

UREC Terms of Reference

Constitution

There are four full University Research Ethics Committees (URECs). All are equally able to undertake an ethical review of any relevant research project being conducted within the University. They report, via the Research Ethics Oversight Committee, to the Research Compliance Committee. In addition, a Proportionate University Research Ethics Committee operates digitally for the review of low-risk projects adhering to a set of defined criteria (see Appendix 4).

Objectives of the Committees

The objectives of the Committees are to maintain ethical standards of practice in research, to protect participants of research and researchers from harm, to preserve the participants' rights and to provide reassurance to the public and to outside bodies that this is being done. It is also the aim of the Committees to facilitate, not hinder, valuable research, and to protect researchers from unjustified criticism.

In pursuit of these objectives, the Committees draw on a number of internationally and nationally recognised guidelines. These include:

UK Research Integrity Office *A Framework of Policies and Procedures for University Research Ethics Committees* <http://ukrio.org/wp-content/uploads/J-Oates-A-framework-for-research-ethics-committees.pdf>

The ESRC Framework for Research ethics <https://www.ukri.org/councils/esrc/guidance-for-applicants/research-ethics-guidance/framework-for-research-ethics/#contents-list>

Department of Health, *Governance arrangements for NHS Research Ethics Committees (GAfREC)* (2011) <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/governance-arrangement-research-ethics-committees/>

World Medical Association, *Declaration of Helsinki* (revised Fortaleza, Brazil, October 2013) <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

US Government, *The Common Rule and DHHS Regulations* <http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html>

Membership

Each full UREC committee should have at least 16 members drawn from divisions/schools across the University, including PS colleagues, and, where possible, at least one member with no contractual relationship with the University. PGR students may also serve on the UREC, though numbers may be limited to 2 per committee.

In the first instance, faculties will be invited to nominate members roughly in proportion to the number of applications submitted by each division/school, with the proviso that each /school should have at least one member.

Should this not result in the required number of nominations the Research Governance, Ethics and Integrity (RGEI) team will advertise any vacancies through a variety of University channels such as faculty specific newsletters, bulletins, announcements and early career researcher email distribution lists.

If sufficient membership numbers cannot be maintained, the RGEI team may need to liaise with senior colleagues regarding the potential impact that insufficient membership will have on service delivery

Members also participate in the Proportionate UREC in which low risk research is reviewed digitally via the ERM system without the need for a formal meeting. The proportionate committee operates a monthly rota system with each UREC member being expected to participate in this rota at least twice during the calendar year, during which time they are not required to attend the normally scheduled full UREC meeting. The rota consists of up to 8 members with 5 acting as reviewers and 3 as Chair. All comments are submitted electronically with each application being reviewed by 1 reviewer and 1 Chair.

The expected term of service for UREC membership is 2 years in the first instance, which should be supported by their line manager, or supervisor in the case of PGR students. When members resign from service, they are required to provide at least 3 months' notice in writing to enable the RGEIT to secure a replacement from their division/school.

Attendance: Full UREC Committees

Face to face discussion is an important element in reaching an ethical opinion and members are expected to attend all scheduled full UREC meetings. The only exception to this being when they are serving on the Proportionate UREC and in this case the minutes will note that their absence is due to their participation on the proportionate rota.

When, however, extenuating circumstances prevent attendance (i.e. sickness, annual leave, conferences, etc) members are still expected to provide meaningful and detailed comments in advance of the meeting, where possible. For a maximum of 2 occasions per academic year, these instances of extenuating circumstances will be recorded as 'apologies with comments'

on the minutes and members are expected to notify their Secretary of their absence in advance of the meeting. Further occasions of absence will be recorded as 'apologies' providing the member notifies their Committee Secretary in advance of the meeting. Occasions of absence in which advanced notification is not provided to the Committee Secretary will be recorded as 'absent'. Please note that scheduled regular teaching clashes do not constitute an extenuating circumstance and members are expected to make alternative arrangements should this occur (i.e. take a leave of absence, change Committees or stand down from UREC service).

If members are continually absent their UREC Chair will write to them in the first instance to seek clarification on the cause of the absences and discuss if alternative arrangements are needed. If after this discussion the absences continue, the RGEI team will write to the relevant Faculty representative to seek a replacement member. Attendance is also reported annually to the Faculty Deans, Research Directors and Directors of School Operations.

Attendance: Proportionate UREC

For the Proportionate UREC, members are expected to perform a detailed review and submit meaningful comments within the specified period.

Detailed and meaningful comments

Detailed and meaningful comments are defined as those which point out specific issues to be corrected in the application and supporting documentation or specific points for clarification via the digital review process or during the Committee discussions. They must contribute new and relevant information over and above that provided by other members. This does not include comments which are duplicated from other members or limited to statements such as 'I agree with the above'. The decision regarding whether the comments made by a specific member fit with this definition is at the discretion of the Chair

Any issues regarding lack of meaningful contributions by members will be raised with the RGEI team, either by the relevant full UREC Chair or by the proportionate rota Chair. Feedback received from the proportionate rota Chairs will be shared by the RGEI team with the member's full UREC Chair. In all instances, the full UREC Chair will contact the member to discuss how best to support their continued involvement with the UREC and what, if any, additional training may be required. Where contributions continue to fall below expectations after additional support is provided, members may be asked to stand down from the UREC.

Confidentiality

All discussions that take place during a full UREC meeting (including before and after the applicant(s) attend) or as part of a proportionate UREC review are confidential and details of which are not to be disclosed outside of the Committee meeting. Any member who is found to break the confidentiality of UREC discussions may be asked to resign with immediate effect

by the Chair of the Research Oversight Committee, and the RGEI team will write to the relevant Faculty representative in order to seek a replacement member.

Chairs, Deputy Chairs and Secretaries

Each committee shall identify a Chair who shall be appointed for an initial period of three years. Where a vacancy arises, expressions of interest will be sought from appropriately experienced members and, where necessary, interviews may be held before the appointment is finalised. Before taking post, the Chair will provide written confirmation from their Head of School/Division that they support them in this role for the defined period. Any renewal of this role would be subject to approval from the Head of School/Division.

Each committee shall also identify arrangements for a member to deputise for the Chair, by electing at least two permanent Deputy Chairs, or a Deputy Chair rota of those willing to act as Chair. Members may be invited, at the discretion of the Chair, to become a Deputy Chair after they have completed one years' service. In addition to acting as Chair for full UREC meetings, Deputies will also be expected to act as a Chair for Proportionate Review.

In rare circumstances and where no Chair or Deputy is available to Chair the meeting, the Research Ethics Manager may act as an emergency Chair to ensure applicants are not unduly delayed.

Each committee shall have a Secretary who services the committee meetings and assists in all correspondence following the meetings. Secretaries will be members of the RGEI team, with the team also responsible for ensuring deputy cover is available.

The role of the secretary during a UREC meeting is to take accurate minutes, participate in panel discussions, contribute expert advice where relevant, and in the event a vote is required to reach a consensus, to participate in this process alongside their fellow UREC members. In this capacity, the secretary is an active and equal part of the decision-making process, ensuring that both their expertise and their record of the meeting support the committee's outcomes.

Quorum

A quorum shall be six members, including the Chair or their nominated deputy and the Secretary.

Should a quorum not be reached the meeting will continue but the Secretary will send members who did not attend a summary of the outcomes and ask for comments. Members are expected to review this summary and provide their comments to the Secretary within 3 working days. The Chair will then be asked to act on behalf of the committee and confirm the final outcome in the ERM system.

Frequency of meetings

Meetings of full UREC shall be held approximately every four-to-six weeks throughout the academic year from September to July. The Proportionate UREC operates digitally throughout the entire year (including August but excluding any bank holidays or University closure dates).

Meetings of the full UREC are subject to cancellation should there be a substantial lack of ethics applications submitted for review, or where unforeseen circumstances prevent a meeting taking place.

Scope and Duties

- a) To receive applications for any proposed research involving human participants, their tissues or data to be undertaken by University of Manchester members of staff or students where the research would raise ethical concerns and there is no appropriate local process for approval.
- b) To consider such research on behalf of the University, and to approve it as proposed, or to approve it under certain defined conditions or specific requirements, or to refuse approval (for decision options see 'e' below).
- c) Where the research has been reviewed and approved by another research ethics committee (REC) who are recognised by this University, further review by the University Research Ethics Committee (UREC) will not normally be required. Recognition in this context applies to all UK NHS RECs, the Military of Defence REC (MODREC) and other UK RECs at higher education institutions, providing the project is led by that institution. The recognition of any other UK based REC would be at the discretion of the Research Ethics Oversight Committee.
- d) The Committee, after reviewing each application, has the following options available:
 - A favourable ethical opinion
 - A provisional favourable ethical opinion, subject to specified revisions and/or clarifications to be approved by the Chair outside of a Committee meeting. The Chair can in exceptional circumstances circulate a revised application to the lead reviewers or whole committee for comment.
 - An unfavourable ethical opinion with or without recommendations for re-submission (a decision which is rarely given)
 - In rare circumstances, it may not be possible for the Committee to form an ethical opinion due to lack of information or other unforeseen circumstances. In those instances, applicants may be invited to return to the next meeting of the respective UREC to discuss their revised proposal.

Operational Procedures for the full UREC Committees

- a) Committees will normally receive no more than 6 applications to review at any one meeting.

- b) Applications will normally be provided to Committee Members two weeks before the meeting via the on-line Ethical Review Manager (ERM) system. However, in exceptional circumstances when applications may need to be distributed later than this, the RGEI team will ensure members receive all applications at least 1 week and 2 days in advance of the meeting.
- c) Applications will be considered at convened meetings of the Committee with a final decision being reached for each application as outlined in 'Scope and Duties, point e' and clearly explained to the applicant by the Chair during the meeting.
- d) Following the meeting the Chair (or their Deputy) will grant final approval via the ERM system to studies conditionally approved at convened meetings if they are satisfied the outlined revisions/clarifications have been made. Alternatively if revisions have not been made to the satisfaction of the Chair (or their Deputy) the application will be returned to the applicant in the ERM system for further revisions to be made. In the event an unfavourable decision was reached during the meeting, the Chair will confirm this decision in the ERM system to enable the Secretary to generate the appropriate letter.
- e) Meetings should last no more than three hours and every effort should be made to keep to time as to minimise any possible delays to the applicants.
- f) Members are expected to have read all the applications prior to the meeting and submitted detailed and meaningful comments within ERM. A Committee will use a system of lead reviewers whereby members will be asked to concentrate in detail on one or two specific applications, but members are still expected to read through all applications and add comments as appropriate.
- g) Each member should ensure their full name is visible on screen where meetings are conducted over Zoom/Teams. For meetings conducted in person, members should have their name plate clearly visible for any attending applicant(s) (these should be provided by the Committee Secretary).
- h) Before an applicant(s) is/are invited into the meeting room the Chair should ask committee members to discuss any ethical issues that should be raised or any other clarifications required. An agreement should be reached on the main issues to be discussed versus those that will be communicated in the feedback letter.
- i) The committee discussions are confidential. The committees include members at different stages of their academic career as well as lay members, and members have different levels of experience on research ethics committees. Members should take this into account when discussing disagreements within the committee.
- j) The applicant(s) should be admitted to the meeting by the Secretary and will be greeted by the Chair. Where meetings are held in person, the applicant(s) will be asked to sign an attendance register to confirm their attendance for the minutes. The Committee will then discuss the main ethical issues or points of clarification with the applicant(s). Members must be polite and courteous at all times and should expect the applicant(s) to also be polite and courteous at all times.

- k) Major ethical issues or areas requiring clarification should be discussed with the applicant(s) during the meeting. The Chair should inform the applicant(s) additional minor revisions will be outlined in the feedback letter generated in ERM and the meeting time will be used to discuss the most important issues or clarifications.
- l) Where further deliberations are required, applicants may be asked to return to the waiting room following the initial discussions with the Committee.
- m) After the meeting the Chair should screen the comments in the ERM system, editing as appropriate and deciding which comments should be included in the feedback letter to the applicant(s). In the event an unfavourable opinion is granted, the Chair will review the discussion points for inclusion in the feedback letter. The Secretary should then review the screened comments, making any final adjustments as necessary, before sending the feedback letters to the applicant(s) within the agreed turnaround times.

Operational Procedures for the Proportionate UREC Committee

- a) The Committee should receive no more than 36 applications to review throughout the month. In the event only 2 Chairs can serve on the rota in a given month this limit may be reduced to 24.
- b) Each application will be reviewed by 1 of the reviewers on the rota as well as 1 of the Chairs.
- c) Each application must be reviewed within 16 working days of being assigned to the Committee to enable the Secretary to communicate the decision (and any required revisions) to the applicant(s) via the ERM system. Therefore, reviewers must read and submit their detailed and meaningful comments within 8 working days of being assigned to the application.
- d) The Chair will then have 8 further working days to review the comments made by the reviewer, screen as appropriate and make the final decision as outlined in section 'Scope and Duties, point 'e' above.

Conflict of Interest

When a UREC member (including the Secretary) perceives a conflict of interest – for example, when they have a direct involvement in the research project being reviewed or has had personal dealings with the individual and the application being reviewed by the Committee – they shall declare this to the Chair. In these circumstances, one of the following decisions should be taken in consultation with the Chair (or their Deputy):

Full UREC

- a. The member confirms they are able to remain impartial and participates in all discussions as normal.

- b. The member remains in the meeting while the applicant is present and is present for the Committee discussion but abstains from participating
- c. The member remains in the meeting during the applicant's attendance but leaves the meeting when the Committee is discussing the application
- d. The member leaves the meeting both while the applicant is present and while the Committee is discussing the application

Proportionate UREC

- a. The member abstains from reviewing the application

Being a member of the same school or division for the application does not by itself constitute a conflict of interest.

If the Chair of a meeting perceives a conflict of interest, they shall invite a Deputy to chair for that item and then act in the same way as above. The Deputy will also handle any associated follow up actions.