



CENTRAL UNIVERSITY RESEARCH ETHICS COMMITTEE (CUREC)

Standing Orders of the Oxford Tropical Research Ethics Committee (OxTREC)—a subcommittee of CUREC

The Standing Orders of the Oxford Tropical Research Ethics Committee (OxTREC) are as follows:

- 1) The responsibilities and membership of OxTREC are set out in Council Regulations 15 of 2002.
- 2) The members recommended by the Chair of OxTREC for appointment under Regulation 13.8 (5)-(12) shall normally represent the following areas of activity:
 - (i) one physician
 - (ii) one paediatrician
 - (iii) one laboratory-based research worker
 - (iv) one statistician
 - (v) one epidemiologist
 - (vi) one nurse/social scientist
 - (vii) one primary care practitioner
 - (viii) one ethicist
 - (ix) two external (lay) members.
- 3) Under the Regulations, OxTREC has the right to co-opt up to four members when deemed necessary to enhance the Committee's knowledge base and to ensure thorough ethical review of research studies.
- 4) Ethical approval must be secured before any research [which falls under the University's requirements for ethical review] may proceed. In the case of research requiring review by OxTREC, this approval is secured by completion of an OxTREC application form (either full or minimal risk) and its scrutiny and approval by OxTREC or, exceptionally, CUREC.
- 5) OxTREC accepts jurisdiction over University medical and health-related research involving human participants and personal data which takes place outside the UK and the EU, or where the research is funded by the US National Institutes of Health (NIH) or another US federal funding agency, and where previously collected samples will be shipped, processed and adopted into existing Human Tissue Repositories within the university.
- 6) OxTREC review does not replace the need for ethical review within the country where the research will take place: final approval by OxTREC is dependent on approval having been obtained from the relevant local ethics committee(s).
- 7) OxTREC meetings take place once every two months. In exceptional circumstances, expedited review outside the normal committee cycle may be possible at the discretion of the OxTREC Chair.
- 8) The dates of OxTREC meetings shall be published a year ahead to enable researchers to submit applications within the timescales specified.
- 9) The quorum is five members of the committee, including the Chair or Vice-Chair and one external (lay) member.
- 10) OxTREC shall use the documentation and procedures determined by CUREC, so that applications can be reviewed effectively. Low risk applications (those requiring an OxTREC minimal risk application form) will be reviewed on a rolling basis by the OxTREC Manager or by a suitably qualified and delegated member of the Research Governance Ethics and Assurance (RGEA) team, and, in exceptional circumstances, by the Chair (or his/her nominee). Higher risk applications (those requiring the OxTREC full committee application form) will be reviewed at the Committee's bi-monthly meetings.

- 11) Changes to any of the application forms or to the procedures for review described in paragraphs 7--10 shall be submitted to CUREC and only adopted by OxTREC following approval by CUREC.
- 12) Approval of an OxTREC full committee application must be secured by the agreement of a minimum of five OxTREC members, including at least one external (lay) member. A summary of the committee's comments will be recorded in the minutes of the OxTREC meeting, which will be reviewed and approved by the Chair and Vice-Chair. Approval of the application will be contingent upon receipt of a satisfactory response to the comments from the applicant. Final approval will be given by the Chair, for transmission by the OxTREC Officer to the applicant.
- 13) At the discretion of the Chair, in the event of a meeting not being quorate, the opinion of absent members shall be sought by email and included, as appropriate, in the discussion (if known in advance) and/or in the minutes of the meeting.
- 14) If any member has a personal interest in an application which is to be discussed, s/he must recuse themselves for the duration of that discussion.
- 15) The Chair may invite researchers to attend the meeting at which their proposals are considered where this would expedite scrutiny.
- 16) The Committee may invite persons outside the committee to attend and contribute to discussion where they may provide special expertise or relevant views of external bodies.
- 17) OxTREC shall reach one of the following decisions about each study:
 - Approve study
 - Approve study subject to minor amendments/clarifications
 - Invite resubmission following major amendment/revision (as outlined by the committee)
 - Defer decision (in exceptional circumstances, where the committee needs further advice)
 - Refuse approval
 - Decline jurisdiction - referring to an external body (such as a committee associated with the Health Research Authority of the NHS) for approval
 - Refer to CUREC (in exceptional circumstances only)
- 18) The applicant will be informed of the decision and the reasons for it as soon as possible. The normal time frame is 30 days for minimal risk applications, and 14 days following the next committee meeting for full committee applications.
- 19) For minimal risk applications: after an initial review by the OxTREC Manager or delegate, further written information or clarification may be requested from the applicant. During this period, the time frame is suspended, to be restarted when a response satisfactory to OxTREC is received. The OxTREC Committee then ratifies the approved Minimal Risk Studies in the next Full Committee Meeting and any queries can be raised at that time
- 20) Amendments to approved studies should be submitted to OxTREC via email to include a letter explaining the reasons for amendment together with the previously approved documentation with all changes tracked. Amendments shall be considered by the OxTREC Manager with email referral to the Chair where necessary. An answer should be given to the applicant within 15 days wherever possible.
- 21) Where the amendment is so substantial that it needs to be treated by OxTREC as a new application, the time frames set out in paragraph (18) will apply.
- 22) Changes to an approved research study may be made by the researcher without prior approval from OxTREC where those changes are necessary to eliminate immediate hazards to research participants. Changes made to eliminate immediate hazards must be notified to OxTREC within 25 days by submission via email of an explanatory cover letter together with the previously approved documentation with changes tracked.
- 23) For all approved studies: OxTREC requires researchers to submit (a) an annual report on the anniversary of the date of approval using the annual report form available on the OxTREC website; (b) an end of study report within 12 months of completion of the study using the end of study report form available on the OxTREC website, (c) all monitoring related reports such as protocol deviations/violations, adverse events, breaches and incidents.
- 24) OxTREC shall be notified within seven days of the adverse event of any unexpected serious adverse consequences to participants in research projects they approved, or to the researchers themselves.

- 25) CUREC may audit a sample of applications each year.
- 26) OxtREC shall retain records for three years after receiving the end of study report for a research study.
- 27) At the end of each academic year, OxtREC shall report to CUREC on:
- the names, affiliations and occupations of committee members and of deputies (if used);
 - the number and dates of meetings held;
 - the number of applications considered, and the decisions reached on each;
 - statistics of the time taken between acceptance of application to final decision;
 - the training undertaken by its members;
 - the results of any audit of applications;
 - the results of any review of progress reports.