

Assurance Committee and Research & Knowledge Exchange Committee
Paper Number AC 23/68
Paper Number RKEC/20/13

MIDDLESEX UNIVERSITY

ASSURANCE COMMITTEE
RESEARCH & KNOWLEDGE EXCHANGE COMMITTEE

UNIVERSITY ETHICS COMMITTEE

MIDDLESEX UNIVERSITY RESEARCH ETHICS POLICY FRAMEWORK

1. Middlesex University is a charitable body dedicated to teaching and research for the public good. It is committed to safeguarding the academic freedom of its staff and students to research, study, and publish, and it shall not permit the independence or integrity of its teaching or research to be compromised. This document should be read in conjunction with the *Middlesex University Code of Practice for Research: Principles and Procedures* and the *Middlesex University Definition of Research*. The Middlesex University Research Ethics Policy Framework applies to all fields of research and all staff. This includes those in honorary positions and all students, and their supervisors engaged in research, (regardless of whether it is externally funded or not). It includes students at collaborative partner institutions registered as Middlesex University students, and external researchers who wish to undertake research on university premises and/or with staff/students.
2. Research is governed by a range of ethical, legal and professional frameworks, obligations and standards which researchers must comply with. The frameworks that regulate research practice change over time. Ethical concerns can also change over time, and new legal obligations and professional standards will be introduced periodically. This framework includes and refers to current and general policies, principles, codes of practice, obligations and guidelines. However, all researchers have a responsibility to ensure they have up-to-date knowledge of the frameworks, standards and obligations that apply to their work and the requirements of relevant professional, statutory and regulatory bodies and/or other discipline specific guidance. They must also ensure that their research is subject to active and appropriate consideration of ethical issues (Ref: UUK Revised Concordat to Support Research Integrity, October 2019).

Procedures for ensuring consideration of ethical issues in research,

- 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 \(2018\)](#) the [Concordat to Support Research Integrity \(2012\)](#)
- [The concordat to support research integrity](#) and The Association of Research Ethics Committees document – [A Framework of Policies and Procedures for University Research Ethics Committees \(2013\)](#) 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:

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- **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 free to withdraw at any time without giving a reason and without a threat of any adverse effect.*
 - **Beneficence.** *The research must be worthwhile and have beneficial effects that outweigh any risks; it follows that the methodology must be sound and conducted to the highest standards of **rigour** so that best results will be yielded.*
 - **Non-maleficence.** *Any possible harm must be avoided or at least mitigated by robust precautions.*
 - **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).*
 - **Integrity.** *The researcher must be open and honest about any actual or potential conflicts of interest and conduct their research in a way that meets recognised standards of research integrity.*
 - **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.*
 - **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.*
 - **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.*
3. Research ethics review processes therefore provide 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*).
4. Evidence of research ethics review, and in some cases, approval is normally required for research funding, e.g., by research councils such as the ESRC (see [ESRC Framework for Research Ethics \(FRE\) 2015](#)) 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

5. The University Ethics Committee (UEC) is to oversee and review ethical issues, particularly those relating to human subjects, human materials and other data as they pertain to programmes of research, postgraduate research ethics and the ethical implications of project proposals for undergraduate and postgraduate taught courses. It is principally concerned with maintaining and advising on the development of 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. The University does not undertake research using animals protected by the Animals (Scientific Procedures) Act (ASPA), covering all living adult vertebrates and cephalopods. Any research considering the use of animals, will be referred to the University Ethics Committee.
6. The UEC works in concert with the Faculty Research Ethics Committees (FREC's) and those from MU's Campuses in Dubai and Mauritius. The structure recognises the diversity of

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academic disciplines within the University and the different approaches and the distinct requirements of activities in different subjects, while ensuring appropriate academic ethical oversight is maintained in a flexible and responsive manner that adheres to relevant professional and disciplinary requirements and/or codes of conduct.

7. All Faculty and Campus Ethics Committees report to the University Ethics Committee (UEC), which in turn reports to both the Research & Knowledge Exchange Committee (for research matters) and the University's Assurance Committee (for taught programmes), which are both sub-committee of Academic Board. All committees are required to follow the *Middlesex University Code of Practice for Research: Principles and Procedures* for identifying and dealing with potential conflicts of interests.

Faculty Ethics Committees and Campus Ethics Committees responsibilities

8. The UEC together with Faculty and Campus Ethics Committees 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 and not hinder, valuable research, and to protect research workers from unjustified criticism.
9. Faculty Ethics Committees and Campus Ethics Committees are responsible for reviewing ethical issues in relation to research proposals to ensure that key principles of ethical research are addressed. All committees are expected to act independently, free from bias and undue influence. Ideally these committees should be multidisciplinary to reflect the range of different perspectives, philosophical and methodological presented in individual research proposals and should include member(s) independent of the institution. Faculty and Campus Ethics Committees are encouraged to include members from other similar peer committees to facilitate discussion and to share good practice.
10. Faculty and Campus Ethics Committees 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 University Ethics Committee. These arrangements should be document in their Terms of Reference and recorded in the minutes of any meeting.
11. Faculty and Campus Research Committees 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 may differ from the Middlesex Research Ethics (CRIS) System's specified timescales (on the MyLearning area) and in the standardised templates communications, and provide feedback on what is required to be done to meet necessary ethical standards and achieve ethics approval if refused. The decisions of Faculty and Campus Ethics Committees must be transparent and are accountable to the University's Ethics Committee.
12. Faculty and Campus Ethics Committees are responsible for providing an approval letter signed by the Chair or designated person. Approved applications cannot be backdated. Ethics approval should be valid for the duration of the research project as specified on the application form and Faculty and Campus Ethics Committees may need to include processes that allow for monitoring/progress reports to be submitted on an annual basis.
13. It is recommended that the constitution of Faculty or Campus Research Committees should consider the following principles when compiling their membership:
 - Be multidisciplinary,
 - Include both men and women,

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- Include at least one appropriately trained external member with no affiliation to the department or research institution.
- Include members with a broad experience of and expertise in the subjects and areas of research regularly reviewed by the committee and who have the confidence of the research community.
- Include at least one member who is knowledgeable in ethics.
- Include members who reflect the ethnic diversity of the local community.
- Include members who represent a broad range of methodological expertise.
- Be constituted so that conflicts of interest can be avoided.

The remit, responsibilities and composition of Faculty and Campus Ethics Committees as outlined above, should comply with the ESRC guidance (above) and follow the model of standard operating procedures as recommended by the [Association of Research Ethics Committees document](#).

Responsibilities of principal investigators, supervisors and all researchers

14. 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 Faculty or Campus Ethics Committees or the University's Ethics Committee may be liable to investigation for misconduct in research (see *Code of Practice for Research: Principles and Procedures, section Definitions of Research Misconduct*).
15. External researchers seeking to undertake research on university premises and/or with university staff/students must be supported by an internal member of staff acting as a sponsor for the research, who will submit the external research proposal to the relevant Faculty or Campus Ethics Committee for review/approval.

Responsibilities of supervisors

16. 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 he/she must have an appropriate academic member of staff as his/her supervisor. The supervisor is responsible for ensuring compliance with the required ethics review and approval procedures.

Research requiring ethical review and approval.

17. 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. (Note: The following activities are not considered research: routine audit, performance reviews, quality assurance studies, testing within normal education requirements, literary or artistic criticism.) This does not by default, exempt proposals from ethical scrutiny and if any student or staff member is in any doubt, they should seek advice from the Chair of their Faculty or Campus Ethics Committee.
18. 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.*
19. *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*

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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.

20. *An 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.*
21. Research ethics review and/or approval is achieved by submission to the Middlesex Research Ethics application form (or equivalent) submitted to the relevant Faculty or Campus Ethics Committee.

Documentation generally required for submission to Faculty or Campus Ethics Committee

- a) Research Ethics application form detailing research aims, design and ethical issues arising from the research, rationale and actions to be taken to mitigate concerns.
- b) Participant Information sheet (where applicable)
- c) Informed consent form (where applicable)
- d) Details of materials for data collection e.g., copy of questionnaire, interview guide.
- e) Debriefing sheet (where applicable)
- f) Data Protection Checklist for Researchers (where applicable)
- g) 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)
- h) Security sensitive categories questionnaire (where applicable, and if not completed as part of the application form)

Responsibilities of researchers following review/approval

22. 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 Faculty or Campus Ethics Committee 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**. Any 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**.

Research ethics review/approval appeals.

23. If staff or students are dissatisfied with the decision made by the Faculty or Campus Ethics Committee, he/she should initially discuss this with the Chair of the committee. If the matter is not resolved an appeal against the decision of the Faculty or Campus Ethics Committee may be made to the University Ethics Committee.

Failure to meet ethical, legal and professional obligations.

24. According to the [Concordat to Support Research Integrity](#) (2012/19) 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*

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Practice for Research: Principles and Procedures for Handling Allegations of Research Misconduct.

Research ethics enquiries and complaints

25. Enquiries and complaints regarding a research project should be addressed to the relevant Chair of the Faculty or Campus Ethics Committee. If the matter is cannot resolved, it should be referred to the University Ethics Committee. It may then be referred to the Pro Vice Chancellor for Research and Knowledge Exchange or to the University's Provost.
26. Annual and interim reports from Faculty or Campus Ethics Committees, copied to the relevant Dean of Faculty should be submitted to the University Ethics Committee by the specified deadline. The purpose of the reports is to provide the University Ethics Committee with a means of monitoring research and ethical approval processes and arising issues; act a self-monitoring and reflection exercise to ensure any issues are identified at the local level and addressed immediately, and as a means to formally identify specific training needs, and to inform the design of new or revised practices to be responsive to additional internal or external professional, legal or ethical obligations and standards.
27. Reports from collaborative partners with joint provision should also be submitted to their aligned Faculty or Campus Ethics Committee and reflected in their report or submitted directly to the University Ethics Committee.

Institutional monitoring

28. The University Ethics Committee reports to the University's Research and Knowledge Exchange and the University Assurance Committee (both sub-committees of Academic Board). Annual reports from the Faculty and Campus Ethics Committees/Deans of School/Faculty and collaborative partners are reflected in annual report of the University Ethics Committee, along with any documents produced or work undertaken by the committee. The University Ethics Committee's annual report is submitted to the Assurance Committee.

Ad hoc audits

29. The audit process ensures that a random selection of research pertaining to different Faculty or Campus Ethics Committees will occasionally be audited. The process involves verifying that:
 - a) Approved submissions are available and complete,
 - b) Correct forms are being used for approval,
 - c) Research is undertaken only after approval is granted,
 - d) Amendments and extensions for approval have been submitted timely and appropriately,
 - e) Evidence of signed consent forms is available on request and otherwise appropriately filed.
 - f) Questions on data storage and data sharing may also be asked.
30. Where an ad hoc audit considers that a study is being conducted in a way that is not in accord with the conditions of its approval or in a way that does not protect the rights, dignity and welfare of research participants, the Chair of the relevant Faculty or Campus Ethics Committee should meet with the researchers concerned with a view to resolving those difficulties. In more extreme circumstances the Chair of the Faculty or Campus Ethics Committee may revoke ethics approval for the research and require that the research is suspended or discontinued. All relevant parties (e.g., funding bodies), Chair of the University Ethics Committee etc. must be notified immediately and a provided with a report documenting all aspects of the evidence and decision-making process.

AB 13.3.23

This Research Ethics Review Framework was approved by the Assurance Committee July 2014. It is due for review in July 2019.

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