Standing Orders of the Medical Sciences Interdivisional Research Ethics Committee (MS IDREC)

The Standing Orders of the Medical Sciences IDREC (MS IDREC) are as follows:

1) Ethical approval must be secured before any research falling under the University’s requirements for ethical review may proceed. This approval is secured by the completion of a CUREC checklist or, where appropriate, a full CUREC application form and its scrutiny and approval by MS IDREC, the Oxford Tropical Research Ethics Committee (OxTREC), the Social Sciences and Humanities Interdivisional Research Ethics Committee (SSH IDREC) or, exceptionally, CUREC.

2) The MS IDREC will accept jurisdiction over projects that use research methodology relevant to subject areas which fall in departments within the Medical Sciences and Mathematical, Physical and Life Sciences. Exceptionally, MS IDREC may consider projects from Social Sciences and Humanities departments/faculties on the grounds of the subject or methodology of the research, rather than by the department/faculty in which the research will be carried out, or to which the principal researcher is attached.

3) One regular meeting of MS IDREC will take place each term. Exceptionally, meetings may be called at other times at the Chair’s discretion if required for discussion of urgent matters.

4) MS IDREC shall use the documentation and procedures determined by CUREC, so that applications can be effectively reviewed by either the IDREC Secretariat (applications using only the CUREC 1 checklist), MS IDREC by email circulation (applications requiring the CUREC 2 or CUREC 3 form) or, where deemed necessary, at meetings of the Committee (certain higher-risk applications requiring the CUREC 3 form).

5) 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 MS IDREC following approval by CUREC.

6) If a project involves NHS staff, facilities, premises or data, or the administration of any licensed drug or other (non-drug) substance to healthy volunteers, then the project proposal will be referred to the Clinical Trials and Research Governance (CTRG) team prior to ethical review by the MS IDREC.

7) Checklists for ‘lower risk’ projects (i.e. using the CUREC 1 checklist) may be reviewed by the IDREC Secretariat. If the IDREC Secretariat finds reason for uncertainty about whether a CUREC 1 application should be approved, they will consult with the Chair who, if necessary, will consult Committee members. Similarly, a CUREC 2 or CUREC 3 application may be brought to a full Committee meeting at the discretion of the Chair if concerns are raised during the email review, or if it requires policy decisions of wider application than the individual proposal.
8) Approval of a CUREC 2 research proposal must be secured by the agreement of a minimum of five MS IDREC members, including at least one external member. The Chair will provide a summary of the comments and give final approval, for transmission by the IDREC Secretariat to the applicant.

9) Approval of a CUREC 3 research proposal must be secured by the agreement of a minimum of eight MS IDREC members, including one external member. The full MS IDREC membership should comprise no fewer than two medically qualified members with current experience in the prescribing of licensed drugs. The medically qualified MS IDREC members will review proposals and, if appropriate, expert medical and/or pharmacy opinion will be sought, prior to the meeting, on their recommendation. The reasons for seeking expert opinion, or not, will be documented. All CUREC 3 applications may be considered, by the full Committee, via email review. If concerns are raised during the review process, then these must be discussed at a meeting of the Committee, which may be conducted via teleconference if there is a wait of more than 2 months until the next scheduled meeting. The Chair will provide a summary of the comments and give final approval for transmission by the IDREC Secretariat to the applicant.

10) Unless otherwise specified, the quorum is five of the members of the Committee, including one external, to include the Chair. This quorum applies to decisions made at meetings and by email correspondence.

11) 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) or in his/her final comments and approval.

12) The Chair may invite researchers to attend any meeting at which their proposals are referred for consideration where this would expedite scrutiny.

13) 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.

14) MS IDREC shall retain records for seven years after making a decision on research projects.

15) MS IDREC shall reach one of the following decisions about each project.
   - Approve project
   - Approve project once minor amendments have been made
   - Defer decision (in exceptional circumstances, where the Committee needs further advice)
   - Refuse approval
   - Decline jurisdiction (referring to the SSH IDREC, OxTREC or an external body (such as an NHS REC)) 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 CUREC 1, and 60 days for CUREC 2 and CUREC 3 applications.

17) After an initial review by the IDREC Secretariat or Committee, 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 the MS IDREC is received. A final decision should then be made and communicated to the applicant within the maximum total of 60 days (in the case of CUREC 2 and CUREC 3 applications) wherever possible. The applicant will be informed when this timetable cannot be met and given a new deadline for approval.

18) All amendments to approved CUREC 1 projects, and minor amendments to CUREC 2 projects, shall be considered by the IDREC Secretariat. CUREC 2 major amendments and all CUREC 3 amendments will be reviewed by email referral to the Committee (but may be approved by Chair’s action at the discretion of the Chair). An answer should be given to the applicant within 15 days wherever possible.

19) Where the amendment(s) are so substantial that they need to be treated by the MS IDREC as a new application (particularly amendments resulting in a CUREC 2 or CUREC 3 application), or if they are complex amendments to a CUREC 2 or 3 project, the 30-day deadline will apply. The applicant will be informed if this deadline cannot be met.

20) Changes to an approved research project may be made by the researcher without prior approval from the MS IDREC where change
   - is necessary to eliminate immediate hazards to research participants; or
   - involves only logistical or administrative aspects of the research

21) Changes made to eliminate hazards must be notified to the MS IDREC within 25 days by the submission of a copy of the original checklist or application form, if one was submitted, with changes highlighted. All changes, for example the addition of a new researcher, should be notified to the MS IDREC.

22) The Committee has the right to suspend the application or amendment until it is deemed satisfactory for approval.

23) MS IDREC is not responsible for ethical review of research involving Investigative Medicinal Products (IMPs), Investigative Devices, NHS patients, ionising radiation, or people lacking the capacity to consent. Such research will require review by an NHS ethics committee.

24) MS IDREC is not responsible for ethical review of research involving human participants or personal data outside the European Union if the research meets any of the following criteria:
   - The research involves a medical, therapeutic, or pharmaceutical intervention of any kind
   - The participants are recruited by virtue of being under the care of a healthcare professional
   - The research may identify conditions which require the attention of a healthcare professional
   - The research involves an invasive procedure (Type A in the CUREC glossary)
   - The research is funded by the US National Institutes of Health or another US federal funding agency

Applications to review such research will be made to the Oxford Tropical Research Ethics Committee (OxTREC) or, if such research is subject to NHS ethics requirements, to the appropriate NHS Research Ethics Committee (REC).
25) MS IDREC may require reports from researchers on any projects that are considered to pose appreciable or uncertain risk to participants, and may reconsider their approval of the project in the light of any report.

26) MS IDREC also require progress reports from a sample of projects approved each year to enable them to monitor the ethical aspects of research in progress.

27) MS IDREC shall be notified within seven days of the adverse event of any unexpected adverse consequences to participants in research projects they approved.

28) At the end of each calendar year, MS IDREC 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 proposals considered
   - statistics of the time taken between acceptance of application to final decision
   - the results of any review of annual progress/monitoring reports.