UNIVERSITY OF LEICESTER

Research Governance Office Sponsorship Standard Operating Procedures

Convening a Data Safety Monitoring Committee/Trial Steering Committee

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1.0 Introduction and Scope

This Standard Operating Procedure (SOP) defines the circumstances under which a Data Safety Monitoring Committee (DSMC) and/or Trial Steering Committee (TSC) are required, and describes the process to be adopted when convening a DSMC or TSC for research studies (referred to as 'trials' hereafter) sponsored by the University of Leicester (UoL).

2.0 Which trials require a Data Safety Monitoring Committee and/or Trial Steering Committee?

A DSMC and/or TSC may form part of the oversight and management of a trial. The decision about whether or not a DSMC or TSC is required will depend on the complexity, duration and end-points of the research. The decision will be made in collaboration with the Chief Investigator, and will be considered as part of the Sponsor Review process (S-1002) (and where applicable, the Sponsor Risk Assessment, SOP S-1003). There may also be a requirement from the funding award body as a condition of funding.

UoL as Sponsor would expect that a DSMC and TSC be established for trials involving:

- Clinical Trials of Investigational Medicinal Products (CTIMPs)
- Medical Device Trials
- Subjects with life-threatening illnesses
- Vulnerable populations and/or with significant potential risk of harm, or
- Unknown or uncertain risks

DSMC and TSCs may be appropriate for all types of randomised trials, including those not using Investigational Medicinal Products/Medical Devices (e.g., interventional research (surgical/radiotherapy/clinical practice), and/or large multi-centre research, research with a long duration, complex endpoints, and/or certain populations (i.e., paediatric, those lacking mental capacity).

The European Medicines Agency (EMA) Guidance on Data Monitoring Committees provides an overview of when a DSMC may be required.

Where a discussion about whether a DSMC or TSC is required occurs, the evidence of the discussion must always be recorded (i.e., in the Sponsor review documentation and/or the Sponsor Risk Assessment) and stored in the Trial Master File (TMF). Subsequent plans to establish a DSMC or to put other formal safety monitoring arrangements in place must be described in the Protocol.

3.0 Data Safety Monitoring Committee (DSMC)

Procedures must be in place to ensure that there is no unavoidable increased risk for harm to trial participants and to ensure that the research continues for an adequate period of time and is not stopped too early to answer its scientific questions.

The DSMC is a group of people, independent of the research team, who assess the progress, safety data and, if needed critical efficacy endpoints of a trial by reviewing the accumulating data and advising the Sponsor (directly or indirectly) on the continuing and future management of a trial. A DSMC mainly review safety and efficacy data, but where appropriate may also be asked to review quality and compliance data. DSMCs also go under different names like Data (Safety) Monitoring Board, Data Monitoring Committee or Data Monitoring and Ethics Committee.

The DSMC is usually 'unblinded' and therefore is privy to interim comparisons by arm. They often see data in a format that is not normally widely shared beyond the DSMC, or a statistical analysis team. Therefore, care must be taken to ensure that blinded research staff do not inadvertently see or have access to the unblinded report(s) used by the DSMC.

The Sponsor and the investigators bear the final responsibility for the conduct of the trial. This responsibility cannot be delegated to a DSMC.

3.1 Who sits on a Data Safety Monitoring Committee?

DSMC work is a multidisciplinary task, usually consisting of three (3) or more experts from different scientific areas e.g;

- Qualified clinicians are required to assess the clinical aspects of safety and/or efficacy monitoring.
- Biostatistical expertise are required as often statistical methods will be applied in the monitoring process.,
- Experts in research ethics to oversee the ethical considerations, particularly in relation to participant safety.

For practical reasons the number of members of a DSMC should be limited. It is recommended that at least one member of a committee has served previously on a DSMC. Ideally, all individuals should be independent of the Sponsor, Trial Management Group (TMG)/ TSC and not part of the same institution as any of the applicants or members of the research team.

4.0 Trial Steering Committee (TSC)

The TSC provides independent oversight of the conduct, progress, and scientific integrity of a trial. The TSC reviews trial performance, recruitment, and emerging quality or operational issues, and advises the Sponsor and trial management team on significant decisions such as protocol modifications, changes to trial conduct, or trial continuation. The TSC is established to ensure the trial remains scientifically valid, ethically sound, and compliant with Good Clinical Practice, while maintaining independence from the day to day running of the trial.

The TSC considers recommendations from the DSMC on participant safety and trial continuation within the context of wider trial progress and oversight, supporting balanced and informed decision making in academically sponsored trials.

4.1 Who sits on a Trial Steering Committee?

The TSC must have a majority independent representation, including the Chair and statistician. Lay members or patient representatives are desirable. The Chair must ensure that the TSC members have sufficient expertise between them to support robust oversight of the trial. Observers may be invited to attend meetings.

5.0 Charters

The role and function of the DSMC and TSC should be described in writing before they review any trial data. This should be described in a Charter which covers the membership, roles and remit, permissible recommendations, frequency and organisation of meetings, how decisions are reached, whether they are advisory or executive and who they report to (how and when).

Suggested template charters are provided in Appendix 1 & Appendix 4.

It should be clear within the Charter that only appointed members are entitled to vote and the Chair will have a casting vote.

6.0 Conflicts of Interest

Committee members must ensure that any possible conflicts of interests are declared at the outset (the 'Conflicts of Interests Form' appended to the charters can be used here) and any new conflicts of interests are declared and recorded in the minutes of each committee Meeting.

DSMC meetings to review unblinded data will be "closed" meetings at which the Sponsor and blinded members of the research team will not be present. The DSMC may also hold "open" and/or "executive session" meetings with the Sponsor to discuss conclusions and recommendations.

7.0 Reporting Responsibilities

It is the role of the both the TSC and DSMC to make recommendations to the Sponsor on the continuing and future management of a trial. For example, they may recommend the need to modify the protocol and/or to terminate the trial early.

It is the responsibility of the Sponsor to communicate DSMC recommendations to the regulatory authorities in an appropriate manner. If DSMC recommendations require the implementation of an Urgent Safety Measure (USM) it is important that the USM is implemented immediately and then subsequently reported in accordance with SOP S-1029. Where appropriate, the Sponsor should notify the REC of any recommendations made by the DSMC/TSC that impact participant safety and/or the conduct of the trial and provide summary reports where appropriate. It is not necessary for the REC to see minutes of DSMC/TSC meetings; however, meeting minutes and recommendations letters should be provided to the Sponsor for their records and should be filed in the TMF, as appropriate (e.g., at the end of the trial for closed reports)).

It is important that any outputs from the DSMC and/or TSC are clearly documented to ensure that the data used to make decisions are robust and the decisions

themselves are documented and retained. It is advised that the documentation verifies who prepared and checked any reports and listings - this being particularly important if unblinded reviews are taking place to provide evidence that the research team remained blinded.

8.0 Development Record

The table below summarises the revisions introduced in this version. Full historical change records are available within archived SOP versions.

Date	Version number	Description of changes
April 2026	5.0	• Minor wording and typographical corrections made throughout. Addition of section on Trial Steering Committee, and addition of Appendix 4 TSC Charter template. • Appendix 2 and 3 now obsolete as incorporated into Appendix 1 and 4. • Removal of responsibilities table as responsibilities are laid out within the body of the SOP. • Removal of full historical SOP review record; only the latest approved revision is now displayed, with prior versions retained in the document archive.