Research and Enterprise

Standard Operating Procedure

Research Governance

Title:	**Convening of Trial Steering Committees and Data Monitoring Committees for Clinical Trials**		
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number

1. Purpose

This Standard Operating Procedure (SOP) provides guidance on convening Trial Steering Committees (TSC) and Data Monitoring Committees (DMC) for Clinical Trials that are sponsored by the University.

2. Scope

This SOP applies to all Clinical Trials where the University is acting in the capacity of Sponsor/Lead Co-Sponsor. It applies to all members of University staff; both academic and support staff as defined by Statute 1, including honorary staff and students.

3. Responsibilities

3.1 Sponsor

The Sponsor has overall responsibility for defining the requirement for project TSCs, and DMCs, but will usually delegate this role to the CI.

3.2 Chief Investigator (CI)

The CI has delegated responsibility for setting up and managing TSCs, and DMCs. Where a Clinical Trial Unit (CTU) or Clinical Research Organisation (CRO) is involved, this responsibility may be assigned to that organisation.

4. Procedure

4.1 Trial Steering Committee

4.1.1 Purpose

The role of the TSC is to provide the overall supervision of the trial. The TSC should monitor progress and conduct and advise on scientific credibility. The TSC will consider and act, as appropriate, upon the recommendations of the DMC and ultimately carries the responsibility for deciding whether a trial needs to be stopped on grounds of safety or efficacy.

4.1.2 Membership

The TSC should consist of an independent chair, together with at least two other independent members and usually the CI as a minimum. At least one independent member should be an experienced research physician, with expertise in the relevant therapeutic area or other appropriately experienced individual. The TSC may also involve a lay representative.

4.1.3 Charter

A template for the TSC Charter document can be found on the MRC website. This should be adapted for the specific trial and signed off by all members. It should be reviewed on an annual basis, and any revisions agreed by all members.

4.1.4 Committee Meetings

The TSC should meet at least annually, or at a frequency agreed by the Chair and Chief Investigator. The frequency of meetings should be documented in the Charter. Minutes of the meetings should be held in the Trial Master File/Research File.

4.2 Data Monitoring Committee

4.2.1 Purpose

The role of the DMC is to assess at intervals, the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the Sponsor and TSC whether to continue, modify, or stop a trial.

4.2.2 Membership

The DMC should consist of three independent members (minimum); at least one physician with expertise in the relevant therapeutic area; at least one experienced statistician and at least one other independent member. For some projects the Sponsor may agree that no DMC is required, or a DMC with less than three independent members can be convened, but this should be clarified on a case-by-case basis. In such cases the TSC would be required to take on the role of the DMC. Members of the DMC shall be completely independent of the research project and not be the same individuals as the TSC.

4.2.3 Charter

A template for the DMC Charter document can be found on the MRC website. This should be adapted for the specific trial and signed off by all members. It should be reviewed on an annual basis, and any revisions agreed by all members.

4.2.4 Committee Meetings

The DMC should meet at least annually, or at a frequency agreed by the Chair and Chief Investigator. The frequency of meetings should be documented in the Charter. Minutes of the meetings should be held in the Trial Master File. If a trial is blinded, then minutes from the DMC should be held securely and separately to prevent unblinding.

5. References

Health Research Authority: www.hra.nhs.uk (last accessed May 2022)

UK Policy Framework for Health and Social Care Research (2017): https://www.hra.nhs.uk/documents/1962/Final_Accessibility_uk-policy-framework-health-social-care-research_.pdf (last accessed May 2022)

MRC GUIDELINES FOR MANAGEMENT OF GLOBAL HEALTH TRIALS Involving Clinical or Public Health Interventions (v5.0): https://www.ukri.org/wp-content/uploads/2021/08/20220202_Guidelines-for-Global-Health-Trials-2017-v5-final.pdf (last accessed May 2022)

MRC Regulatory Information, Toolkits and Templates: https://www.mrcctu.ucl.ac.uk/our-research/other-research-policy/regulatory-information-toolkits-templates/ (last accessed May 2022)

MRC Short Guide: Trial Steering Committees (TSCs) https://www.ukri.org/wp-content/uploads/2022/03/MRC-170322-ShortGuideTrialSteeringCommittees.pdf (last accessed September 2022)

NIHR Good practice guidelines on the recruitment and involvement of public members on Trial Steering Committees (TSCs) / Study Steering Committees (SSCs) https://www.nihr.ac.uk/documents/good-practice-guidelines-on-the-recruitment-and-involvement-of-public-members-on-trial-steering-committees-tscs-study-steering-committees-sscs/27348 (last accessed September 2022)

NIHR Research Governance Guidelines Trial Steering Committees and Study Steering Committees https://www.nihr.ac.uk/documents/research-governance-guidelines/12154 (last accessed September 2022)