
Guidance 3xvii Research Ethics

Middlesex University is committed to maintaining high standards of **ethics in research**. This means abiding by the principles of ethical research (see *Section 2 Code of Practice for Research: Principles and Procedures*) and appropriate ethical procedures (see *Section 3 Code of Practice for Research: Principles and Procedures*). To this end, the following guidelines and procedures are designed to support researchers at all levels in conducting research according to relevant ethical, legal and professional frameworks, obligations and standards, in whatever context and are therefore also drawn from and consistent with the British Educational Research Association fourth edition (2018) of the *Ethical Guidelines for Educational Research (2018)* <https://www.bera.ac.uk/researchers-resources/publications/ethical-guidelines-for-educational-research-2018>, the *Concordat to Support Research Integrity (2019)* <http://www.hefce.ac.uk/whatwedo/rsrch/infrastruct/concordat/http://www.hefce.ac.uk/whatwedo/rsrch/infrastruct/concordat/> (and the Revised concordat to support research integrity October 2019) and The Association of Research Ethics Committees document – A Framework of Policies and Procedures for University Research Ethics Committees (2013) <http://s3.spangfish.com/s/21217/documents/independent-membership/12-11-13-framework-complete.pdf>. According to these documents there is common agreement that research should be underpinned the highest standards of rigour and integrity and the following basic principles of ethical research:

1. **Autonomy.** The participant must normally be as aware as possible of what the research is for and be free to take part in it without coercion or penalty for not taking part, and also free to withdraw at any time without giving a reason and without a threat of any adverse effect.
2. **Beneficence.** The research must be worthwhile in itself and have beneficial effects that outweigh any risks; it follows that the methodology must be sound so that best results will be yielded.
3. **Non-maleficence.** Any possible harm must be avoided or at least mitigated by robust precautions.
4. **Confidentiality.** Personal data must remain unknown to all but the research team (unless the participant agrees otherwise or in cases where there is an overriding public interest, or where participants wish their voices to be heard and identified).
5. **Integrity.** The researcher must be open about any actual or potential conflicts of interest, and conduct their research in a way that meets recognised standards of research integrity.
6. **Fidelity:** Researchers have an obligation to respect the contract of trust with their participants and a responsibility to ensure participants understand the risks involved when engaging in research projects and maintain a **duty of care** to their human participants and subjects of research (including animals, the environment, cultural objects and precious artefacts) and to maintain the safety and be respectful of the rights, dignity and welfare of all those involved in research.
7. **Justice and Fairness:** This refers to avoiding discrimination and bias and applies particularly to the recruitment of participants. The researcher has a responsibility to ensure that issues such as equality and diversity are respected throughout the research process.
8. **Veracity:** Researchers must be honest in all aspects of the research process, including in the presentation of research goals, intentions and findings; in gathering data; disclosure of information to participants, and must preserve accuracy when publishing.

Research ethics review processes therefore provide additional safeguards for staff, students and participants, and can positively contribute to further understanding of ethical issues, research methods and processes for students and staff. Research which involves the collection, processing of personal data must comply with the *University Data Protection Policy* and the *University Research Data Policy* and should be managed in accordance with the *University Data Management Policy*. Failure to consider and seek review/approval of the ethical, legal and safety implications of a research project may constitute researcher misconduct (see *Middlesex University Code of Practice for Research: Principles and Procedures*).

Evidence of research ethics review, and in some cases, approval is generally required for research funding, e.g., by research councils such as the ESRC (see ESRC Framework for Research Ethics

(FRE) 2022 <https://www.ukri.org/councils/esrc/guidance-for-applicants/research-ethics-guidance/framework-for-research-ethics/>) and sometimes for the publication of research results. However, duplication of full ethics review should be avoided.

Committee structure for research ethics review and approval at MU

The University Research Ethics Committee (UREC) is concerned with maintaining and developing the University's ethics policy framework in line with best practice and appropriate national and international standards and guidelines particularly those relating to research investigations involving human participants and animal subjects (*see MU Statement on the Use of Animals in Research, Teaching and Practice*) carried out in the University or under the auspices of the University, by its faculties, staff, students and partners.

The UEC operates a framework of delegated authority to Faculty Research Ethics Committees (FRECs) and Departmental Research Ethics Sub-Committees (DRESCs). This structure reflects the diversity of academic disciplines within the University and recognises the different approaches and the distinct requirements of activities in different subjects, while ensuring appropriate academic ethical oversight in a flexible and responsive manner adhering to relevant professional body requirements and/or codes of conduct.

Departmental Research Ethics Sub-Committees (DRESCs) report to their Faculty Research Ethics Committee (FREC) which reports to the University Ethics Committee (UEC). The UREC reports to the Assurance Committee and the Research & Knowledge Exchange Committee both of which are sub-committees of Academic Board. All sub-committees and committees must follow the *Middlesex University Code of Practice for Research: Principles and Procedures* for identifying and dealing with potential conflicts of interests.

Research Ethics Committees' Responsibilities

The UREC together with FRECs/DRESCs aim to maintain ethical standards of practice in research, to protect participants in research and researchers from harm, to preserve the participants' rights, to take account of legitimate interests of other individuals, bodies and communities associated with the research and to provide reassurance to the public and to outside bodies that these are being done. It is also the aim of the committee to facilitate, not hinder, valuable research, and to protect research workers from unjustified criticism.

Faculty Research Ethics Committees (FRECs) through their Departmental Research Ethics Sub-Committees (DRESCs) are responsible for reviewing ethical issues in relation to research proposals to ensure that key principles of ethical research are addressed. FRECs and DRESCs are expected to act independently, free from bias and undue influence. Ideally, FRECs and DRESCs should be multidisciplinary to reflect the range of different perspectives, philosophical and methodical, presented in individual research proposals and include member(s) independent of the institution. FRECs and DRESCs are encouraged to include members from other FRECs/DRESCs to facilitate discussion between different ethics committees and to share good practice.

FRECs/DRESCs are responsible for specifying arrangements for processing of ethics applications, for proportionate or expedited (fast-track) review of applications, for reporting decisions and/or further requirements, processing requests for extensions, modifications, progress review reports and referring appeal cases and/or complaints to the UREC if not resolved by the FREC/DRESCs.

FRECs/DRESCs should publish a projected timetable on the time needed to consider a proposal (including the maximum number of working days to complete the review process given a complete submission from the researcher) where this differs from the Middlesex Online Research Ethics (MORE) specified timescales (on the MyLearning area) and in the standardised template communications (i.e., 25 days), and provide feedback on what needs to be done to meet necessary ethical standards and achieve ethics approval if refused. The decisions of FRECs/DRESCs have to be transparent and are accountable to the UREC.

FRECs/DRESCs are also responsible for providing an approval letter signed by the Chair or designated person. Approved applications should not be backdated. Ethics approval should be valid for the duration of the research project as specified on the application form and FRECs/DRESCs may need to include processes that allow for monitoring/progress reports to be submitted on an annual basis.

It is recommended that the constitution of a FREC/DRESC should consider the following principles of membership:

- Be multidisciplinary
- Include both men and women
- Include at least one appropriately trained external member with no affiliation to the department, university or research institution;
- Have members with a broad experience of and expertise in the areas of research regularly reviewed by the FREC/DRESC, and who have the confidence and esteem of the research community;
- Include at least one member who is knowledgeable in ethics;
- Include individuals who reflect the ethnic diversity of the local community;
- Have members who represent a broad range of methodological expertise;
- Be constituted so that conflicts of interest are avoided.

Management of the committees: Maintain independence, confidentiality and impartiality from faculty and department management in respect to the appointment of chairs, ethics applications, processes, procedures and decisions. The University Research Ethics Committee is responsible for the management and functioning of all sub-committees.

The remit, responsibilities and composition of FRECs/DRESCs, as defined above, complies with the ERSC FER (2015) and follows the model of standard operating procedures as recommended by the Association of Research Ethics Committees document – A Framework of Policies and Procedures for University Research Ethics Committees (2013)

<http://s3.spangfish.com/s/21217/documents/independent-membership/12-11-13-framework-complete.pdf>.

Details of the *Research Ethics Committee Terms of Reference* (including frequency of meetings, membership and chair of the committees) can be found in Appendix 2.

Details of the *Research Ethics Sub-Committee Terms of Reference* (including frequency of meetings, membership and chair of the committees) can be found in Appendix 3.

FRECs/DRESCs are responsible for determining appropriate business procedures and managing the documentation for their meetings with administrative support provided by Academic Registry. The overall framework for the practice and operation of the ethics processes at Middlesex are contained in the Middlesex University Ethics Policy Statement (2019) ref: Paper AC 18/47

Responsibilities of principal investigators, supervisors and all researchers

It is the responsibility of the principal investigator, supervisor and all researchers to ensure that appropriate consideration is given to ethical and compliance issues pertaining to their research activities; to comply with the *Middlesex University Code of Practice for Research: Principles and Procedures*; to seek advice, ethics review and/or approval of their research and to conduct and manage their research activity in accordance with their professional/statutory/regulatory body Code of Conduct/Code of Ethics/Research Governance Framework. Researchers who fail to refer relevant projects for ethics review and/or deliberately act against the requirements of their FREC/DRESC or the UREC may be liable to investigation for misconduct (see *Code of Practice for Research: Principles and Procedures, section Definitions of Research Misconduct*).

Responsibilities of supervisors

Students undertaking research must be supervised by an academic member of staff, acting as the project supervisor. For joint provision, the supervisor may be a member of staff of the partner institution. If a member of staff is also a student conducting research, then s/he must have an appropriate

academic member of staff as their supervisor. The supervisor is responsible for ensuring compliance with the required ethics review and approval procedures.

Research requiring ethical review and approval

All proposed research activity* (defined as any form of disciplined inquiry that aims to contribute to a body of knowledge) to be undertaken by staff or students, which requires data collection involving human participants and/or personal data must be reviewed prior to research commencing. (*The following activities are not considered research: routine audit, performance reviews, quality assurance studies, testing within normal education requirements, literary or artistic criticism.)

According to the ESRC Framework for Research Ethics (2015) *“while data collected and stored as a record at an individual level is considered ‘human data’, material already in the public domain is not. For example, published biographies, newspaper accounts of an individual’s activities and published minutes of a meeting would not be considered ‘personal data’ or sensitive personal data requiring ethics review, nor would interviews broadcast on radio or television or online, and diaries or letters in the public domain.*

Information provided in forums or spaces on the internet and web that are intentionally public would be valid to consider ‘in the public domain’, but the public nature of any communication or information on the Internet should always be critically examined, and the identity of individuals protected unless it is critical to the research, such as in statements by public officials.

Ethics review may not be required for anonymised records and data sets that exist in the public domain. This includes, for example, datasets available through the Office for National Statistics or the UK Data Archive where appropriate permissions have already been obtained and where it is not possible to identify individuals from the information provided. Specific regulations relate to the use of administrative data and secure data (see website for details in appendix). Other data providers are likely to specify their own restrictions on the access to and use of their data. These must be complied with. There may be some circumstances where ethics issues arise with the use of secondary data.” See ESRC Framework for Research Ethics (2015) for further guidance.

Research ethics review and/or approval is achieved by completion of the Middlesex University Online Research Ethics (MORE) review system – for staff and students. Online applications are submitted to the relevant Research Ethics Committee.

Documentation required for submission to FRECs/DRESCs

1. Completion of the Middlesex Online Research Ethics (MORE) system application detailing research aims, design and ethical issues arising from the research, rationale and actions to be taken to mitigate concerns with the following documents as required:
2. Participant Information sheet (where applicable) including a link to the University’s Privacy Notice for Research Participants when personal data is being processed.
3. Informed consent form (where applicable)
4. Details of materials for data collection e.g., recruitment message (where relevant), copy of questionnaire, interview guide
5. Debriefing sheet (where applicable)
6. Data Protection Checklist for Researchers (where applicable)
7. Risk Assessment (required if research is to be conducted away from Middlesex University property (or premises of an approved partner institution), otherwise leave this blank. Institutions/locations listed for data collection must match original letters of acceptance)

Responsibilities of researchers following review/approval

Compliance with ethics requirements is expected and the responsibility of the researcher and supervisor where applicable. Following review/approval the researcher (staff or student supported by their supervisor) must

- Report (in writing) any adverse effects or potential risks (serious or non-serious) to participants, the researcher(s) or others to the relevant FREC/DRESC and include details of mitigating actions or amendments to the study.
- Seek research ethics re-approval for any proposed changes in previously approved research applications or apply for an extension to current ethics approval to the committee through completion and submission of the **Amendment to Ethical Approval Form MORE online sub-**

form. The changes may not be implemented without prior review and approval, except where necessary e.g., to immediately avoid harm.

- If the research is on-going and would benefit from extending to beyond the end date specified, the researcher must complete and submit the **Extension to Ethical Approval Form MORE online sub-form**. **If the research continues beyond the approved end date of the research, without an agreed extension, a full submission will normally be required.**

Research ethics review/approval appeals

If staff or students are dissatisfied with the decision made by the FREC/DRESC s/he should discuss this with the Chair of the committee. If the matter is not resolved an appeal against the decision of the may be made to the relevant committee higher in the hierarchy. For example an appeal against the decision of a DRESC should be made to the relevant FREC and an appeal against the decision of a FREC should be made to UREC.

Failure to meet ethical, legal and professional obligations

According to the *Concordat to Support Research Integrity (2012/2019)* research misconduct is characterised as behaviour or actions that fall short of the standards of ethics, research and scholarship required to ensure that the integrity of research is upheld. See *MU Code of Practice for Research: Principles and Procedures for Handling Allegations of Research Misconduct*.

Research ethics enquiries and complaints

Enquiries and complaints regarding a research project should be addressed to the relevant Chair of the FREC/DRESC. If the matter is not resolved it should be referred to the University Research Ethics Committee. It may then be referred to the Deputy Vice-Chancellor.

Documentation relating to the research ethics approval process can be found here.

<http://www.intra.mdx.ac.uk/research-business/Research-ethics/index.aspx>

The MORE system can be accessed at <https://MOREform@mdx.ac.uk>