University of Manchester

Policy on the Ethical Engagement of Human Participants in Research

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1. Introduction

1.1 Purpose

1.1.1 The purpose of this policy is to ensure research involving human participants conducted by University of Manchester (University) staff, students and postgraduate researchers adheres to globally recognised ethical standards and principles as well as University requirements and expectations. These include, but are not limited to, the UNESCO Universal Declaration on Bioethics and Human Rights, the Declaration of Helsinki, Belmont Report, the Health Research Authority and the University's Code of Good Research Conduct.

1.1.2 The policy sets out the University's requirements for ethical review of research involving human participants that is carried out by University staff or students (including undergraduates, postgraduate taught and postgraduate research).

1.1.3 Failure to adhere to this policy may constitute research misconduct or academic malpractice in accordance with the University's Code of Practice for Investigating Concerns about the Conduct of Research[1] or Academic Malpractice procedure.

1.2 Scope

1.2.1 This policy applies to all research involving human participants, their data or tissue, including research that is conducted as part of a student's degree programme at the University of Manchester (see definition of research in 2.1 below) which is supervised by a University member of staff. It also applies to funded and non-funded projects conducted by members of staff and is applicable to research which is conducted in person or via digital means (e.g. online, telephone, etc).

1.2.2 This policy outlines the responsibilities of all those involved in the research ethics review processes, including researchers (staff or student), supervisors, ethics committee members and members of the Research Governance, Ethics and Integrity Team.

1.2.2 This policy reflects the diversity of disciplines and, where appropriate, discipline-specific professional standards and best practice.

[1] UG and PGT students should refer to the Policy on Ethics Approval of Research on Human Participants in Taught Assessment.

2. Definitions

2.1 **Research**: primary data collection or secondary data analysis intended to 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 a 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 is not classed as research[2] in this Policy. Similarly, student placements are not routinely subject to research ethics review, unless research (as defined above) is conducted during the placement and the results of which will form a part of a dissertation, thesis or final mark of a module.

2.2 **Researchers**: Those conducting research, as defined above, including staff and students at all degree levels (UG, PGT and PGR).

2.2 **Research ethics**: a set of globally recognised principles that govern the standard of conduct for research involving human participants. They ensure that the welfare, self-determination, privacy and legal rights of both the participants and researchers are protected.

2.3 **Human participants**: living or recently (less than 100 years) deceased human beings (e.g. cadavers and human remains) who are the subjects of research including their tissues/bodily fluids and data/records (e.g. medical records, financial records, criminal convictions, test results, attainment information, demographic information, etc).

2.4 **Data**: any information being gathered about a human participant such as their thoughts, beliefs, characteristics or information about their personal habits or experiences. Examples include, but are not limited to, observations, audio recordings, questionnaires, films, photographs, social media postings and archaeological samples from human beings.

2.5 **Human tissue**: any material derived from the human body, including tissue extracted for the purposes of DNA/RNA analysis[3].

2.6 **UREC**: University Research Ethics Committee who provide an independent review of proposed research involving human participants.

2.7 **Research Ethics Review:** The process whereby a research project is subject to an independent review proportionate to its level of risk that considers the risk benefit ratio and must provide a favourable ethical opinion before participant recruitment can begin.

[2] 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

[3] More information on human tissue can be found here.

3. Governance Arrangements

3.1 **Research Compliance Committee** is responsible for setting the standards and ensuring that the University meets its obligations to comply with the regulations that govern its research. It receives quarterly reports from the Research Ethics Oversight Committee.

3.2 **Research Ethics Oversight Committee** provides oversight of the URECs, ensuring ethical standards of research across the institution, reviewing and approving new guidance and policy and resolving any reported incidents (e.g. adverse events, ethical breaches, appeals or complaints) in relation to UREC-approved research.

3.3 **University Research Ethics Committees (UREC)** undertake an ethical review of any relevant research project in the University with a view to upholding the following ethical principles:

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.

4. Roles and Responsibilities

4.1 Researchers:

It is the responsibility of researchers 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 peer review (appropriate to the nature of the project[4]).
- Checking guidance on whether their project requires research ethics review and completing the University's Ethics Decision Tool.
- If ethical review is required, ensuring this is sought and a favourable opinion received before recruitment of participants or data collection.
- Reading and adhering to the guidance provided on how to complete an ethics application, including, ensuring that any applications for ethical review are rigorous, well-written and contain all the supporting documentation.
- Ensuring that all participant-facing documentation used during the project (e.g. participant information sheets, consent forms, etc) are UK GDPR compliant, written in lay language and tailored to the specifics of the project, enabling participants to give informed consent.
- Ensuring that any projects which are classed as ethically exempt still adhere to all research ethics best practice requirements and expectations (including UK GDPR) and obtaining a letter of ethical exemption before they proceed with their research.
- Ensuring that changes to the project are submitted as formal amendments as outlined in section 9 and that these are approved by the Ethics Committee prior to being implemented.
- Ensuring that any breaches/potential breaches of research ethics approval or policy are reported to the Research Governance, Ethics and Integrity Team (RGEIT).

4.2 Supervisors:

It is the responsibility of supervisors to provide guidance and support to their students in relation to how to conduct their research ethically and in accordance with University policy as well as all relevant UK legislation (e.g. UK GDPR). This includes:

- Discussing the ethical implications of any work during supervision meetings.

[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)

- Ensuring students complete the University's Ethics Decision Tool for their project and verifying the path taken and outcome advice received.

- Ensuring students apply for research ethics review and receive a favourable opinion for their projects if required under University policy before undertaking any recruitment or data collection activities. If research ethics review is not required for the project, ensuring that students consider whether they should apply for a letter of ethical exemption prior to undertaking the work (PGT and PGR only).

- Ensuring that all participant-facing documentation used during the project (e.g. participant information sheets, consent forms, etc) are UK GDPR compliant and tailored to the specifics of the project, enabling participants to give informed consent.

- Ensuring that students adhere to all research ethics best practice recommendations and University expectations and requirements (e.g. the use of approved survey platforms and advertising sites).

- Ensuring that changes to the project are submitted as formal amendments as outlined in section 9 and that these are approved by the Ethics Committee prior to being implemented.

- Ensuring that any breaches/potential breaches of research ethics approval or policy are reported to the RGEIT.

4.3 Schools/ Departments/Divisions:

It is the responsibility of Heads of School to put processes and procedures in place to ensure that researchers and supervisors fulfil their responsibilities as outlined above. These responsibilities can be delegated to Heads of Department/Division.

Schools/Departments/Divisions that have template processes in place for the approval of low/medium risk student projects are responsible for resourcing these processes adequately, including administrative support, as well as ensuring regular communications with the RGEIT who provide the necessary training and system maintenance (see 4.4 below).

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) is recognised in the School's workload allocation model.

Schools are responsible for ensuring that students cannot conduct research involving human participants unsupervised and are aware that they are not permitted to do so.

4.4 Research Governance, Ethics and Integrity Team (RGEIT):

It is the responsibility of RGEIT to facilitate compliance with policies and standards of research ethics and integrity and to support Schools with the delivery of those standards via training and guidance, and through the development and maintenance of the online Ethics Review Manager (ERM) system. The RGEIT co-ordinates the URECs and audits the ethical review processes and procedures to ensure they are working effectively.

4.5 Responsibilities of URECs and Committee Members:

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 research participants. The URECs 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 school ethics committees where an approved template system is in place for the approval of low-risk student projects.

The URECs 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. Requirements for Research Ethics Review

The ethical implications for any proposed piece of research should be considered. Certain types of research involving human participants, their data or tissue must be *independently* reviewed by a properly constituted Research Ethics Committee (REC). This is, generally, where a proposed research project:

- has the potential to cause harm, upset or significantly inconvenience a participant
- seeks confidential or sensitive personal information about a participant or group
- potentially has an unequal relationship between the researcher and the participant whereby the participant could be seen to be coerced into participation
- involves vulnerable or dependant groups
- involves invasive procedures, physical testing or psychological intervention
- involves topics which may cause embarrassment, distress, anxiety or fatigue
- involves topics which are likely to result in disclosures related to safeguarding, malpractice, potentially illegal/harmful activities or whistleblowing
- involves data collection which puts the researcher at physical risk of danger due to the fieldwork destination/available resources
- involves the use of secondary data without appropriate consent arrangements from data subjects

More information on the types of research that require research ethics review and appropriate routes for review can be found on the Research Ethics Website. Researchers should use the

University's Ethics Decision Tool to determine whether, and what type of, research ethics review is required.

6. Ethical Exemptions

6.1 Some types of research carry minimal ethical risk whereby the ethical considerations of the project can be mitigated by self-reflection as opposed to independent ethical review. If researchers have the intention to publish the results of the work, they should apply for a formal letter of ethical exemption prior to undertaking any recruitment or data collection activities. As a general principle, letters of ethical exemption cannot be provided in retrospect.

6.2 Researchers must adhere to all research ethics best practice recommendations, including the use of UK GDPR compliant participant documentation. Information on how to request a letter of ethical exemption can be found on the Research Ethics website.

7. Requirements for Health and Social Care Research

7.1 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 Research Governance Pack.

7.2 Research requiring approval by an NHS REC must have a research governance sponsor. The University will act as research governance sponsor for projects led by a University member of staff and student projects supervised by a member of staff including honorary members of staff if they are substantively employed by a partner NHS Trust. The University will continue to sponsor for 12 months ongoing projects led by Emeritus staff on the basis the study will be closed out within that timeframe. New studies will not be approved for sponsorship if they are led by Emeritus staff.

7.2 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 rarely a need to get additional approval from one of the URECs[5]. Studies that do not require NHS REC approval must submit for ethical approval from one of the URECs, if directed by the University's Ethics Decision Tool or Research Governance, Ethics and Integrity (RGEI) Support Officer. If it is confirmed that neither NHS REC or UREC is required, the HRA approval application will proceed without ethical review.

[5] The only exception to this being a study which has both UK and international arms. The UK arm of the study would receive approval from the NHS REC and a submission to the UK would be required in order to review the ethical considerations of the international sites.

8. Breaches of Ethics

8.1 The following constitute a breach of ethics:

a) To begin recruitment or data collection for a research project requiring research ethics review without having first obtained a favourable ethical opinion.

b) Deviating from the ethically approved research methods, including but not limited to changing the wording on participant facing documentation, recruiting additional groups of participants, adding new data collection methods or locations of fieldwork or adding additional questions or themes to your data collection tools.

c) Failure to adequately protect participant data, including breaches of confidentiality.

d) Coercion when recruiting participants, including undisclosed conflicts of interest.

e) Failure to report any adverse events or serious adverse events that occur during the study.

8.2 Potential consequences of breaches of ethics:

a) Harm to research participants.

b) The researcher and their research not being covered by the University's insurance policy.

c) The deletion of data collected unethically.

d) Data breaches, notification to the Information Commissioner and subsequent fines.

e) A mark of zero in coursework/dissertation.

f) A mark of less than 40 for a dissertation with no opportunity to re-sit.

g) Investigation of research misconduct/academic malpractice leading to disciplinary proceedings.

8.3 Breaches and potential breaches of NHS REC/HRA approval should be reported to RGEIT via the SOP for Reporting Incidents. Breaches and potential breaches of UREC or Division/School approval should be reported to RGEIT as outlined in the UREC Incidents Procedure.

9. Adverse Events and Serious Adverse Events

9.1 Adverse events are defined as any event that has had a negative effect on the welfare of a research participant or a member of the research team. This includes, but is not limited to:

- Distress that is not resolved at the end of an interview/focus group
- Disclosure of information in relation to professional misconduct that must be reported to an employer, professional body or similar organisation
- Minor harm to a participant as a result of an accident (e.g. slip and fall or minor abrasions due to the removal of electrode pads from the skin).

- A research participant becoming overly aggressive/abusive towards the research team.
- A member of the research team becoming distressed as the result of an interview/focus group discussion.

9.2 Serious adverse events are defined as any event that has had a significant negative effect on the welfare of a research participant or a member of the research team. This includes, but is not limited to:

- Distress that led to a formal or informal referral to urgent professional help
- Disclosure of safeguarding concerns or concerns related to current or future planned illegal activities that must then be reported to the relevant body or authority.
- Significant harm to a research participant for example as a result of faulty study equipment or the research team failing to adhere to approved study procedures (e.g. failure to calibrate equipment before using).

9.3 All adverse events and serious adverse events for UREC approved studies must be reported to RGEIT as outlined in the UREC Incidents Procedure. It is usually the case that study activity should be halted until the incident is considered by RGEIT to be resolved. If alternative study arrangements are required, these will be decided by RGEIT and the research team informed in writing.

9.4 All adverse events and serious adverse events for NHS REC/HRA approved studies must be reported to RGEIT via the Incident Reporting SOP. In some cases, the NHS REC/HRA may also need to be informed as outlined in the NHS REC safety reporting requirements and timelines but this will be decided by RGEIT and the research team informed in writing.

10. Amendments

10.1 Researchers are required to seek a formal amendment to the existing ethical approval for any planned or unexpected but necessary change the approved methodology or supporting documentation of their study. Specific details of the requirements for amendments can be found in the Guidance for Submitting Amendments.

10.2 Requests for amendments must be sought and approval received prior to implementing the changes. Failure to do so constitutes a breach of this Policy and will be investigated as such.

10.3 Ethical approval is granted for a maximum period of 5 years and extensions to this period are not permissible. If data collection for a project needs to exceed the 5-year limit, researchers will be required to submit a new application for ethical approval.

10.4 Details of how to submit a formal amendment in the ERM system as well as timeframes for consideration of such requests can be found on the Research Ethics website.

11. Progress and End of Study Reporting

11.1 All research studies that receive approval from the UREC are required to submit a progress report in the ERM system every 12 months as well as an additional report at the conclusion of the study. Information related to these requirements and the process for doing so can be found on the Research Ethics Website.

12. Complaints

12.1 Complaints generally fall into the following categories:

- Complaints against a UREC or School/Division Committee
- Complaints about the research ethics process
- Participant complaints about University of Manchester research projects
- Complaints about a member of the RGEIT

12.2 Details of how to raise complaints, appropriate contacts as well as timeframes for resolution for all of the above can be found in the UREC Incidents Procedure.

13. Appeals

13.1 Researchers have the right to appeal decisions undertaken by the UREC or a School/Division Committee. Details of how to make an appeal as well as the timeframes for consideration and possible outcomes can be found in the UREC Incidents Procedure.

14. Collaborative Research

14.1 Research that has received prior approval by another research ethics committee recognised by the University Research Ethics Oversight Committee[6] will usually be accepted by the University provided that *notification of such approval* is provided to the RGEI Support Officer and a check is undertaken by the team to ensure that the details of the approval are in accordance with University policies and procedures. It should be noted that approvals received from the NHS REC are exempt from this requirement and should instead be retained by the research team in case of future query.

14.2 It is generally expected that when a University of Manchester member of staff is named as the PI of a collaborative project and, therefore, has oversight across all project activities, research ethics review should be sought at UoM. Additional approvals from collaborating partners may also be required, depending on the ethical policies at their respective institutions.

If the PI of a project is not a University of Manchester member of staff, the ethical approval from a collaborating UK based institution can usually be accepted in lieu of our own, provided it adheres to the general expectations and requirements as outlined in this Policy. Should RGEIT identify that the ethical approval received by a collaborating partner directly contradicts accepted practice at the University of Manchester (e.g. the use of the Gillick Competency Assessment for those aged 12 years and below), the research team will be required to seek ethical approval at the University of Manchester; the purpose of which is to enable the research team to discuss the ethical practices of the project in more detail and reach a consensus with collaborating partners regarding study procedures and ethical requirements.

14.3 Research projects conducted outside of the UK should be reviewed by a local ethics committee in accordance with the expectations of that country/locality. In order to ensure that researchers are also conducting their research in accordance with UK standards and the

[6] 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)

principles and legislation governing UK research, such studies also need to be reviewed by the UREC, unless they are deemed ethically exempt under this Policy.

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