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) Ethics approval must be secured before any research involving human participants, human tissue and/or personal data that falls under the University's requirements for ethics review may proceed. Review and approval of the research is undertaken by the 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 applications that use research methodology relevant to subject areas from departments within the Medical Sciences and Mathematical, Physical and Life Sciences. Exceptionally, MS IDREC may consider applications from Social Sciences and Humanities departments/faculties on the grounds of the subject or methodology of the research.

3) One regular meeting of the MS IDREC will take place each term. This should preferably be in-person, but may be conducted via teleconference as deemed necessary. Exceptionally, meetings may be called at other times at the Chair's discretion if required for discussion of urgent matters.

4) The MS IDREC shall use the documentation and procedures agreed by CUREC, so that applications can be effectively reviewed. Ethics review will be conducted by either the IDREC Secretariat (applications categorised as medium risk in the online ethics application system[1]), MS IDREC by email circulation (applications categorised as high risk) or, where deemed necessary, at meetings of the Committee (certain high applications).

5) Changes to the online application form (with the exception of minor administrative changes) or to the procedures for review described herein shall be submitted to CUREC and only adopted by the MS IDREC following approval by CUREC.

6) If research involves NHS staff, facilities, premises or data, then the proposal will be referred to the Sponsorship group within the Research Governance, Ethics and Assurance (RGEA) team prior to ethics review by the MS IDREC.

7) Applications for 'medium risk' research may be reviewed by the MS IDREC Secretariat. If the MS IDREC Secretariat finds reason for uncertainty about whether an application should be approved, they will consult with the Chair who, if necessary, will consult Committee members. Similarly, a high risk 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.

[1] Note that applications submitted to the MS IDREC would never be categorised as low risk (requiring only department review) in the online ethics application system.

8) Approval of a high-risk research proposal that does not involve administration of drugs/substances must be secured by the agreement of a minimum of four MS IDREC members, including at least one external member. The Chair will provide a summary of the comments and give the final decision on approval, for transmission by the MS IDREC Manager to the applicant.

9) Approval of a research proposal where any licensed drug, or other (non-drug) substance is to be administered to healthy volunteers must be secured by the agreement of a minimum of five 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 on their recommendation. The reasons for seeking expert opinion, or not, will be documented. All licensed drug applications will be considered via email review. A minimum of two medically qualified members will be included in the review panel, with one of these assigned as lead reviewer. If a Committee member requests a meeting, or concerns are raised during the review process, then these must be discussed at a meeting of the Committee, which may be conducted via teleconference as appropriate. The Chair will provide a summary of the comments and give the final decision on approval, for transmission by the MS IDREC Manager 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 their 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 training, special expertise or relevant views of external bodies.

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

15) The MS IDREC shall reach one of the following decisions about each application.
    - Approve
    - Approve once recommended 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 timeframe is 30 days for medium risk, and 60 days for high risk applications. This is timed from receipt of a complete and valid application.

17) After an initial review by officers, further written information or clarification may be requested from the applicant. During this period, the timeframe 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. The applicant will be informed when the timings detailed in item 16 cannot be met and given a new deadline for approval. Extra time should be allowed in complex cases and outside of University term.

18) All changes to approved research should be notified to the MS IDREC as an amendment. All amendments to approved medium risk studies shall be considered by the IDREC Secretariat. Amendments to higher risk studies will be reviewed by email referral to the Committee (but may be approved by Chair's action at the discretion of the Chair). A response 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, or if they are complex amendments to high risk research, the 30 day deadline will apply. The applicant will be informed if this deadline cannot be met.

20) Changes to approved research 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 immediate hazards must be notified as a formal amendment to the MS IDREC within 25 days by the submission of a copy of the original application form with changes highlighted.

22) The MS IDREC shall be notified within seven days of the event of any unexpected adverse consequences to participants, or to the researchers themselves, where the event is related to the research.

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

24) The MS IDREC is not responsible for ethics 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.

25) The MS IDREC is not responsible for ethics review of research involving human participants, human tissue and/or personal data outside the UK and 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 (Class 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).

26) The MS IDREC may require reports from researchers on any research that is considered to pose appreciable or uncertain risk to participants, and may reconsider their approval of the research in the light of any report.

27) The MS IDREC require annual progress reports from a sample of studies approved each year to enable them to monitor the ethical aspects of research in progress.

28) At the end of each calendar year, the 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 and amendments considered
    - statistics of the time taken between acceptance of application to final decision;
    - the training provided to researchers by the MS IDREC Manager;
    - the results of any review of annual progress/monitoring reports.