



Standing Orders of the Oxford Tropical Research Ethics Committee (OxTREC)

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

- 1) Ethical approval must be secured before any research involving human participants and/or personal data, falling under the University's requirements for ethical review, may proceed. This is secured by review and approval of the research by OxTREC, the Medical Sciences Interdivisional Research Ethics Committee (MS IDREC), the Social Sciences and Humanities Interdivisional Research Ethics Committee (SSH IDREC) or, exceptionally, CUREC.
- 2) 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.
- 3) 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).
- 4) OxTREC meetings take place once every two months. These meetings will normally be in person, but may be held by video conference if circumstances make this appropriate. In exceptional circumstances, expedited review outside the normal committee cycle may be possible at the discretion of the OxTREC Chair.
- 5) The dates of OxTREC meetings shall be published a year ahead to enable researchers to submit applications within the timescales specified.
- 6) The quorum is five members of the Committee, including the Chair or Vice-Chair and one external (lay) member.
- 7) 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.
- 8) If any member has a personal interest in an application which is to be discussed, s/he must leave the room for the duration of that discussion.
- 9) The Chair may invite researchers to attend the meeting at which their proposals are considered where this would expedite scrutiny.
- 10) 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
- 11) OxTREC shall use the documentation and procedures determined by CUREC, so that applications can be reviewed effectively, either by the Research Ethics Manager for OxTREC (lower risk applications requiring only a minimal risk application form) or by the full Committee (higher risk applications requiring a full committee application form).

- 12) Changes to any of the application forms (with the exception of minor administrative changes) or to the procedures for review described herein shall be submitted to CUREC and only adopted by OxTREC following approval by CUREC.
- 13) Applications for lower risk research (i.e. those using the minimal risk application form, known as 'minimal risk applications') are reviewed on a rolling basis by the Research Ethics Manager for OxTREC (with email referral to the Chair/Vice-Chair if necessary). Further written information or clarification may be requested from the applicant during the course of the review. During this period, the time frame set out in paragraph (16) below is suspended, to be restarted when a response is received from the applicant. Approval of the application will be contingent upon receipt of a satisfactory response to the comments from the applicant.
- 14) Applications for higher risk research (i.e. those requiring a full committee application form, known as 'full committee applications') are reviewed by the full Committee at its bi-monthly meetings. 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, Vice-Chair and Committee statistician. 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 Secretariat to the applicant.
- 15) 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)
- 16) 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. The applicant will be informed if this timetable cannot be met and given a new deadline for approval.
- 17) 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 Research Ethics Manager for OxTREC (with email referral to the Chair/Vice-Chair where necessary). A response should be given to the applicant within 15 days wherever possible.
- 18) 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 (16) will apply. The applicant will be informed if this timetable cannot be met and given a new deadline for approval. 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.
- 19) 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; and (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.

- 20) OxtREC may audit a sample of applications each year.
- 21) OxtREC shall retain records for seven years after receiving the end of study report for a research study.
- 22) 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, amendments and reports considered;
 - statistics of the time taken between acceptance of application to final decision;
 - the results of any audit of applications;
 - the results of any review of progress reports.