University Centre Middlesbrough
Research Ethics Policy

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Contents

1.0 Introduction

University Centre Middlesbrough (UCM) is committed to maintaining standards of professional conduct in all research activities. Central to the principles that guide research is that research must be conducted in accordance with the highest contemporary ethics standards. This Policy provides information on research ethics at UCM. The Policy covers research involving the collection of data and/or biological samples from human participants. It also provides links to internal and external advice, and full details of the UCM Research Ethics Committee (REC).

The research ethics review process is part of the REC remit to scrutinise and advise on ethical considerations relating to any research carried out by, and for, UCM, which involves investigations with humans or human materials.

This Policy also contains procedures staff or students must follow when completing research at UCM.

The following College policy documents should also be consulted in conjunction with this policy:

- Anti-Fraud and Bribery Policy
- Staff OR Learber ITAcceptable Use Policy
- Discipline, Suspension and Dismissal Procedure of all Staff (excluding Senior Potholders)
- Data Protection Policy (General Data Protection Regulations (GDPR) Policy)
- Research Ethics Policy
- Health, Safety, Welfare Policy
- Procedure for dealing with allegations of academic malpractice or misconduct.

2.0 Definitions

2.1 Definition of Research

'Research' for the purposes of this Policy is to be understood as:

- original investigation undertaken in order to gain knowledge and understanding;
- work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors;
- scholarship;
- the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights;
- the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction.

2.2 Definition of 'research activity'

Research activity is defined as UCM research activity where:

- UCM takes on ultimate responsibility for the research, and/or, the activity is being undertaken in fulfilment (or part-fulfilment) of a UCM programme of study/academic award,

and/or,

- A member of UCM staff, or a student enrolled at UCM is:

- the Chief Investigator (CI) or Academic Supervisor,

and/or,

- holds the research funding.

3.0 Research on Human Participants

It is essential that all UCM research is assessed, or reviewed, for ethical issues **before** any potential participants are contacted. To do this, the REC Project Registration and Risk Checklist (see Appendix 1) should be completed and returned to heoffice@mbro.ac.uk. The REC Chair will then assess whether an ethics review will be required (a response will be received within 7 working days). Research that has been deemed to contain ethics-related implications should go through the full research ethics review process, achieved by fully completing the REC Proforma (see Appendix 2) and returning it to heoffice@mbro.ac.uk.

Any research involving UCM students may require agreement from the Safeguarding Team and/or from the Associate Director of the Department concerned. Any research involving UCM staff may require agreement from Human Resources.

3.1 Ethics Principles for Research Involving Human Participants

There are six principles[1] that must be adhered to when conducting UCM research:

Principle 1: Compliance with protocol

Research with humans conducted by UCM employees and their agents and assignees should be aware of the range of research ethics, and in particular comply with an explicit approved protocol[1], defining how valid consent to participate is sought, gained and recorded, how data are collected, stored and accessed, and how participants are informed of their rights within the study.

Approval of the protocol should be gained from the UCM Research Ethics Committee (REC) before data collection commences, and if directed by the REC from other bodies such the Safeguarding Team, Human Resources and departmental managersas appropriate.

Principle 2: Valid consent

Potential participants should always be informed in advance, and in understandable terms, of any potential benefits, risks, inconvenience or obligations associated with the research that might reasonably be expected to influence their willingness to participate.
Consent should always be gained in a consistent manner, as specified in the research project's ethics protocol. This should normally involve the use of an information sheet about the research and what participation will involve, and a signed consent form. Sufficient time should be allowed for a potential participant to consider their decision between the giving of the information sheet and the gaining of consent.

Except in exceptional circumstances, where the nature of the research design requires it, no research shall be conducted without the opt-in valid consent of participants. In the case of children (individuals under 16 years of age) no research shall be conducted without a specified means of gaining their valid consent (or, in the case of young children, their assent) and the valid consent of their parents or guardians, or persons who are legally responsible or appointed to give consent on their behalf.

1 In these Principles, the term 'protocol' refers to a filed document which specifies the procedures for recruiting participants and gathering and managing data, with which all research staff agree to comply.

Where participants are involved in longer-term data collection, the use of procedures for the renewal of consent at appropriate times should be considered.

No inducement to participate should be offered prior to seeking consent, either in the form of payments or of gifts. Reasonable recompense for inconvenience and time contributed to the research and reimbursement of travelling expenses can be offered (subject to approved financial support being available).

Participants should be informed clearly that they have a right to withdraw their consent at any time up to a specified date, that any data that they have provided will be destroyed if they so request up to a specified date, and that there will be no adverse consequences for participants if they choose to withdraw or request data destruction. However, it must be clear that withdrawal after a specified date may not be possible as it would unduly affect the study.

Principle 3: Openness and integrity

Researchers should be open and honest about the purpose and content of their research and behave in a professional manner at all times.

Researchers should comply with ucm's principles for integrity in the general conduct of research.

Where an essential element of the research design would be compromised by full disclosure to participants prior to their involvement, such withholding of information should be specified in the project protocol and explicit procedures stated to obviate any potential harm arising from such withholding.

Deception or covert collection of data should only take place where it is essential to achieve the research results required, where the research objective has strong scientific merit and where there is an appropriate risk management and harm alleviation strategy.

Participants should be given opportunities to access the outcomes of research in which they have participated and debriefed if appropriate after they have provided data.

Principle 4: Maximising benefit and protection from harm

Researchers should make every effort to maximise the benefits of research while minimising the risks of any harm, either physical or psychological, arising for any participant, researcher, institution, funding body or other person or community.

Researchers should comply with the requirements of the UK Data Protection Act 2018, the Freedom of Information Act 2000 and any other relevant legal frameworks governing the management of personal information in the UK or in any other country where the research may be conducted.

Where research involves children or other vulnerable groups, an appropriate level of disclosure should be obtained from the Disclosure and Barring Service for all researchers in contact with participants.

Where harm does nevertheless arise in the course of research, researchers should take remedial steps.

Participants should be given information as to whom they may contact in the event of any issues arising in the course of the research that cannot be resolved with members of the project team.

Principle 5: Confidentiality
Except where explicit written consent is given to reveal identities, researchers should respect and preserve the confidentiality[2] of participants' identities and data. The procedures by which this is to be achieved should be specified in the protocol.

Principle 6: Professional codes of practice and ethics
Where the subject of a research project falls within the domain of a professional body with a published code of practice and ethical guidelines, researchers should explicitly state their intention to comply with the code and guidelines in the project protocol.
Research within the UK NHS should always be conducted in compliance with an ethical protocol approved by an appropriate NHS Research Ethics Committee.

4.0 Legal and Ethical Requirements

UCM and its researchers must comply with all legal and ethical requirements relating to their research. Research must be conducted in accordance with the highest contemporary ethics standards, and researchers must obtain the required ethical approvals. In particular, researchers must comply with the following requirements:

- Researchers who are planning to collect data or biological samples from human participants must submit protocols for ethics review by the Research Ethics Committee where appropriate and abide by the outcome of such reviews.

- Researchers collecting or using information about living individuals (personal data) must also comply with the requirements of UK General Data Protection Regulations (GDPR) legislation and register their project with ucm's Data Protection Officer.

Research data can also be subject to the Freedom of Information Act and the Environmental Information Regulations. Researchers must deal appropriately with any requests for information made under this legislation.

4.1 Research Data and Records

Research data and records must be accurate, and sufficiently detailed and complete in the context of the conventions of the relevant discipline to enable verification of research results and to reflect what was communicated, decided or done.

[2] Note that the duty of confidentiality is not absolute in law and may be overridden by more compelling duties such as the duty to protect individuals from harm or in the public interest – such as in research involving public officials. Where a significant risk of such issues arising is identified in the risk assessment, specific procedures to be followed should be specified in the protocol.

Data, including electronic data, must be recorded in a durable, secure and retrievable form, be appropriately indexed, and comply with any relevant protocols. Appropriate levels of data security should be applied based on a systematic assessment of sensitivity and risk.

The individual researcher is responsible for the retention and archiving of data and must comply with any external requirements (e.g. funders), and the terms on which ethical approval was granted. Where there are no specific external requirements for retention, the researcher should keep the data as long as is necessary for the purpose of the research, and in line with any data collection agreements, or funder or institutional requirements.

It is the responsibility of each researcher to monitor research outputs and to ensure that the institution complies with its obligations to funders to manage intellectual property arising from research and to disseminate the results of publicly funded research.

Data forming the basis of publications must be available for discussion with other researchers. Where confidentiality provisions apply, the data must be kept in a way that allows reference by third parties without breaching confidentiality. Where data are obtained from limited access databases or via a contractual arrangement, written indication of the location of the original data, or key information regarding the database from which it was obtained, must be retained by the researcher of the unit.

It should be recognised that offering a right of confidentiality to research participants and other persons associated with research cannot be an absolute right. Certain circumstances, such as a risk of imminent harm to a person or persons, or the disclosure of information such as an undetected serious crime, may require a researcher to act in the public interest or in the interest of protecting a person(s), by passing on the information to an appropriate agency such as the police. Where the nature of the research is such that there is a significant risk of such disclosures arising, any agreement made with participants or other persons associated with the research, such as may be made via an information sheet and consent form, should be clear about the limits of any confidentiality right.

4.2 Lawful bases for processing data
In order to remain compliant with General Data Protection Regulations (GDPR), you must have a valid lawful basis in order to process personal data. The lawful bases for processing are set out in Article 6 of the UK GDPR. At least one of these must apply whenever you process personal data:

(a) Consent: the individual has given clear consent for you to process their personal data for a specific purpose.

(b) Contract: the processing is necessary for a contract you have with the individual, or because they have asked you to take specific steps before entering into a contract.

(c) Legal obligation: the processing is necessary for you to comply with the law (not including contractual obligations).

(d) Vital interests: the processing is necessary to protect someone’s life.

(e) Public task: the processing is necessary for you to perform a task in the public interest or for your official functions, and the task or function has a clear basis in law.

(f) Legitimate interests: the processing is necessary for your legitimate interests or the legitimate interests of a third party, unless there is a good reason to protect the individual's personal data which overrides those legitimate interests. (This cannot apply if you are a public authority processing data to perform your official tasks.)

Further information on each of the above bases can be found on the Information Commissioners Office website.

5.0 Procedures

A simplified flowchart of the Ethical clearance procedure is included here in Appendix 4.

5.1 Ethical Clearance

Ethical clearance is required for *all* UCM research activity, except those projects which consist *entirely* of literature review, desk or library-based research. Projects which are entirely literature or desk and/or library-based do not need to receive Ethical clearance but staff and students undertaking such research should be familiar with ucm's policies on use of the internet in research (see Considerations section). Students, in particular, should also be made aware that some areas of literature and library-based research may nevertheless involve sensitive or controversial material which will require a degree of care when accessing and handling. Literature or library-based work which is *primarily* carried out *external* to ucm, for instance in an off-site archive, requires ethical clearance.

Ethical clearance is obtained by application to the Research Ethics Committee (REC) before research commences:

Application can be made via two routes:

- *REC Project Registration and Risk Checklist (see Appendix 1)* – this form is completed if the staff member and/or student is unsure if ethics related implications exist within the proposed research. The REC Project Registration and Risk Checklist form is submitted to heoffice@mbro.ac.uk for consideration by the REC chair. The REC chair will review the form within 7 days and state via return email if there are ethics related implications within the proposed research. The weekly submission deadline for fully completed REC Project Registration and Risk Checklist forms is **Thursday at 5.00pm**.

- *REC Proforma (see Appendix 2)* – this form is completed once the REC chair has reviewed the REC Project Registration and Risk Checklist form and deemed there to be ethics related implications. If staff and/or student researchers believe their proposed research has ethics related implications, they can complete the REC Proforma without completing the REC Project Registration and Risk Checklist form. The weekly submission deadline for fully completed REC Proforma forms is **Thursday at 5.00pm**, via heoffice@mbro.ac.uk.

5.2 Dissertations and Projects

For the purposes of applying this policy, there are two distinct categories of projects:

1. Those not involving human participants and/or not involving potential physical or psychological risk to the researcher(s) themselves. These projects will usually be **entirely desk and/or library-based** and the same kind of research will be done by an entire group of students. These projects **DO NOT** require ethical clearance. However, the member of staff responsible for the module in which such work is occurring must keep a **record** that confirms that these projects meet the criteria of

"**entirely desk and/or library-based**" and such a record must be available for audit by REC if requested.

2. Those which do involve human participants, and/or involving potential or psychological risk to the researcher(s) themselves. In these cases, ethical clearance **WILL** be required.

5.3 Chair's Action or Full REC Referral

Upon review of the REC Project Registration and Risk Checklist form, the Chair of the REC will decide if the proposed research can be approved. If the Chair decides they cannot approve the research, it would be referred to the REC. This decision will be made within 7 days, with the researcher notified via email.

5.4 Case of Doubt

If a member of staff, a supervisor, or student, has concerns about the ethical propriety of a piece of research they should approach the Chair of the REC for advice as early in the project planning stage as is possible, and certainly well before preparing and submitting an application for clearance.

5.5 Supplementary Documentation

If the research involves data collection from or about human participants, normally the following documentation will be attached to the application for clearance by the Approval route:

- Consent Form
- Participant Information Sheet
- Data collection tools e.g. Questionnaires, Topic Guides for Focus Groups, Semi-structured interview questions (as appropriate)
- Gatekeeper consent if the research is dependent upon the approval of a third-party organisation such as a researcher's place of work.

As stated in the Ethics Principles for Research Involving Human Participants section, the expectation is that research with human participants will be conducted on the basis of **valid informed consent.**

Projects seeking clearance for methods involving variation from this may be approved by the REC, but only in very specific contexts in which the lack of proper information is justified by the value of the research proposed and ucm is not exposed to undue risk nor would insurance cover be compromised. The Chair of the REC may need to seek confirmation regarding UCM's insurance status as part of the review process in such projects.

5.6 Contact Details

The personal contact details of researchers should not be used in study documentation - in all cases only College contact details should be used. For undergraduate student research the Academic Supervisor's College contact details should be used.

If telephone contact details are required this should either be the supervisor's college number, or a dedicated number for that study only.

5.7 External (Non-UCM) Approvals and Permissions

It is the responsibility of the applicant for clearance to determine which external approvals and permissions are required for the project they propose and to detail that data in their application. It is the responsibility of the applicant to ensure that the Governance standards and requirements of all relevant external bodies or agencies are adhered to in the planning and conduct of the research. Disclosure and Barring Service (DBS) checks are commonly needed for researchers working in certain areas.

The REC will not accept an applicant's self-verification of such checks. As a result, documentary proof in some form must be included with any applications for clearance.

6.0 Research Ethics Committee (REC)

The REC will consist of a chair, internal members and external consultants if required. The REC will review fully completed REC Proformas and decide if the proposed research project contains ethical concerns.

Once an application has been passed for review, a decision will be made, and a formal response sent via email, within 21 working days; however, some applications can take longer.

6.1 Cases of REC Concern

Where the REC has concerns about the ethical propriety of the proposed research project, these concerns will be sent in writing to the applicant and a response invited. In addition, a member of the REC may be nominated to work with the researcher(s), to assist them in addressing the issues identified during review.

6.2 Referral to Academic Board

When a REC is unable, after dialogue with the researcher(s) concerned, to resolve concerns and assure itself of the ethical propriety of research, it shall refer the matter to the Academic Board for action.

6.3 Appealing REC Decisions

Applicants may appeal a final decision made by an REC, but only after first attempting to resolve any issue by dialogue. Appeals may be made only with regards to *procedural error* by an REC and not on the basis of *ethical judgement and/or disagreement*. Appeals will be made to Academic Board, whose decision on appeal matters is final. Any appeal will be overseen by the Chair of Academic Board.

6.4 Filing of REC Project Registration and Risk Checklist/REC Proforma Forms.

A single electronic copy of the REC Project Registration and Risk Checklist form and REC Proforma must be filed in the HE Office SharePoint site upon completion and signature by the Chair of the REC (or following approval upon referral to Academic Board).

6.5 Post clearance audit of projects

It is a condition of ethical clearance that a small number of projects will be audited each year to ensure that:

- applicants are using the appropriate route for ethical clearance;
- that project protocols are being followed, particularly after ethical Approval;
- that any research design changes that may affect the ethical propriety of the research are being reported on;
- that proper checks and balances are being made across ucm to ensure legal compliance.

The audit should have taken place by the last meeting of the REC for the academic year in question and will be overseen by the Chair of the REC and the Chair of Academic Board. Projects selected for audit and the results should be reported on as part of the REC's Annual Report. It is expected that the projects audited will be selected from the full diversity of levels, including staff projects.

7.0 Considerations

7.1 Exceptions to REC Process

If after completing the Risk Checklist in Appendix 1 (Section A4), the students and supervisor are satisfied that there are no identifiable risks associated with the research project, then the exemptions identified in a and b below, may be applied.

a. If students are working on studies that include research (or group research) at Levels 4 or 5 that are classroom-based (i.e. students are conducting research on their peers) there is no requirement to follow the Research Ethics registration process, provided the necessary approvals are in place – see Appendix 1 Section A3.

b. If students are working on studies that include research (or group research) at Levels 4 or 5 that based solely in their work or work placement setting, (i.e. students are conducting research on their peers or clients of their work setting) there is no requirement to follow the Research Ethics registration process, provided the necessary approvals are in place – see Appendix 1 Section A3.

7.2 Implications for the Assessment Process

A criterion for submission of level 6/7 dissertations/projects is obtaining of ethical clearance. *Failure to complete such procedures will invalidate submission for assessment.*

Level 6/7 dissertations/projects which commenced with ethical clearance, but for which contact between supervisor and student ceased during preparation, *cease to be ethical* and will *invalidate submission for assessment*. Assessment Board regulations must reflect the above.

7.3 Recruitment of participants for research projects

Recruitment of human participants must be completed carefully and with respect, normally ensuring proper and valid consent is obtained from participants.

If inducements of any kind are used, not exclusively but particularly monetary incentives (beyond expenses) to encourage participation, this must be completed with careful consideration of the risk of manipulation and or coercion.

It is expected that members of staff will not normally be approached to be recruited as participants in student dissertations or research work.

Students who use the UCM logo for materials designed to recruit participants for research projects must request the use of this logo via their supervisors, who should contact the HE Office. Staff are free to use the UCM logo on their recruitment materials as is.

7.4 Use of the Internet in Research

In any project using the internet as a search or research tool,researchers should have read the Learner IT Acceptable Use Policy, Section 2 – Internet, e-mail and Social Media Use. .

7.5 Use of Freedom of Information or Other Legislation to Obtain Data

Researchers may not compel individuals or organisations to supply research data through the use of legislative provisions, for example by using the Freedom of Information Act or the

Environmental Information Regulations. Applications for specific exceptions to this requirement can be submitted to Academic Board for consideration on a case-by-case basis.

8.0 Summary of Potential Liabilities of Researchers

Summary of potential legal liabilities of researchers

8.1 Harm occurs to participants, property, resulting in claim of negligence:

a) Negligence involves lack of proper process of risk assessment and can be intentional or reckless.
b) Going via institution's REC procedures constitutes protection.
c) Research conducted without proper procedural accountability severs the protection of the institution's indemnity arrangements and leaves the researcher open to personal liability for negligence. In practice, this means that if a researcher chooses not to apply for ethical clearance, and a claim is made against them by a participant for any reason, then the researcher may be personally liable. This may also apply in cases where a researcher has applied for ethical clearance but who chooses to ignore requirements placed upon the research protocol by the REC in order for it to proceed; or who subsequently changes the research design previously approved in the protocol submitted to an REC without notification.
d) Lack of valid consent:

Researcher may be exposed for criminal and/or civil assault or battery which may attract a criminal punishment of a fine and/or imprisonment and a civil claim for damages.

e) Breach of confidentiality:

Criminal liability for the institution under Data Protection Act 2018 for serious breaches of the Act which attracts a maximum fine of £500,000 and financial claim for damages by participants for breach of common law duty of confidentiality against the institution or individual researchers. In addition, potential criminal sanctions exist for failure to disclose criminal activity where discovered.

Appendix 1

REC Form available here.

Revision History		
Version	Date	Detail
1.0	September 2017	
1.1	August 2018	Document edited for clarity and to homogenise presentation and implement URLs to College website HE Essential Information page.
1.2	March 2020	Guidance added regarding group, classroom/peer-based research at Levels 4 and 5.
1.3	December 2020	Further guidance added regarding group, classroom/peer based, or work setting research at Levels 4 and 5. Incorporates the HE code of practice for research, previously a seperate document.
1.4	January 2022	Checked for accuracy.
1.5	October 2023	Specific references to 'undergraduate' projects removed as policy covers postgraduate projects, too.
1.6	October 2024	The policy and process has been revised and simplified through harmonising and rationalising all sections in response to feedback from staff, students and the Research Ethics Committee about the complexity and useability of the document.
1.7	July 2026	• Logo removed pending update. • References to the College or Middlesbrough College replaced with University Centre Middlesbrough (UCM).