relevant material' as defined by the Act cannot be stored on campus (for example overnight). Please see HTA guidance Relevant material under the Human Tissue Act 2004 | Human Tissue Authority (hta.gov.uk) on relevant materials for definitions of tissues that fall within the scope of the Act and seek further guidance from the Research Governance team. If samples originating from humans are to be used in research, details of how these fall out of scope of the Act must be provided including reference to validated protocols used to render tissues acellular.

6.6 **Investigations involving the use of Ionising Radiation** (e.g. x-rays): All investigators seeking approval for proposals involving the use of hazardous substances (see https://www.hse.gov.uk/pubns/books/l5.htm) should contact Health and Safety for advice and should follow the Guidance on Exposure to Hazardous Substances: Guidance on Hazardous Substances, and should make reference to this guidance within the submission form.

6.7 **Investigations involving the use of Hazardous Substances:** All investigators seeking approval for proposals involving the use of hazardous substances should contact the Faculty Health and Safety lead for advice, and protocols to be applied must be logged and appended to the ethics application.

6.8 **Investigations under the Mental Capacity Act 2005:** The research provisions in the Mental Capacity Act 2005 apply in England and Wales to 16-17 year olds and adults (18 years and over) who lack the capacity to give or withhold their consent to participate in a study.

Fundamentally a person must be assumed to have capacity unless established otherwise. A person is unable to make a decision if s/he is unable to: understand the information relevant to the decision; retain that information; use, or weigh up, that information in the process of coming to a decision, or communicate the decision (by any means). Studies involving participants who are 'lacking capacity' e.g. who are unable to give consent under the Mental Capacity Act 2005, require approval from the Health Research Authority. Please see the HRA Guidance on Social Care Research.

6.9 **Investigations involving animals:** Research falling under the Animals Scientific Procedures Act (ASPA) (1986) requires approval by the Animal Welfare and Ethical Review Body (AWERB) hosted by the Faculty of Health and Life Sciences. Non-ASPA, including Schedule 1 activities should be reported to AWERB on an annual basis.
If your proposed research activity will involve the use of animals or their tissues, an ethics application is required. Declaration of the use of animals or their tissues can be actioned within Worktribe. FREC/ RIO will be notified, enabling dissemination of the proposal for review, to appropriate colleagues within AWERB. No work is to commence until Ethical approval for the work is confirmed and that all appropriate licences are in place.

6.10 **Self-Experimentation:** Self-experimentation in research is an approach in which the experimenter conducts the experiment on themselves, including using their own biological samples. Ethics approval is required for self-experimentation as per normal University processes for ethical approval. Researchers should explore the rules of any intended publishers for research outputs before the application is submitted for ethics approval. It is expected that all usual measures to protect the self-participant and data are followed.

Where an undergraduate or taught post-graduate student is participating in research that generates data to be used in fulfilment of their own education qualification, the supervisor must ensure informed consent is sought from the student and the same safeguards are put in place as if an unaffiliated participant were being recruited.

7. INSURANCE

7.1 The University maintains a Public Liability Policy, which indemnifies it against its legal liability for accidental injury to persons (other than its employees) and for accidental damage to the property of others. Any unavoidable injury or damage therefore falls outside the scope of the policy.

7.2 The Insurance relates to claims arising out of all normal activities of the University:

7.2.1 Professional Indemnity insurance cover will protect DMU staff if they provide designs, specifications, advice or instructions as any part of their job along with the nature and scope of the research work.
7.2.2 Clinical Trials cover is available but insurers will require a detailed specification of the project to evaluate new medical treatments such as use of device, drugs and vaccines etc.
7.2.3 DMU also have a Public and Products Liability Policy.

7.3 Insurers require to be notified of anything of an unusual nature by submission of an Insurance Questionnaire along with a copy of the research proposal. In particular, where tests on new

drugs or equipment are sponsored by an external body, the trials may need to be covered by the insurance policy of the sponsoring organisation rather than the University.

7.4 Insurance will require complete specifications of the research projects before the necessary cover is offered. Insurance for projects to be conducted overseas will depend on the regulations and jurisdiction in the country/ies in question.

7.5 It is the responsibility of the applicant to arrange insurance cover for the project if it falls outside of the scope of the University's Public Liability Policy. Details of such cover should be included in the submission.

7.6 Participants should be told their position with regard to insurance cover in the event of an accident, injury, or ill-health befalling them as a result of taking part in the investigation.

8. GUIDANCE ON THE APPLICATION PROCESS

8.1 The following guidance is provided for investigators seeking approval from the Faculty Research Ethics Committee:

8.1.1 All staff and PGR applications (once supervisors have had sight of these and commented on them) go directly to the relevant FREC. Each PGR/staff application will be considered by at least two members of FREC. If deemed to raise concerns or be more than minimal risk, the application might be escalated for consideration by the whole committee.

8.1.2 Undergraduate and taught postgraduate will be initially viewed by the relevant supervisor or module leader. Undergraduate and postgraduate taught research projects should be low risk and may be approved at a programme level. Where, exceptionally, the study is deemed to be more than minimal risk (Appendix 2), this will be escalated to the relevant FREC.

8.2 If at any stage the ethics reviewer or FREC feels the application for ethical approval is to be rejected, this will normally be referred back to the researcher with the deficiencies of the application identified, giving the researcher the opportunity of a further submission.

8.3 Where an application for ethical approval is not approved at FREC, the researcher has the opportunity to appeal to UREEC. The researcher and person(s) responsible for considering the application have the right to attend the meeting and speak to the issue. The decision of UREEC is final and the matter is concluded at this point.

8.4 Disagreement with the academic judgement of FREC does not constitute grounds for an appeal.

9. DATA PROTECTION ACT AND CONFIDENTIALITY

9.1 There should be an acknowledged obligation to protect the participants from possible harm and to preserve their right to privacy. There is also a requirement to protect the researcher and the university from regulatory or civil action in the event of a breach. The data privacy and confidentiality of the participants should be maintained and the investigator's intentions in the matter of data privacy and confidentiality should be made known to the participants. Any investigator intending to process personal data should be made aware of and comply with the

provisions of the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018 (DPA18) UK GDPR guidance and resources | ICO and familiarise themselves with DMU's GDPR Guidance for Researchers. The University's Data Protection Policy can be found on the University's Data Protection Policy webpages. Participants should be informed of DMU's Privacy Policy, how their data will be processed and the legal basis for doing so.

9.2 It is advisable that researcher complete the DPIA Checklist RESEARCH.docx checklist prior to completing their Worktribe ethics application. The Information Governance Team will provide feedback and advise on whether a full DPIA is needed. This process is separate to the ethics process, however, feedback from the IG team may be relevant to your ethics application, and will need to be included as part thereof.

9.3 Ethical review must take place before any research involving human participants or identifiable personal, special category or confidential data is undertaken. DMU's indemnity insurance will not cover research without approval. Failure to obtain approval at the appropriate time will result in disciplinary procedures being instigated. It may also lead to a breach of funding conditions and/or to publication of the research findings being retracted by the publishers.

9.4 Issues which need to be considered in all projects involving human participants or identifiable personal data include:

9.4.1 Anonymity

9.4.1.1 Data are only considered to be anonymous when the data subject cannot be identified by the data or ANY combination thereof.

9.4.2 Confidentiality

9.4.3 Informed consent

9.4.3.1 Consent to participate and UK GDPR consent are different things. It is not recommended to use consent as a lawful basis for processing information.

9.4.4 Safety of the participant

9.4.5 Safety of the researcher(s)

9.4.6 Complaint's procedure

9.4.7 Data protection

- Freedom of information requests
    - Be aware that data can be requested as part of an FOI request. It is good practise to be aware of the data that is held and where it is stored.
- Transportation of data (especially where crossing borders)
- Storage of data (where and how long)
- Destruction of data
- Re-use of personal data
    - Is consent in place to be able to do this and can this be evidenced?
- In the case of international research, local legislation and requirements
    - The scope of GDPR will still apply even if the participants are based in another country. Carry out the DPIA Checklist RESEARCH.docx and name the countries where data will be processed.

10. SOME KEY CONSIDERATIONS

10.4 Recruitment of Participants

10.4.40 The recruitment of participants should wherever possible be via a notice, or, if verbally, through a group approach rather than to individuals. Recruitment notices should clearly explain the scientific purpose of the research and details of what volunteers can expect if they agree to participate. Where possible relevant permission should be sought to display posters, and if displayed on campus, should only be displayed on designated notice boards.

10.4.41 If staff or students are invited to volunteer to take part, special consideration should be given to the motives that might prompt them to volunteer. It is not normally desirable for students in close contact with a member of staff acting as investigator to be recruited, as they may feel vulnerable to pressure from someone in a position to influence their careers. On the other hand, it is normally reasonable for students to be recruited to take part in teaching exercises where one of the primary objectives is to enable them to make their own observations.

10.4.42 Where investigators are in a position of authority over participants, e.g. if they are students on a module taught by the investigator, they should be assured that they are free to withdraw at any point and that this will not be detrimental to their progression.

10.5 Vulnerable Groups

10.5.40 Recruitment from vulnerable groups may raise ethical issues which require special consideration. Vulnerable individuals may be incapable of giving valid consent, such as persons who lack capacity under the Mental Capacity Act, people detained under the Mental Health Act, prisoners, and people under the age of 18. An approach in such cases should be made to the authority or individual with legal responsibility for the participant. Special care should be taken in considering investigations involving the elderly and women of childbearing potential should not be recruited for any study which could be harmful to pregnancy. Participants should be considered vulnerable if they are likely to be distressed by the nature of the study or may feel coerced into taking part.

10.5.41 The University Research Ethics Committee has produced guidance on Working with Children and Young People. Investigators are advised to read the guidance carefully before embarking upon a research project which involves participants under the age of 18. Investigators should also ensure that study documentation is appropriate to the age of the participants. Investigators should establish whether or not they need to seek Disclosure and Barring Service (formerly CRB) clearance.

10.6 Deception

10.6.40 There should be no deception or misrepresentation that might affect a person's willingness to participate in an investigation, nor about the possible risks involved. It is recognised that some studies involve deception of the participant and would be invalid if this were not so. If deception is considered necessary in a study, it should not involve the participant in any risk, such as unexpected anxiety or distress, lowering of self-esteem, or any form of long-term psychological or physical harm. The use of any deception must be explicitly made known in the ethics application, together with justification and any mitigating actions. Where deception is necessary, revelation should normally follow participation as a matter of course and should be designed into the

experimental procedure. Participants should be debriefed on the true nature of the study as soon as is possible.

10.7 Inclusion/Exclusion criteria

10.7.40 It is essential that the Faculty Research Ethics Committee should be given full details of the basis for the selection of participants including any inclusion/exclusion criteria. Inclusion or exclusion criteria must be cognisant of any Equality Act issues (e.g. by projected characteristics). Particular care should be taken to exclude participants who suffer from physical, physiological or emotional conditions which could be affected/aggravated by the proposed procedures. Submissions should include any questionnaire which is to be used in the selection process.

10.8 Incidental Findings

10.8.40 When planning research, investigators should consider what arrangements are needed to inform participants (or those legally responsible for the participants) of any health related (or other) problems previously unrecognised in the participant. This is particularly important if it is believed that by not doing so the participant's well-being is endangered. Investigators should consider whether or not it is appropriate to recommend that participants (or those legally responsible for the participants) seek qualified professional advice, but should not offer this advice personally.

10.8.41 In studies where incidental findings are possible, for example, studies involving blood tests or MRI scans, investigators should, for example only, request permission to inform the participant's GP of incidental findings before the start of the study. GP details should be collected for this purpose from participants before they commence the study. Other subsequent actions may be reasonable depending on the nature of the research.

10.9 Minimising Risks to Participants

10.9.40 No investigation involving human participants should involve more than minimal risk to their physical or mental well-being. All risks should be measured/weighed against the scientific benefit of the study. All risks should be fully explained to participants, including precautions taken to minimise those risks.

10.10 Financial Incentives

10.10.40 There should be no financial inducement that may cause (or create the impression of causing) coercion, actual or implied, and that might persuade people to take part in an investigation against their better judgement. Any payment made to volunteers should be for expenses, time, and never for hazard to the person. All payments to participants in the form of cash, vouchers, merchandise or entry into prize draws, must be approved by the Faculty Research Ethics Committee. For studies that have multiple elements to them, payment on a pro rata basis should be considered.

10.11 Withdrawal from Investigations

10.11.40 Participants must be free to withdraw from the investigation at any stage, without having to give any reasons, and should be told they have this right when or before they provide consent to take part in the study. An opportunity should be provided for participants to discuss privately their wish to withdraw. It is recognised that it may not

always be possible to disaggregate data from the study once it has been anonymised and this should be clearly explained to participants before the research commences.

11. SUPPORTING DOCUMENTS

11.4 **Participant Information Sheets:** Investigators should give each participant full details of the nature, object and duration of the proposed investigation in a form that is readily understood (this may be written or verbal depending on the targeted participants). The participant should be told what procedures the investigation will involve and whether any discomfort or inconvenience is likely to be entailed during the investigation or afterwards. Investigators should also provide information and advice about any foreseeable risks, for example only, to health to which participants may be exposed. Details on how long data and/or samples will be retained should be included, as well as information on how the data and samples will be used. It is good practice to offer participants the opportunity to visit the location of the study, have procedures demonstrated and/or inspect/test equipment before the commencement of the investigation. This ensures that participants are fully informed about what will happen to them during the investigation. Participants should be given sufficient time to consider the Participant Information Sheet before being asked to give their consent.

11.5 **Informed Consent:** The full, informed and voluntary consent of the participant must be obtained before the investigation begins; that is to say, consent freely given with proper understanding of the nature and consequences of what is proposed. In the cases of participants under the age of 18, or with some other potentially vulnerable groups, it may be necessary to obtain consent from the parent/guardian or carer, and this needs to be documented. Written consent may be dispensed with only with the agreement of the Faculty Research Ethics Committee.

11.6 **Other Documents:** Any other documents being used during the study should be provided with the ethics application such as copies of questionnaires, draft interview questions, assent forms for children under 18.

12. DURING THE STUDY

12.4 **Unexpected Damaging Consequences:** Any unusual or unexpected symptoms arising or any significant untoward event affecting a participant during or after an investigation should be communicated promptly with the individual's consent to the participant's own doctor, and to the Faculty Research Ethics Committee. The study should be stopped in the individual concerned and it should be considered whether it is advisable to stop the investigation as a whole. If a participant withdraws from an investigation, for whatever reason, the investigator should take reasonable steps to find out whether any harm has come to the individual as a result of participation in the study.

12.5 **Amendments to the Study:** If any changes are required to the study/ activity post apporval, an amendment must be submitted to the relevant FREC. Approval must be confirmed before any change to the study protocol is actioned. For details regarding amendments, including change classifications (minor/ major), see Appendix 3: Making Amendments to an Approved Ethics Application

12.6 **Study End Date:** Ethical approval remains valid until the study end date provided in the application, or after a period of three years, whichever is sooner. Requests for extensions beyond the study end date or three-year limit can be submitted to the FREC with a re-evaluation of the ethical issues related to the study.

12.7 **Records of Investigations:** The investigator should keep full records of all training, consents and procedures carried out.

12.8 **Annual Reports:** The investigator for a research study meeting the criteria for 'high risk' research (Appendix 2: Framework for Identifying Research Ethics Risk.) should submit an annual progress report to the approving Committee, including an end of study report.

13. Non-compliance and Misconduct

13.4 The University expects that all research carried out in its name complies with the requirements and expectations of the RECoP. Where a research study or researcher is suspected to be in breach of the RECoP, action may be taken at Faculty or University level to resolve this.

13.5 In the interests of openness, good practice and the reputation of the University, members of staff and students of the University, and members of the public, are entitled to raise concerns about the correct ethical practices in research, and particularly in relation to compliance with research ethics. Concerns or complaints should be directed to the Pro Vice Chancellor Enterprise and Research.

13.6 DMU considers that failure to gain ethical approval before starting a project, non-compliance with conditions specified by an approval body (e.g. funder, external ethical approver) or making significant changes to a research project without notifying an Ethics Panel or supervisor is classified as potential research misconduct. Further detail can be found in the University's Misconduct in Research: Investigation Procedure document.

13.7 A serious breach of research ethics is considered research misconduct and will be dealt with according to the University's Misconduct in Research: Investigation Procedure document. The following are **examples** of what constitutes a serious breach of research ethics (this is not an exhaustive list):

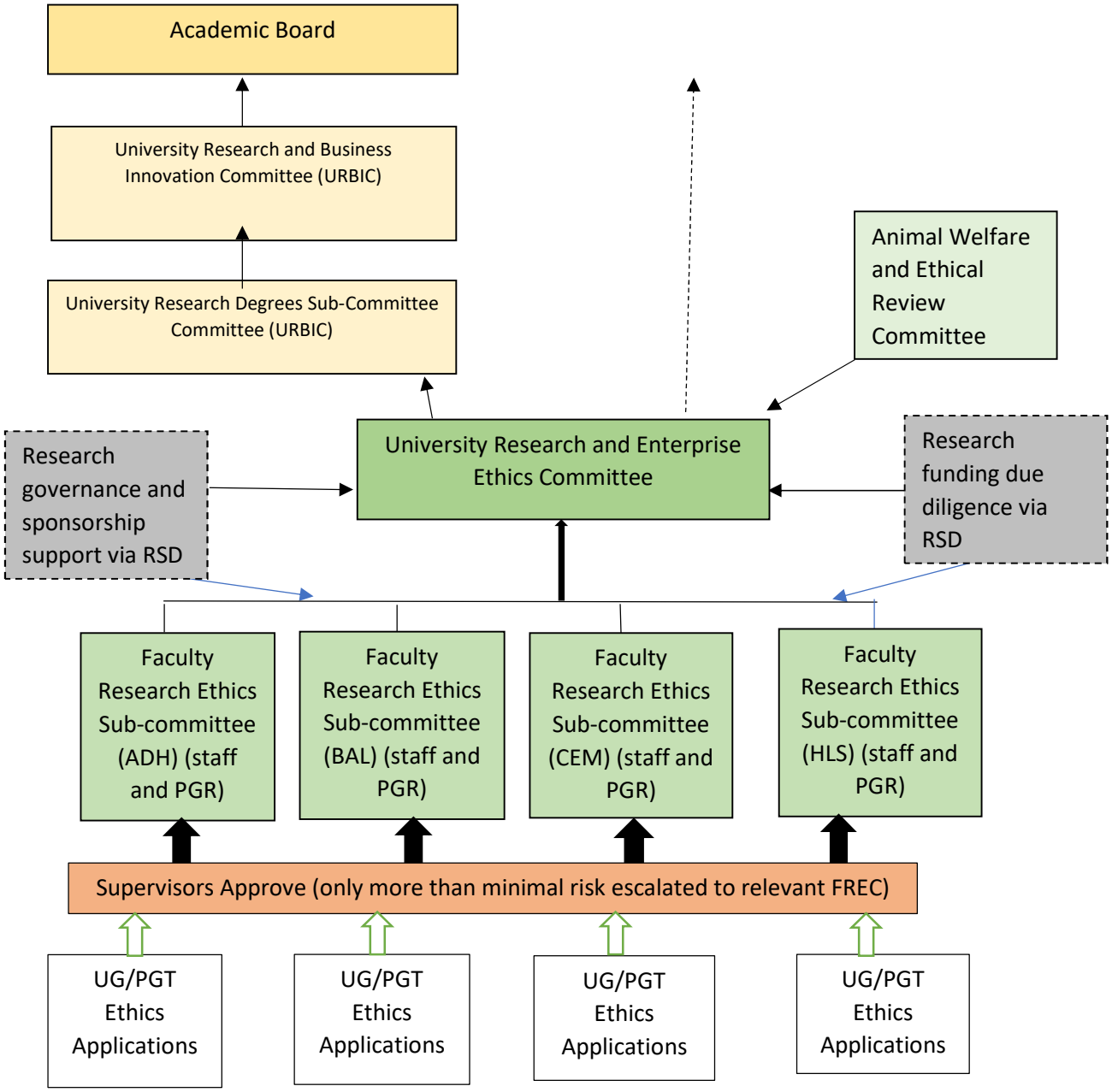
13.4.1 Deliberately attempting to deceive when making a research proposal;
13.4.2 Failure to obtain appropriate permission to conduct research with ethical implications;
13.4.3 Failure to follow protocols contained in ethical consent and/or unethical behaviour in the conduct of research;
13.4.4 Failure to meet relevant legal requirements and/or to follow any protocols set out in the guidelines of appropriate recognised professional, academic, scientific and governmental bodies;
13.4.5 Unauthorised use of information acquired confidentially;
13.4.6 Failure to follow any procedures and health and safety protocols that avoid unreasonable risk or harm to humans, animals or the environment;
13.4.7 The misuse of research findings which may result in harm to individuals, populations, animals or the environment;
13.4.8 Failure to declare a conflict of interest which may significantly compromise, or appear to significantly compromise, the research integrity of the individual concerned and the accuracy of any research findings;
13.4.9 Failure to declare (where known) that an external collaborative partner has been found to have committed research misconduct in the past or is currently being investigated following an allegation of research misconduct.

14. Document History/ Change Log

Version	Date	Change	Notes
2	Sept 2021	Revision to wording regarding secondary data, and other minor updates.	Change implemented Nov 2021
2.1	Sept 2021		
2.2	Nov 2022		
3	10th Feb 2023	Ethics and Governance Structure updated to reflect change from URIC to URBIC;	

		Appendix 3 added for Making Amendments to an Approved Ethics Application.	
4	Dec 2023	• Change log table added. • Update to governance structure • UREC changed to UREEC • Update to 5.10 re 2º data that has been collected at external organisaitons and then brought to DMU. • Removal of research-records-retention-policy.pdf (dmu.ac.uk) • In doc hyperlinks added. • External links checked and updated • Section on GDPR added with additional info re FOI/ participants based abroad. • Section on research with external organisations added.	

APPENDIX 1: ETHICS AND GOVERNANCE STRUCTURE



APPENDIX 2: FRAMEWORK FOR IDENTIFYING RESEARCH ETHICS RISK.

This framework is sits alongside the Research Ethics Code of Practice. It sets out what is regarded as 'more than minimal risk' (low risk) in research ethics, which is further divided into medium and high risk. The relevant risk rating should be selected when submitting and reviewing an ethics application. Further guidance on the criteria can be sought from ethics@dmu.ac.uk.

The list is not exhaustive nor prescriptive, and reviewers/committees may recommend such ratings they feel appropriate based on the overall nature of the proposed research. For example, it may be appropriate to consider a project high risk if there are several medium risk issues. The relevant risk should be applied irrespective of mitigating measures put in place.

Wherever possible, staff and post-graduate research applications that are high risk should be considered by a full Faculty Research Ethics Committee. Researchers should provide an annual report of high-risk research to the approving committee – please contact your Faculty Research Ethics Committee for further information.

Undergraduate and Taught Post Graduate research approved at a programme level should be low risk. In exceptional circumstances, medium risk research can be approved after consultation with the relevant FREC. UG/PGT students should not undertake high risk research.

High Risk

Ethics Issue	Further Guidance	Relevant WorkTribe Section / Question
Research involving potentially vulnerable groups.	For example, children and/or young people, those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship. Dependent or unequal relationships can be defined as pre-existing relationships between participants and researchers or between participants and others involved in facilitating or implementing the research. These relationships may compromise the voluntary character of participants' decisions, as they typically involve unequal status, where one party has or has had a position of influence or authority over the other. **High risk** examples may include relationships between: Carers and people with chronic conditions or disabilities, including long-term hospital patients, involuntary patients or people in residential care or supported accommodation; Prison authorities and prisoners;	Scope / Does your project require external ethical review? Human Participation / Does your research involve participants who are in a potentially vulnerable situation?

Research involving those who lack capacity.	All research involving those who lack capacity (as defined under the Mental Capacity Act 2005 Part 1 Section 2), or who during the research project come to lack capacity, must be approved by an 'appropriate body' operating under the Mental Capacity Act 2005. It is illegal to conduct such research without approval of an 'appropriate body'. An 'appropriate body' is a Research Ethics Committee (REC) recognised by the Secretary of State or Welsh Ministers. All NHS Research Ethics Committees (RECs) in England and Wales are recognised. RECs in Scotland and Northern Ireland are not recognised for the purposes of the Mental Capacity Act. In addition, there is a national Social Care REC (SCREC) established in 2009 under the aegis of the Social Care Institute of Excellence (SCIE), which is recognised as an 'appropriate body' under the Mental Capacity Act. You must contact ethics@dmu.ac.uk before submitting any application for research involving people who lack capacity.	Human Participation / Will informed consent be obtained from the research participants? Human Participation / Does your research involve participants who are in a potentially vulnerable situation?
Research involving sensitive topics.	Including, for example, but not exclusively, participants' sexual behaviour, their illegal behaviour, their experience of violence, their abuse or exploitation, their mental health, or their gender or ethnic status and certain illnesses and/or including bereavement. Such research may fall under the Policy on Conducting Sensitive Research (see Ethics and Integrity webpages).	Scope / Does this project involve the use of sensitive or restricted materials? Human Participation / Does the research involve investigation or possible disclosure of illegal activities or behaviours? Human Participation / Is it possible that this research will lead to awareness or the disclosure of actual or intended harm to a participant or other individual?
Research which may induce psychological stress, anxiety or humiliation, or cause more than minimal pain.	Minimal can be defined as negligible or of a minimum amount, quantity or degree. Examples include:	Human Participation / Is there a risk of physical harm, psychological harm or discomfort for participants, or prolonged or repetitive testing which may be a burden to participants?

	1. Induce physical discomfort and/or pain beyond which that they may routinely encounter in their everyday life. 2. Expose the participants to visual, auditory or other stimuli beyond that which would normally be experienced in everyday life. 3. Alter the participants' normal patterns of sleeping, eating or drinking. Such research could be considered medium risk on a case-by-case basis.	
Research involving intrusive interventions or data collection methods.	This may include, for example, the administration of substances, vigorous physical exercise or techniques such as hypnosis. In particular, where participants are persuaded to reveal information which they would not otherwise disclose in the course of everyday life. Could be considered medium risk on a case-by-case basis.	Human Participation / Does the research involve invasive or potentially intrusive procedures? Human Participation / Does your research involve participants who are in a potentially vulnerable situation?
Research where the safety of the researcher may be in question.	In particular those conducting field research and where research assistants are recruited locally working outside the UK. May include visiting areas of potential or actual known violence or conflict, as defined by the Foreign and Commonwealth Office. May also include travel within the UK to environments that are potentially risky. Could be considered medium risk on a case-by-case basis.	Methodology / Does the research have potential to cause distress or discomfort to any member of the research team? Methodology / Does the research involve lone working? Methodology / Will the research involve international travel and/or travel to a potentially risky environment?
Research which may involve data sharing of confidential information beyond the initial consent given	For example where the research topic or data gathering involves a risk of information being disclosed that would require the researchers to breach confidentiality conditions agreed with participants.	Human participation / Will informed consent be obtained from the research participants?
Research that has the potential to cause	Further guidance should be sought from ethics@dmu.ac.uk before proceeding with research that may cause environmental damage or harm.	Scope / Does the project have the potential to cause environmental damage or harm?

environmental damage or harm.		
Research with pregnant or breastfeeding mothers.	Please seek further advice from ethics@dmu.ac.uk.	

Medium Risk

Ethics Issue	Further Guidance	Relevant WorkTribe Section / Question
Research involving potentially vulnerable groups.	For example, children and/or young people, those with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship. Dependent or unequal relationships can be defined as pre-existing relationships between participants and researchers or between participants and others involved in facilitating or implementing the research. These relationships may compromise the voluntary character of participants' decisions, as they typically involve unequal status, where one party has or has had a position of influence or authority over the other. **Medium risk** examples may include relationships between: Health care professionals and their patients or clients; Teachers and their students; Governmental authorities and refugees; Employers or supervisors and their employees; Service-providers (government or private) and especially vulnerable communities to whom the service is provided (e.g. homeless, rough sleeping).	Human Participation / Does your research involve participants who are in a potentially vulnerable situation? Human Participation / If applicable, describe any existing relationship between the investigator(s) and participant(s) (e.g. teacher-student or employer-employee).

Research involving deceased persons, body parts or other human tissues including bodily fluids (e.g. blood, saliva).	DMU Does not hold a Human Tissue Authority licence and so human tissue falling under the remit of that Act cannot be stored on DMU campus. Commercially sourced tissue is subject to HTA licensing requirements. Please contact ethics@dmu.ac.uk for further guidance.	Human Participation / Will your research involve collecting, storing or processing human tissue samples, including tissue which is purchased from commercial sources? Human Participation / Does the research involve invasive or potentially intrusive procedures?
Research using administrative data or secure data.	Researchers using these data sets will need to be approved by the body supplying the data and keep data in secure areas. In most cases a review confirming that researchers have met these requirements will be sufficient. Issues however may arise when data are linked and where it may be possible to identify participants.	Scope / Does your research involve only secondary data? Data Management / Is there an access control process or a gatekeeper for access to data e.g secondary data? Data Management / Will participant data be anonymous? Data Management / Will participant data be pseudonymised or link-anonymised?
Research involving groups where permission of a gatekeeper is normally required for initial access to members.	This includes research involving gatekeepers such as adult professionals (e.g. those working with children or the elderly), or research in communities (in the UK or overseas) where access to research participants is not possible without the permission of another adult, such as another family member (e.g. the parent or husband of the participant) or a community leader.	
Research involving deception, covert research or which is conducted without participants' full	Includes research using opt-out consent.	Human participation / Will informed consent be obtained from the research participants?

and informed consent at the time the study is carried out.	It is recognised that there are occasions when the use of covert research methods is necessary and justifiable and consent may need to be managed at a point beyond the completion of research fieldwork. Section 10.3 of the Research Ethics Code of Practice provides detailed guidance on conducting covert research. Such research may be considered high risk depending on a case-by-case basis.	Human participation / Will the research involve actively deceiving participants?
Research involving access to records of personal or sensitive confidential information.	Including genetic or other biological information, concerning identifiable individuals. Such projects may require external approvals and advice should be sought from ethics@dmu.ac.uk before proceeding.	Scope / Does your project require external ethical review? Human Participation / Will the research involve discussion or collection of information on potentially sensitive, embarrassing or distressing topics?
Research involving members of the public in a research capacity in research data collection (e.g. community-based participatory research).	Further guidance can be found on the National Co-ordinating Centre for Public Engagement web page regarding ethics in community-based participatory research.	
Research undertaken outside of the UK where there may be issues of local practice and political sensitivities.	In some cases, partnership with a research organisation in the area involved may prove helpful. It is also necessary to check the requirements for ethics review in the countries included in the research.	Scope / Does your project require external ethical review? Scope / Where will the project be undertaken? Human Participation / Please describe how and where the participants will first be approached and by whom.
Research involving respondents through the internet, in particular where visual images are used, and	The British Psychological Society's Ethics Guidelines for Internet-mediated Research should be consulted prior to the commencement of research along with DMU's Guidelines for Internet Mediated Research.	Scope / Where will the project be undertaken?

where sensitive issues are discussed.	The term 'internet-mediated research' (IMR), as used in this document' covers a wide range of quantitative and qualitative approaches to research involving human participants. IMR can be broadly defined as any research involving the remote acquisition of data from or about human participants using the internet and its associated technologies. Participants recruited or identified through the internet, in particular when the understanding of privacy in these settings is contentious or where sensitive issues are discussed - for example in 'closed' discussion groups where there is potential for quotes and visual images to be identifiable.	Human Participation \ Identifying participants Human Participation / Does the project involve study or participation in social media activity?
Other research involving visual/vocal methods particularly where participants or other individuals may be identifiable in the visual images used or generated.	Including visual photo diaries in which the participant may be identified.	Data management / Does the research involve photographs, videos or audio recordings of research participants?
Research involving procedures beyond those normally experienced in everyday life.	Including, but not limited to: 1. Administration of substances. 2. Administration of medicinal products (including placebos). 3. 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. 4. 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. 5. Inhalation of gases. There may be regulatory requirements for all of the above examples for which further advice should be sought from ethics@dmu.ac.uk.	Human Participation / Does the research involve invasive or potentially intrusive procedures? Human Participation / Does the research involve the administration of substances?

	Could be medium or high risk based on the nature of the study.	

APPENDIX 3: MAKING AMENDMENTS TO AN APPROVED ETHICS APPLICATION

An 'amendment' is **a written description of (a) change(s) to an ongoing, currently approved protocol**. Amendments include any change to the study documents that affect scholarly intent, study design or human participant protection. It is imperative that a rationale is also provided for this/these change(s).

Amendments are changes made to a research project after approval from the relevant University's Faculty Research Ethics Committee (FREC) has been given. If you have an approved ethics application and would like to make changes to the protocol in your proposal or any other element, you need to apply for an amendment. The amendment request supersedes the earlier version; only the latest amendment is valid.

There are two possible kinds of amendments: Minor Amendments and Substantial Amendments. If the substantial amendments are likely to affect every part of the form, and change the very nature of the project, it would be advisable to put in a brand new ethics application for review.

For guidance on how to submit your amendment request, please refer to the Help Menu on Worktribe. Details on the process can be found in the videos and your relevant Quick Guide for Applications.

1. Minor Amendments

Minor amendments may be defined as simple, non-substantial changes which do not alter or bring any additional ethical considerations to bear. Minor amendments need to be recorded but do not require ethical review. Minor amendments will be viewed and signed off by the FREC Chair.

All minor amendments to your ethics application must be submitted to the relevant FREC in order for them to have a record of the most recent version of your application for audit purposes.

The following changes are considered to be 'minor amendments':

a. A change of project title only: with the caveat that the project remains the same and only the title is amended.

b. A change to the project end date up to two years (maximum) after the original end date.

c. Extending the team with additional member(s) or changes to individual members, e.g., replacing one post doc with another will not require ethical review if the protocol has not changed. However, a change of principal investigator/supervisor will require a substantial amendment to be submitted. Special care needs to be taken if a student is added. If a student is added to the application in a supporting role a substantial amendment needs to be filed and if the student is becoming the new PI for a project this will require a full new application via Worktribe.

d. Change in emergency contact phone number for the PI and or applicant

e. Inclusion of new research sites with the caveat that nothing else will change (and the new sites are similar to existing sites), e.g., the same protocol will be followed and already approved documents will be used. If different kinds of sites will be used (e.g. adding schools to university sites), this will require a substantial amendment to be submitted.

f. Any combination of the above changes.

2. Substantial Amendments

Substantial Amendments are amendments other than those listed above (under 'Minor Amendments' items a-f).

It would be a substantial amendment if you need to modify your original proposal, bring in new elements in a way which would significantly alter any of the responses you originally made, and if your planned changes affect the ethical issues associated with the project. Examples of substantial modifications include significant changes to the study aims or methodology, addition of an overseas location, or any changes where the risks and ethical issues are vastly increased.

As for any ethics application, substantial amendments are sent out to two reviewers for consideration.

Significant changes may include:

- changes to the design or methodology of the study;
- changes to participant recruitment or involvement;
- a change in the number of participants;
- any change relating to the safety or physical or mental integrity of participants, or to the risk/ benefit assessment for the study;
- changes to study documentation such as participant information sheets, consent forms, questionnaires, letters of invitation;
- temporary halt of a study to protect participants from harm;
- changes in funding arrangements;
- any other change that would result in changes to the previously approved application form.

When completing a substantial amendment, please ensure you:

- Clearly explain what the amendment you wish to make is, and the justification for making the change;
- Insert details of any ethical issues raised by the proposed amendments;
- Include all relevant information regarding the change so that the Chair can make an informed decision, and submit a copy of the sections of your application that have changed with all changes highlighted/underlined for clarity.

If the changes you wish to make alters several sections of your application form, or if your changes amount to essentially a different project to that originally approved, you are advised to submit a new ethical application.