MIDDLESEX UNIVERSITY

**ASSURANCE COMMITTEE**

# UNIVERSITY ETHICS COMMITTEE

**MIDDLESEX UNIVERSITY RESEARCH ETHICS REVIEW FRAMEWORK**

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 Review Framework applies to all staff, those in honorary positions and students and their supervisors engaged in research, (regardless of whether it is externally funded or not), and includes students at collaborative partner institutions registered as Middlesex University students.

### 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 obligations and standards, in whatever context and are therefore also drawn from and consistent with the British Educational Research Association second revision (2011) of the *Ethical Guidelines for Educational Research (2011)* <http://www.bera.ac.uk/system/files/3/BERA-Ethical-Guidelines-2011.pdf>, the *Concordat to Support Research Integrity (2012)* [http://www.hefce.ac.uk/whatwedo/rsrch/rinfrastruct/concordat/](https://owa.mdx.ac.uk/owa/redir.aspx?C=EZNIqV7dHUW-NKS-M7MzqZL6D1znCtBIl0XJyNni-4LxF8Ak8JbIzmiT_LyI2Hl3kgN29PJinmo.&URL=http%3a%2f%2fwww.hefce.ac.uk%2fwhatwedo%2frsrch%2frinfrastruct%2fconcordat%2f" \t "_blank) and The Association of Research Ethics Committees document – A Framework of Policies and Procedures for University Research Ethics Committees (2013) <http://s3.spanglefish.com/s/21217/documents/independent-membership/12-11-13-framework-complete.pdf>. According to this document there is common agreement that the basic principles of ethical research are:

* + **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.
	+ **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.
	+ **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 about any actual or potential conflicts of interest, and conduct their research in a way that meets recognised standards of research integrity.

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. It should also be noted that research conducted without appropriate research ethics review and in some cases, approval, is not covered by the University’s insurance. This means that should a participant make a claim in relation to the research, the staff or student could be personally liable.

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) 2012 <http://www.esrc.ac.uk/about-esrc/information/research-ethics.aspx>) 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 Ethics Committee (UEC) 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 schools, staff, students and partners.

The UEC operates a framework of delegated authority to Research Ethics Committees (RECs) and Research Ethics Sub-Committees (RESCs). 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.

All Research Ethics Committees (RECs) report to the University Ethics Committee (UEC), which in turn reports to the Assurance Committee which is a sub-committee of Academic Board (see Appendix 1 for *Diagram of University Ethics Committee Structure)* and 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’ (RECs and RESCs) responsibilities

The UEC together with RECs/RESCs 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.

Research Ethics Committees (RECs) and Research Ethics Sub-Committees (RESCs) are responsible for reviewing ethical issues in relation to research proposals to ensure that key principles of ethical research are addressed. RECs and RESCs are expected to act independently, free from bias and undue influence. Ideally, RECs and RESCs 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. RECs and RESCs are encouraged to include members from other RECs/RESCs to facilitate discussion between different ethics committees and to share good practice.

RECs/RESCs 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 UEC if not resolved by the REC.

RECs/RESCs 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) and provide feedback on what needs to be done to meet necessary ethical standards and achieve ethics approval if refused. The decisions of RECs/RESCs have to be transparent and are accountable to the UEC.

RECs/RESCs 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 RECs/RESCs 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 REC/RESC 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 REC/RESC, 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.

The remit, responsibilities and composition of RECs/RESCs, as defined above, complies with the ERSC FER (2012) 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.spanglefish.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.

RECs/RESCs are responsible for determining appropriate business procedures and managing the documentation for their meetings with administrative support provided by Academic Registry.

### 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 approvalof 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 REC/RESC or UEC may be liable to investigation for misconduct in research (*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 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

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 (2012) “*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 (2012) for further guidance.

Research ethics review and/or approval is achieved by completion of the Middlesex University Research Ethics Review Form A (or equivalent) submitted to the relevant Research Ethics Committee, or for research in Psychology and Natural Sciences (e.g., for Human Tissue Act Compliance) specific ethical approval forms must be completed and submitted to those Research Ethics Committees.

### Documentation required for submission to RECs/RESCs

1. Research Ethics Review Form A\*detailing research aims, design and ethical issues arising from the research, rationale and actions to be taken to mitigate concerns
2. Participant Information sheet (where applicable)
3. Informed consent form (where applicable)
4. Details of materials for data collection e.g., 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)

\*or specific research ethics review forms for research in Psychology and Natural Sciences (e.g., for Human Tissue Act Compliance)

### 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 REC/RESC 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 D**. 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** **E.**

### Research ethics review/approval appeals

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

### Failure to meet ethical, legal and professional obligations

According to the *Concordat to Support Research Integrity (2012)* 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 REC/RESC. If the matter is not resolved it should be referred to the University Ethics Committee. It may then be referred to the DVC (Academic).

### Research ethics committee reports and identification of training needs

Annual reports from Research Ethics Committees and signed by the Deans of School should be submitted to the University Ethics Committee. The purpose of the report is to 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, as well as to document the annual amount of ethical approvals submissions and outcomes, new or revised practices to be responsive to additional internal or external professional, legal or ethical obligations and standards. Reports from collaborative partners with joint provision should also be submitted to their aligned REC and reflected in the REC report.

### Institutional monitoring

The University Ethics Committee reports to the Assurance Committee (a sub-committee of Academic Board). Annual reports from the RECs/Deans of School and the University Ethics Committee, and any documents produced or work undertaken by the committee are submitted to the Assurance Committee for final approval.

## Ad hoc audits

The audit process ensures that a random selection of research (approximately 10%), pertaining to each REC/RESC, is occasionally monitored. The process involves verifying that:

1. Approved submissions are available and complete
2. Correct forms are being used for approval
3. Research is undertaken after approval is granted
4. Amendments and extensions for approval have been submitted timely and appropriately,
5. Evidence of signed consent forms is available on request and otherwise appropriately filed.
6. Questions on data storing and data sharing may also be asked.

Where an ad hoc audit considers that a study is being conducted in a way which 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 REC/RESC should meet with the researchers concerned with a view to resolving those difficulties. In an extreme situation the Chair of the REC/RESC 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 UEC etc. must be notified immediately and a provided with a report documenting the evidence and decision making process.

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

## Appendix 1: Diagram of MU Research Ethics Committee Structure

## Appendix 2: University Ethics Committee (UEC)

**Terms of Reference**

1. Maintain and develop the University’s ethics policy framework in line with best practice and appropriate national and international standards and guidelines, making recommendations to the Academic Board as necessary about ethical guidelines to be adopted to cover specific areas of academic activity and professional practice through regular monitoring and reporting to the Assurance Committee
2. Monitor, review and make available the range of related policies, which impinge on ethical issues within the University and disseminate new and revised policies to staff and students.
3. Monitor, review and make available lists of relevant reference materials on ethics produced by professional bodies, funding councils and other national bodies, alongside documents pertaining to legal processes and the law, and disseminate new and revised materials to staff and students.
4. Provide guidance and advice to Schools and Services and individual members of staff, collaborative partners, visiting academics and honorary researchers on activities carried out in the name of Middlesex University that may have ethical implications e.g. arising from teaching, research and institutional practice, as specified in the University Code of Conduct: Principles and Procedures.
5. Monitor research ethical approval processes through the submission of annual Research Ethics Committee reports and outcomes of ad hoc audits to the University Ethics Committee.
6. Consider, approve, withhold or withdraw approval for research proposals and/or appeals referred by Research Ethics Committees.
7. Consider complaints of ethical misconduct referred by Research Ethics Committees and where necessary refer unresolved complaints to the DVC Academic
8. Make arrangements for training on ethical matters.
9. Refer matters pertaining to corporate social responsibility to the Corporate Social Responsibility (CSR) Committee
10. Formulate institutional responses to national and international developments relating to ethical issues, in conjunction with the CSR committee where appropriate.

**Membership**

* Member of the University Assurance Committee as Chair of the Committee.
* One representative of each School of the University (nominated by the Dean of each School).
* One representative of the Institute of Work Based Learning
* Data Protection Officer (ex-officio)
* The University’s Equality and Diversity Manager (ex-officio)
* A member of staff from the University’s Corporate Marketing Department
* Up to two representatives of Corporate Services (nominated by the Deputy Vice-Chancellor, Director of Corporate Services)
* A representative of Middlesex University Students’ Union (nominated by the MUSU President)
* Up to two co-opted members, as required, either internal or external (appointed by the committee)
* Secretary to the committee.

**Meetings:** The committee shall meet not less than twice a year

**Quoracy:** Quoracy for formal decisions to be set at 50% of membership.

## Appendix 3: Research Ethics Committees (REC) and Research Ethics Sub-Committees(RESC)

The functions of RECs and RESCs include the oversight of staff and student (UG and PG) research proposals and to implement and improve arrangements for ensuring good ethical standards e.g., through staff training and up-dating and within all levels of academic provision.

Research Ethics Sub-Committee allow subject/departmental level responsibility for ensuring staff and students give close attention to ethical issues in their proposals for and in the conduct of research activities carried out in the name of Middlesex University, whether externally or internally funded or unfunded. They operate on behalf of and report to the Research Ethics Committee within their School structure.

The key principles of RECs and RESCs include:

* Maintaining robust procedures.
* Utilising the existing knowledge and experience of staff members appropriately.
* Improving arrangements for and attention to user involvement issues in research processes.
* Awareness of diversity and the promoting discussion, understanding and adoption of good practice of different approaches adopted by distinct subject areas where appropriate.
* Awareness of the distinct requirements in different areas e.g., clinical work, fieldwork, placements etc.
* Maintaining the independence and integrity of committee decisions and e.g., so that no member is subject to pressure from interested parties and decisions are overturned on appropriate grounds.
* To implement and improve arrangements for ensuring good ethical standards, there are a number of related needs including:
	+ The need for continuing staff training and updating.
	+ The need to build attention to ethical issues into core curricula.
* Research ethics committee arrangements may need to be responsive to the following conditions and constraints:
	+ The expectations of funding bodies, key stakeholders and/or partner institutions.
	+ The expectations of professional bodies.

**Terms of Reference**

1. Responsibility for ensuring staff and students give close attention to ethical issues in their proposals for and in the conduct of research activities carried out in the name of Middlesex University, whether externally or internally funded or unfunded.
2. Provide and/or request guidance and/or training for staff and students to ensure research is conducted safely and appropriately in accordance with the ethical principles as specified in the University Code of Conduct: Principles and Procedures and meet the requirements of the Law e.g., with regard to Data Protection.
3. Identify relevant codes of professional conduct relevant to the subjects and ensure that appropriate ethical dimensions are incorporated within undergraduate and postgraduate provision and ethical approval processes for staff and students and inform the UEC of any changes in the ethical codes of professional bodies in relevant discipline areas, in order that the University's procedures remain valid.
4. Liaise with School Executive and/or University Ethics Committee on ethical issues or REC in the case of RESCs.
5. Liaise with the School Research Degrees Committee on ethical issues, ensuring close attention is given to ethical issues at the registration and transfer stages of each research student’s career.
6. Specify arrangements for submission of ethics applications, for proportionate or expedited review of applications, for reporting decisions and/or further requirements, processing requests for extensions, modifications, progress review reports and appeals process to the UEC (or REC in the case of RESCs) in a competent and timely manner.
7. Review, approve or withhold approval for research proposals submitted by staff and student researchers within and associated with the School. (This may be delegated to Research Ethics Sub-Committees.)
8. Ensure ethics review is independent, competent and timely and adopts a blind review process where possible.
9. Protect the dignity, rights and welfare of research participants.
10. Consider the legitimate interests of other individuals, bodies or communities associated with the research.
11. Consider the safety of the researcher(s).
12. Make informed judgements of the scientific merit of proposals, or check that such judgements have already been made.
13. Refer unresolved applications or complaints to the UEC or REC in the first instance for RESCs.
14. Self-monitor ethical approval procedures through the preparation of annual School Reports on Ethical Issues, including RESC reports where appropriate, for submission to the UEC.
15. Undertake ad hoc audits of research projects with ethics approval.
16. Disseminate and where appropriate, implement, the recommendations of the UEC and/or REC/RESCs.

**Membership**

* Chair – Deputy Dean or Nominee
* Members with special/relevant expertise
* A student representative
* An independent member or lay person and/or a representative from another RECs/RESCs

**Secretary**

* Administrative member of staff from Academic Registry

**Frequency of meetings**

* Minimum of twice per year, with arrangements for virtual meetings when needed