SOP number	**51.036**	Version	**3.0**
Title	**Trial Steering Committee for Trials involving an Investigative Medicinal Product (CTIMP) Sponsored by NHSGGC or Co-Sponsored by NHSGGC and the University of Glasgow**		

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SOP category	NHS GG&C Sponsor R&I

Staff category

Staff Category	**R**	**A**	**C**	**I**
Research & Innovation Systems & Operations Manager		X		
Sponsor Research Co-ordinators	X			
R&I Innovation Co-ordinator	X			
Project Managers	X			
University of Glasgow Research Governance Manager & Officer			X	
R&I Sponsor Pharmacy			X	
Chief Investigators			X	
Data Managers			X	
R&I Governance			X	

1. Scope

This procedure applies to Sponsor representatives for Clinical Trials of Investigational Medicinal Products (CTIMPs), Clinical Investigations of Medical Devices (CIMDs), and, where appropriate, other high-risk studies (e.g. Surgical, involves a novel device etc.), Sponsored by NHS Greater Glasgow & Clyde (NHSGGC) or Co-Sponsored by NHSGGC and the University of Glasgow (UoG).

Set up and management of a TSC for studies managed by the GO CTU is delegated to the GO CTU and will follow their equivalent SOPs.

2. Purpose

The purpose of this SOP is to describe the process to determine when a Trial Steering Committee (TSC) is required and to detail the requirements of the group, timelines and content of TSC charter. These activities help to ensure Sponsor oversight for this type of trial activity.

The expectation of the Sponsor is that every CTIMP/CIMD shall have a TSC. This study type must also have a named Project Manager, who will help with the administration involved in this, and any other, trial committees.

These studies may also require an Independent Data Monitoring Committee (IDMC) to be established as described in SOP 51.023. The requirement for an IDMC will be identified during the Sponsor Risk Assessment as per SOP 51.004.

3. Procedures

3.1. Determining Whether a TSC Is Required

The expectation of the Sponsor is that every CTIMP/CIMD shall have a TSC. This study type must also have a named Project Manager, who will help with the administration involved in this, and any other, trial committees.

The final decision rests with the Sponsor.

3.2. Setting Up a Trial Steering Committee

This is the responsibility of the Sponsor, with input from the Chief Investigator (CI), and will be set up before, or as close to the date of the first patient recruited as possible. The Study Project Manager (PM) will normally act as the Committee Co-Ordinator.

3.2.1. Identifying Members

A TSC may be made up of personnel directly involved in the trial and individuals who are independent of the trial. The TSC shall consist of an independent chair, together with at least two other independent members and usually the CI and Sponsor Representative as a minimum. At least one independent member must be an experienced research physician, with expertise in the relevant therapeutic area. The TSC must involve a lay representative. The majority of non-independent members will come from the Trial Management Group, however, may include Principal Investigators (PIs) of key clinical sites and other experts as deemed appropriate.

When members have been identified by the CI and agreed with Sponsor they will be approached officially by the Sponsor, with the assistance of the Project Manager, with a request to take part using Forms 51.036A and 51.036B for trials Sponsored by NHSGGC alone, and Co-Sponsored with University of Glasgow, respectively. They will also be sent a draft Charter based on the MRC template (link below, Section 3.3), including a Competing interests statement and the current version of the protocol. Email responses from members must be confirmed to be in place before the first meeting takes place. These must be filed within the TMF.

3.3. TSC Charter

It is expected that the TSC will meet to review the research protocol and associated documentation before enrolment to the research project commences or as soon after as possible. The TSC must also agree the TSC Charter. The Medical Research Council's CTU template for the TSC Charter (https://www.mrcctu.ucl.ac.uk/our-research/other-research-policy/regulatory-information-toolkits-templates/), including a Competing Interests statement, will be used unless otherwise defined by the funder. Once signed by all committee members this will be stored in the Trial Master File (TMF) as per SOP 51.016.

The TSC charter will specify the minimum number of members required for meetings to be considered quorate, along with attendance expectations. The TSC charter will be reviewed as required, and if updates are needed, a revised version will be prepared and re-signed by all committee members.

3.4. TSC Meetings

The role of the TSC is to provide oversight for the trial. It will also provide advice through its independent Chairman to the Trial Management Group (TMG), Funder and Sponsor on all aspects of the trial.

The TSC will convene at least annually, or as otherwise required by relevant trial stakeholders, to review progress and conduct of the active trial and any sub-studies (this detail will be contained within the TSC charter).

They will be provided with any relevant literature, which may impact on the scope and/or validity of the project by the CI, or delegate, in advance. The study data centre will also provide any information agreed with the TSC in the Charter for each meeting. This may include, e.g. protocol deviations affecting endpoints data / safety data). If the TSC recommend that a trial be stopped they will inform the Sponsor immediately (within 24 hours (one working day)). Documentation and minutes of TSC meetings, will be taken by the Project Manager (or delegate) as committee co-ordinator, indicating actions taken by the CI to address recommendations. These will be stored securely within Project Manager's section of the TMF as per SOP 51.016.

Attendance will be taken and the meeting confirmed quorate prior to commencement. If the meeting is not quorate, it may be that this will need to be re-scheduled, however details will be included in the Charter.

3.5. Reports and Recommendations

The committee Chair will provide a completed report to the Sponsor after each meeting indicating whether they consider that the study should continue as is, be amended, or halted. These reports will be held in the Sponsor Systems section of the TMF (see SOP 51.016). Recommendations made by the TSC over the course of a trial will be given full consideration by the Sponsor and research team. The outcome of these considerations may result in modifications being made to the study protocol and associated study documents.

3.6. Role of the TSC in Trial Close-Out (Or Early Termination)

Trial close-out refers to the time period when recruitment and follow-up visits are completed (according to the protocol) and end of study notifications are being submitted. Any closure prior to this is considered an early termination as per SOP 51.019.

The role of the TSC at project close out is to review the research outputs i.e. final report and/or any papers prior to publication. The role of the TSC at early termination is to reach a consensus on any modification required to the research outputs to be generated.

The role of the CI at project close out is to ensure that the TSC are informed when recruitment and follow up have been completed. The role of the CI at early termination is to ensure that the TSC are approached for their opinion and confirmation that early termination is acceptable for the research project.

The contribution of the TSC (and the IDMC if applicable) must be appropriately acknowledged in the final report and/or any papers.

4. Referenced documents

- SOP 51.004 – Risk Assessment
- SOP 51.016 - Preparation and Maintenance of a Trial Master File
- SOP 51.019 - Sponsor – End of Study Procedures
- SOP 51.023 - Sponsor Process for an IDMC
- Form 51.036A - Letter of Invitation to TSC member NHSGGC sole Sponsor
- Form 51.036B - Letter of Invitation to TSC member NHSGGC/UoG Co-Sponsor
- MRC CTU Template TSC Charter and Annexes (https://www.mrcctu.ucl.ac.uk/our-research/other-research-policy/regulatory-information-toolkits-templates/)
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5. Related documents

- MHRA Good Clinical Practice Guide

6. Document history

Version	Date	Description	Retrospective Implementation
1.0	25/06/2020	Scope, purpose and procedures updated. URL link to MRC included. Author, Approver and Released by updated.	No
2.0	25/08/2022	Staff Categories expanded Added reference to CRUK CTU equivalent SOPs Included additional statements re make up of TSC Added information on approaching potential members Added Forms 51.036A and 51.036B Updated link to MRC CTU TSC Charter	No
3.0	22/12/2025	Update to SOP template Changes throughout in line with changes to SOP 51.025 Updated link for MRC TSC Charter Template Addition of information on TSC being quorate	No