Research Services

RESEARCH ETHICS CODE OF PRACTICE

CONTENTS

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

2.10.5 Institutional Research: any research conducted or commissioned by DMU which might include:

2.10.5.1

4.5.1

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.

information being disclosed that would require the researchers to breach confidentiality conditions agreed with participants.

for example the administration of substances (Appendix 2).

4.6 Ethics Panels are responsible for reviewing and approwle for reved(n)2.2 (fid)13 (ar)11GR anicrexa.68 T[2 (b)1

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.

- Does the research involve human participants?
- Is the project research?
- Is the project funded by the MOD (Ministry of Defence), or does it involve MOD employed staff or participants?

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.

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 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.

Regarding data collected at other institutions:

- The data will be pre-exisiting 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.
- If the data is sourced from an institution with a different ethical culture to our own, be it a home institution or overseas, a light-touch ethical review by the FREC may be required. This is to ensure ethics, integrity and data standards are adhered to.

Anyone who is unsure whether their proposed use of secondary data requires ethical approval should discuss soseo ashndte(o)-9 (s Tw 0.30ir 0 T0.001 Tc 028 0 Td [(d)2.2 (at)-3 (a)18.7 (c)-4.9F (.)-2a

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

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

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 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 UREE

10. SOME KEY CONSIDERATIONS

10.1 **Recruitment of Participants**

10.1.1 The recruitment of participants should wherever possible be via a notice, or, if verbally,

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12.3 **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.

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

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

13. NON-COMPLIANCE AND MISCONDUCT

13.1 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 RECo

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)	
5	Nov 2024	Section 5.10 updated to include the following; if the data is sourced from an institution with a different ethical culture to our own, be it a home institution or overseas, a light-touch ethical review by the FREC may be required. This is to ensure ethics, integrity and data standards are adhered to. Appendix 3 updated to provide further guidance as to what kind of changes would trigger an amendment and to simplify the process for minor amendments.	

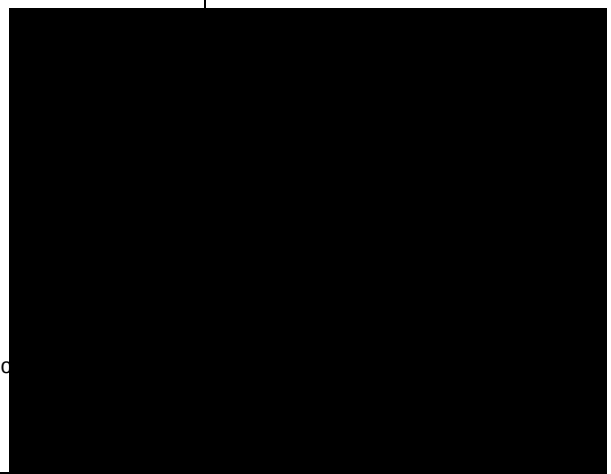
APPENDIX 1: ETHICS AND GOVERNANCE STRUCTURE

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.

	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?
	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?



1.

	Please seek further advice from ethics@dmu.ac.uk.	

Medium Risk

Ethics Issue	Further Guidance	[redacted]

	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?

It is recognised

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

APPENDIX 3: MAKING AMENDMENTS TO AN APPROVED ETHICS APPLICATION

Making Amendments to an Approved Ethics Application

An 'amendment' is **a written description of (a) change(s) to an ongoing and currently approved protocol**. Amendments include any change to the study activity or documents that affect scholarly intent, study design, the risks posed by the study or human participant protection.

Amendments are changes made to a research project after approval from the relevant approving body has been given (For Undergraduate or Taught Masters students the approving body is the Module Leader, for PhD students or staff the Faculty Research Ethics Committee (FREC) is the approving body).

If you have an approved ethics application and would like to make changes to the protocol in your proposal or any other element, you may need to apply for an amendment. New amendment requests supersede earlier versions; only the latest submitted amendment request is valid.

There are two possible kinds of amendments: Minor Amendments and Substantial Amendments. Certain administrative changes to your study might not require an amendment and need only be noted in your study documentation, including in milestone reports if you are required to submit them.

a

a) Clearly explain what the amendment you wish to make is, and the justification for making the change.
b) Insert details of any ethical issues raised by the proposed amendments.
c) Include all relevant information regarding the change so that the Chair or ethics reviewers 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.
d) If the intention is to make a series of changes to a study in quick succession it is advisable to include all changes in one large amendment rather than a series of smaller amendments, as this will significantly streamline the review process.

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.