



Procedure for Research with Human Participants conducted without, or in breach of, QM REC Research Ethics Approval

Definitions

1. “Researcher” refers to any individual conducting research under the auspices of Queen Mary University of London. This includes undergraduate, postgraduate taught and postgraduate research students as well as staff members.
2. “Participants” refers to any individual directly involved in, or affected by, the conduct of Queen Mary research i.e. participants, gatekeepers, facilitators etc.
3. “Risk” will include, but is not limited to, psychological, physical, reputational or economic harm or potential for harm.

Background

4. Queen Mary University of London is committed to supporting research of the highest ethical standards. Ethics review ensures that the rights, dignity and wellbeing of both researchers and research participants are protected.

5. It is a mandatory requirement of University policy that any Queen Mary staff or student member undertaking research involving human participants gains ethics approval through the appropriate route prior to commencing their study.
6. Queen Mary ethics review processes are detailed in the Joint Research Management Office (JRMO) [QM REC website](#). These webpages explain the process by which researchers must apply for research ethics approval, the deadlines for Panel review meetings, and the approximate timeframes within which applications will be reviewed.
- 7. It is clearly stated on the webpages and in the research ethics application that research ethics applications must be submitted, and approval confirmed, before the commencement of research.**
8. Where responsibility for low-risk ethics review has been formally delegated to a Devolved School Research Ethics Committee (DSRECs), the School is responsible for ensuring the above is clearly communicated to all researchers in a timely and efficient manner. DSREC Chairs should communicate any concerns regarding potential or confirmed ethics breaches to the Research Ethics team at the earliest possible opportunity, which will then be notified to the DSREC Sub-Committee Chair, with the option of escalating to the Main Committee of QM REC.

University Requirements

9. The conduct of human participant research without the appropriate ethics approval contravenes the Queen Mary [Policy on Research with Human Participants](#) and is considered to be a breach of good research practice and, in the case of serious breaches, potential research misconduct.

10. It is the responsibility of all Queen Mary researchers, whether they are staff members or students, to ensure that confirmation of ethics approval is in place before data collection or participant recruitment commences. Students must take responsibility for investigating whether their research requires ethics review, but ultimate responsibility for ensuring students are aware of the University policy and procedure and confirming ethics approval before commencement, lies with the educational supervisor.

11. Researchers are advised that:

- (i) Retrospective ethics approval cannot be granted for any research, under any circumstances.
- (ii) Data collected from humans without ethics approval must be securely destroyed.*
- (iii) Data collected from humans without ethics approval cannot be used in any final dissertation/thesis, report or future publications.*

*Staff only - Depending on the nature and severity of the case, it may be possible to appeal against points (ii) and (iii).

Students – see [Academic Integrity & Misconduct Policy](#) regarding appeals.

Levels of Breach Severity

12. While QM REC maintains that any research conducted without ethics approval constitutes a breach of good research practice, it also recognises that the circumstances behind each case will vary from deliberate and/or malicious to ill-advised, accidental or unintentional.

13. The Research Ethics Team has responsibility for processing cases and will present the details of each case to the QM REC Chair and Deputy Chair for consideration. Cases will be categorised based on the evidence available in each case, the level of intention, and extent of the risk as follows:

Critical Breach:

14. There has been a significant failure to follow due process which has resulted in, or may have resulted in, a serious adverse impact on research participants, the researcher or the University.

Examples:

- a. Research conducted without, or beyond the scope of, ethics approval which potentially put the participants, researcher or the University at risk
- b. Commencement of data collection in parallel to the ethics review process, i.e., while the application is in preparation or under review, but no approval has been issued
- c. Commencement of moderate/high risk research which has been rejected by QM REC or conditionally approved where the conditions have not been met.

15. An appeal will not be considered for a critical breach. For PGR and staff research, the case will be referred to the Research Integrity and Assurance Lead for further action at the earliest possible opportunity.

Major Breach:

16. There has been a failure to follow due process which may have resulted in an adverse impact on research participants, the researcher or the University.

17. Examples:

- a. Research conducted beyond the scope of the ethics approval (where a major amendment would have been required (protocol creep), where the risk to participants, the researcher or the University is minimal.
- b. Research conducted before full ethics approval has been granted (the application has been subject to an initial review and an initial but not a final outcome has been received), where the risk to participants, the researcher or the University is minimal.

- c. Research conducted without ethics approval is place, but the risk to participants, the researcher or the University is minimal.

Minor Breach:

18. There has been a minor failure to follow due process which is unlikely to have resulted in an adverse effect on research participants, the researcher or the University.

19. Examples:

- a. Research extended beyond end date without extension/ amendment request where the research itself is not otherwise altered.
- b. Participant recruitment commenced prior to confirmation of ethical approval, but no data collected.

Student process

20. Where QM REC decides that a breach of research ethics has occurred, the matter will be referred to the Appeals, Complaints & Conduct Office to determine the appropriate outcome or penalty in line with paragraph 87 of the Academic Integrity and Misconduct Policy. The decision of QMERC regarding any research ethics breach is final. Subsequent consideration under the Academic Integrity & Misconduct Policy will be concerned only with the appropriate outcome or penalty (if any).

21. Staff Procedure for escalating breaches of research ethics to the Research Integrity Committee

22. The Research Integrity Committee recognises the autonomy and discretion of QM REC to deal with breaches of research ethics that its officers become aware of. Major and critical breaches of ethics will be referred to the Research Integrity and Assurance Officer for assessment, with a view to further investigation.

Subsequent consideration under Policy 2a: Queen Mary policy on research integrity will be concerned only with whether there is sufficient basis for a research misconduct investigation with the appropriate outcome or penalty

Staff Appeals

23. Subject to the nature of the case, the QMREC Chair or Deputy Chair may be willing to consider an appeal from the researcher to use the research data. This appeal may only be presented with the support of the researcher's Head of School or Faculty, or delegated senior member of staff.
24. The Chair and/or Deputy Chair will then write formally to the researcher (and their supervisor where appropriate) and indicate if they are willing to accept an appeal and will write formally to the Head of School and/or Faculty informing them of the case.
25. The Chair and/or Deputy Chair's decision to consider and/or accept an appeal will be based on the reason why the research was conducted without ethics approval and the extent to which research participants, the researcher and the University may have been put at risk, amongst other factors specific to each case.
26. An appeal will be considered for minor or major breaches, the outcome of which is at the QM REC Chair's discretion.
27. In cases where an appeal is considered, the researcher will be formally notified of the outcome of this appeal and the Head of School/Faculty/Department will be informed as appropriate.

28. If an appeal is accepted, it is the responsibility of the Faculty/Department to ensure that all stipulations are adhered to i.e. secure destruction of data, , and to implement local disciplinary procedures, as appropriate.
29. The Research Ethics Office will maintain a record of all cases and if a researcher or supervisor is involved in any further cases, their previous case will be taken into consideration as part of the review of the current case.
30. The QM REC Chair and Deputy Chair have the authority to refer the case directly to the relevant Research Misconduct Policy & Procedure within the University via the Research Integrity and Assurance Officer, or to stipulate that points (ii) and (iii) must be enforced and refer any decision for further disciplinary action to the Head of School or Faculty.