

UNIVERSITY OF MANCHESTER

POLICY ON THE ETHICAL INVOLVEMENT OF HUMAN PARTICIPANTS IN RESEARCH

1. Background

- 1.1 Research Ethics is a globally recognised set of principles governing the way research involving the interaction between a researcher and other humans, their tissue or data, is designed, managed and conducted. These principles apply equally to all researchers, including our members of staff as well as our undergraduate and postgraduate students and are essential to support good quality research.
- 1.2 Although the origins of formalised research ethics can be found in the medical world (e.g. the regulation of medical research involving patients and healthy volunteers), the general principles have much wider scope and are applicable much more widely to, for instance, include research into the social sciences where interactions with individuals, defined groups or their data are involved. Many professional and research organisations across a range of research disciplines have issued formal research ethics guidance.
- 1.3 The University's [Code of Good Research Conduct](#) recognised the ethical responsibility of its researchers and requires that "researchers should have respect for all participants in, and subjects of, research including humans, animals, the environment and cultural objects. The University expects all researchers to consider the ethical implications of their research and to be aware of their responsibilities to society, the environment, their profession, the University, research participants and the organisation(s) funding the research." Failure to do so constitutes research misconduct in accordance with the University's [Code of Practice for Investigating Concerns about the Conduct of Research](#).

General Principles

- 2.1 Although the specific number of research ethics principles can vary between sources, they are broadly grouped under the following headings:

Respect for autonomy: The participant must be able to choose whether to take part in the research without coercion or penalty for not taking part. They must also be free to withdraw at any time, without giving a reason and without detriment to themselves or any services or treatment they are receiving.

Beneficence: The research must be worthwhile in itself and ensure that any beneficial effects outweigh any possible risks; it follows that the methodology must be sound so that the result will yield meaningful or statistically significant results.

Non-maleficence:	Any possible harm to the participants or researcher must be avoided or mitigated by robust precautions.
Justice:	Research participants must be recruited fairly and not exploited.
Confidentiality:	The right of the participant to ensure their personal data are kept safe, stored securely and shared only with members of the research team for the purposes of the project (unless the participant agrees otherwise).
Integrity:	The researcher must be transparent regarding any known personal, financial, institutional or other gains, they are due to make from the research, acknowledge the relevant contributions of third parties involved in the project and ensure that research outcomes are disseminated appropriately.

2.2 These principles ensure that the welfare, self-determination, privacy and legal rights of both the participants and researchers are protected. To further ensure this protection the University Research Ethics Committees (UREC) review research involving human participants. The University of Manchester policy reflects the diversity of disciplines and, where appropriate, discipline-specific professional standards and best practice.

Requirement for Ethical Review

3. The University of Manchester defines research as primary data collection or secondary data analysis which will lead to:
- The advancement of knowledge or understanding in a given subject area
 - The confirmation of results or reaffirmation of previous work
 - The development of new theories

It may also include exercises to train a student in the techniques of gathering and analysing data, synthesizing ideas and scholarly report writing if forming part of their dissertation/thesis/final year project.

Data collection and analysis which takes place solely as part of research training and which does not aim to generate new knowledge etc. is not classified as research¹.

- 3.1 In principle, all researchers should undertake an ethical review of their own research but certain categories of research involving human participants, their tissue or data must be *independently* reviewed by a properly constituted Research Ethics Committee (REC).
- 3.2 Research projects which are conducted in a country outside of the UK must be reviewed according to UK standards to ensure that our researchers are abiding by the principles and legislation governing UK research. Therefore, these studies will require review by the UREC even if ethical approval has been received in the host country. Researchers will also have to show that they have approval from

¹ More information on the requirements and responsibilities for ensuring ethical approval of research training can be found in the [Policy on Ethical Approval of Research on Human Participants in Taught Assessment](#)

an appropriate authority (such as an ethics committee or gatekeepers) in the host country before they can proceed with the research.

3.3 To begin recruitment or data collection for a research project requiring research ethics approval without having first obtained that approval will be considered a breach of ethics and, depending on the circumstances, research misconduct.

3.4 It is not possible to provide exhaustive checklists of criteria that determine whether or not a proposed research project requires ethical review. Appendix A lists broadly the types of research which *prima facie* should have an independent ethical review (providing the study does not fall into the categories of exemption listed in 3.8 below) but, in general, any research project should undergo independent ethical review if:

- it has the potential to cause harm, upset or significantly inconvenience a participant
- it seeks confidential or sensitive personal information about a participant or group
- there is an unequal relationship between the researcher and the participant whereby the participant could be seen to be coerced into participation

3.5 [The Governance Arrangements for Research Ethics Committees](#) (GAfREC) and [HRA ethics decision tool](#) outline the types of research that will require approval by the National Health Service Research Ethics Committee (NHS REC). More information on these requirements can also be found in the [Faculty Research Governance Pack \(Faculty of Biology, Medicine and Health\)](#)

3.6 Research which involves the NHS in England or Wales will require Health Research Authority and Health and Care Research Wales (HRA and HCRW) approval. In Scotland and Northern Ireland NHS Research requires study wide review by the relevant coordinating function. As well as requiring HRA and HCRW approval or study wide review, some studies may require ethical approval from an NHS REC. Where this is the case, there is no need to get additional approval from one of the URECs. Studies that do not require NHS REC approval must submit for ethical approval from one of the URECs, if directed by the ethics decision tool or ethics signatory. If it is confirmed that neither NHS REC or UREC is required, the HRA approval application will proceed without ethical review.

Research which does not require independent ethical review

3.7 It is accepted that low risk research or research-like activities (e.g. evaluations) need a less rigorous approach to scrutiny and that a degree of proportionality should apply. For the University of Manchester, the following categories of research do not require independent ethical review, providing the noted criteria for each category are met.

- **Evaluation (including course, teaching or service):** A structured process of assessing the success of a programme in meeting its goals and to reflect on the lessons learned.
- **Market research:** Asking members of the public questions about a given subject area of commercial interest.

- **Work with Professionals (including interviews, focus groups, questionnaires, etc):** Research involving professional employees in which you ask them questions that are strictly within their professional remit.

These categories of research do not require independent ethical review (i.e. are classed as ethically exempt) providing all of the following are true:

1. The data are completely anonymous with no personal information being collected (apart from the participant's name, their publicly available contact details, a record of consent and an audio recording of the discussion provided the transcript is fully anonymised and the recording deleted)
2. The data is not considered to be sensitive or confidential in nature
3. The issues being researched are not likely to upset or disturb participants
4. Vulnerable or dependant groups are not included
5. There is no risk of possible disclosures or reporting obligations

- **Secondary data analysis:** Using data that has already been collected for another purpose by another party.

This category of research does not require independent ethical review (i.e. is classed as ethically exempt) providing all of the following are true:

1. The data are completely anonymous
2. The researcher has explicit consent from the data controller to access the data
3. The researcher is able to prove that the data will be used for a purpose which falls within the remit of the original consent provided by data subjects

- If there is any doubt as to whether a study requires ethical review, advice should be sought by contacting the Ethics Signatory for the Division/School.

3.8 Even if the research does not require independent ethical review, researchers must adhere to the published [best practice guidelines](#) concerning informed consent, data protection and mitigation of ethical issues.

Research which has prior ethical approval by a REC at another organisation

3.9 Research that has received prior approval by another research ethics committee recognised by the University Research Ethics Oversight Committee² will usually be accepted by the University provided that *notification of such approval* is provided to the Research Governance, Ethics and Integrity team and a check is undertaken by the team to ensure that the details of the approval are in accordance with UoM policies and procedures.

² All NHS and UK University research ethics committees are recognised ethics committees for this purpose. The University also recognizes some other UK based research ethics committees (a list of these is available on the Ethics web-pages)

Insurance

- 4.1 Most research projects which have a favourable ethical opinion are automatically covered by the University's insurance, but insurance arrangements for some specific categories of research must first be approved by the University Insurance Office or the Insurance Brokers. The UREC or sponsorship review processes will identify studies that potentially fall into these specific categories and liaise with the Insurance Office regarding any additional requirements.
- 4.2 When an institution other than the University of Manchester acts as Sponsor for a research project³ the University's insurance arrangements will apply insofar as the University is implicated, or the members of staff concerned are held by the courts as acting in part or in whole in their capacity as members of the University staff.

Roles and Responsibilities

- 5.1 **The University Research Compliance Committee** receives quarterly reports on the ethical use of humans in research and compliance with regulations and legislation that govern the use of humans in research.
- 5.2 **The University Research Ethics Oversight Committee** receives reports from the four URECs and reports to the Research Compliance Committee on a quarterly basis.
- 5.3 **The University Research Ethics Committees** undertake an ethical review of any relevant research project in the University with a view to:

- maintaining ethical standards of practice in research;
- protecting participants of research and researchers from harm;
- preserving the participants' rights and welfare;
- and providing reassurance to the public and to outside bodies that this is being done.

The Committees will grant each research project one of the following opinions:

- a favourable ethical opinion,
- a provisional favourable ethical opinion subject to a specified list of revisions
- or an unfavourable ethical opinion

An ethical opinion cannot be overturned except by another duly constituted Research Ethics Committee as outlined in the [UREC Appeals Process](#).

5.4 Researchers and supervisors:

It is the responsibility of staff researchers, student researchers and their supervisors to plan and conduct their research within the parameters of ethical practice and with integrity in accordance with the [University's Code of Good Research Conduct](#). This includes:

- Ensuring that any ethical implications of the research have been given proper consideration.
- Ensuring that any risks inherent in the research have been given proper consideration and an appropriate risk assessment has been carried out.
- Ensuring that the project has had an academic review (appropriate to the nature of the project⁴).

³ This typically happens when an NHS Trust acts as a research Sponsor

⁴ In most cases, internal review within the respective research group/team will be sufficient. However in some cases, external independent reviews will be required (depending on conditions attached to funding/contracts)

- Checking guidance on whether ethics approval is required.
- If ethical approval is required, ensuring this is sought and received prior to the commencement of recruitment of participants or data collection.
- Ensuring that any applications for ethical review are complete, well-written, contain all the supporting documentation and will be conducted in accordance with all UK and University policy and legislation (including GDPR).

Staff and student researchers and supervisors must also:

- Inform the Research Governance, Ethics and Integrity Team of any adverse event (i.e. an event which had not been foreseen in the application and was disadvantageous to one or more participants), protocol deviations or ethics breaches.
- Seek a formal amendment to the existing ethical approval for any planned or unexpected but necessary change to the approved methodology or supporting documentation, including extensions to the window of data collection. Specific details of the requirements of amendments can be found in the [Guidance for Submitting Amendments](#). Extensions of the time period for data collection can only be granted by amendment up to a maximum period of five years from the date of approval. Extensions that will last beyond this point will, except in exceptional circumstances, require the submission of a new research ethics application.
- Submit progress/end of study reports in line with conditions of approval

Ultimate responsibility for seeking ethics approval rests with the researcher⁵ and failure to seek ethics approval may result in the researcher not having appropriate indemnity cover and being liable to an investigation for misconduct in research, or for students to an investigation under the student disciplinary procedures. Furthermore, at least in some instances, they may be breaking the law.

Students are not permitted to conduct unsupervised research that is outside of their programme of study.

Data that has been collected without appropriate ethics approval may have to be deleted.

5.5 Responsibilities of Divisions/Schools:

It is the responsibility of Heads of Division/School to appoint Ethics Signatories and to put processes and procedures in place to ensure that researchers and supervisors fulfil their responsibilities as outlined above.

Divisions/Schools that have template processes in place for the approval of low risk student projects are responsible for resourcing these processes adequately.

It is the responsibility of the Head of School to ensure that the workload of staff involved in the ethical review processes (as committee chairs/members or ethics signatories) have their contribution recognised in the School's workload allocation model.

5.6 Research Governance, Ethics and Integrity Team:

It is the responsibility of this central team to set policies and standards in the area of research ethics and integrity and to support Divisions/Schools with the delivery of those standards via training and guidance, and through the development and maintenance of the online Ethics Review Manager system. The central team co-ordinates the University Research Ethics Committees and will audit the ethical review processes and procedures in order to ensure they are working effectively.

5.7 Responsibilities of URECs and Committee Members:

⁵ More information on the requirements and responsibilities for ensuring ethical approval of research training can be found in the [Policy on Ethical Approval of Research on Human Participants in Taught Assessment](#)

The four full URECs as well as the Proportionate Committee are responsible for reviewing and giving an ethical opinion on research projects conducted by members of the University that involve human participants. The committees are of equal status but operate both autonomously and consistently to agreed standards. These have regard to international standards (such as the Helsinki Declaration) national standards (such as those set by the Health Research Authority) and relevant professional bodies. They also reserve the right to delegate these responsibilities to the division/school ethics committees where an approved template system is in place for the approval of low risk student projects.

5.8 Responsibilities of the Ethics Signatory

Every Department/Division/School/Directorate of the University has an assigned Ethics Signatory. The Ethics Signatory is the first point of contact for staff members and supervisors with research ethics queries. Their role is to promote and circulate details about training/guidelines and policy updates provided by the Research Governance, Ethics and Integrity Team and to undertake an initial check of research ethics applications prior to submission to UREC.

Document control box	
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Next review date:	2023
Related Statutes, Ordinances, General Regulations:	Statute X (b)
Equality relevance outcome:	N/A
Related policies:	Code of Good Research Conduct Code of Practice for Investigating Concerns about the Conduct of Research Policy on Ethical Approval of Research in Taught Assessment
Related procedures:	
Related guidance and or codes of practice:	UREC Terms of Reference and Operating Procedures
Related information:	N/A
Policy owner	Director of Research and Business Engagement Support Services (Dr Andrew Walsh)
Lead contact	Research Ethics Manager (Mrs Genevieve Pridham)

Appendix A – Research that requires ethical review

The following categories of research will require independent ethical review by a recognised ethics committee, unless the study has been classed as ethically exempt. The list, however, is not exhaustive and subject to further clarification as legislation and policy evolve:

1. Research involving the collection or use of person-identifiable or special category data
2. Research involving the collection or use of data which is classed as sensitive or confidential
3. Research involving the use of audio/video recordings or photographs
4. Research involving vulnerable groups, including children or adults with special needs
5. Research involving the ingestion (by whatever means of delivery) of any substance by participants
6. Research involving any invasive/semi-invasive procedure or the administration of drugs
7. Research involving the physical testing of participants or the use of medical devices
8. Research involving the use of psychological tests or interventions
9. Research involving privileged access to clinical or personal records, or access to potential volunteers on the basis of their being or having been patients, or the invitation to volunteers to divulge facts about themselves which they would not wish the investigator to allow to become known to other persons
10. Research involving any form of physical risk, distress, embarrassment, anxiety, stress, fatigue or inconvenience to the participant
11. Research involving any form of adverse effect on the personal, social or economic well-being of the participant
12. Research involving social sensitive topics
13. Research likely to uncover illegal or potentially harmful activities

All of the above will require ethics approval from a Research Ethics Committee (UREC or NHS REC) but please note the list is not exhaustive.

To determine if a research study requires ethical approval by the University of Manchester, staff and students should use the [University's Ethics Decision Tool](#).

If after using the tool the researcher is still unsure of the requirements for research ethics approval, they should contact their Ethics Signatory for additional guidance and support.