

Standard Operating Procedure

51.036

Trial Steering Committee for Trials involving an Investigative Medicinal Compound (CTIMP) Sponsored by NHS GG&C or Co-sponsored by NHS GG&C and the University of Glasgow

Version **2.0**

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1. SOP Category

NHS GG&C Sponsor (R&I)

2. Staff Category

- Chief Investigators
- Sponsor Research Co-ordinators
- University of Glasgow Research Governance Manager & Officer
- NHS GG&C Sponsor Project Management Unit,
- Innovation Project Managers
- GU Project Managers
- R&I Innovation Contracts Manager
- R&I Innovation Coordinator
- R&I Sponsor Pharmacy

3. Scope

This procedure applies to clinical trials of investigational medicinal products (CTIMPS) sponsored by NHS Greater Glasgow & Clyde (NHS GG&C) or co-sponsored by NHS GG&C and the University of Glasgow (UoG) and where appropriate other higher risk studies (e.g. Surgical, involves a novel device etc).

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

4. Purpose

This SOP applies to any Chief Investigators (CI), Sponsor staff, Project Managers and Researchers involved in creating the necessary management and oversight committees for Research projects sponsored by NHS GG&C or co-sponsored by NHS GG&C and the University of Glasgow.

The expectation of the Sponsor is that every CTIMP shall have a Trial Steering Committee (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.

5. Procedures

5.1 Trial Steering Committee set up & composition

It is the responsibility of the Sponsor, with input from the CI, to set up the TSC. A TSC may be made up of personnel directly involved in the trial and/or 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 chief investigator and Sponsor Representative as a minimum. At least one independent member should be an experienced research physician, with expertise in the relevant therapeutic area. The TSC may also ideally involve a lay representative. The majority of non-independent members will come from the Trial Management Group, but may include PI's of key clinical sites and other experts as deemed appropriate.

When members have been identified by the Chief Investigator 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 NHS GG&C alone, and Co-sponsored with University of Glasgow, respectively. They will also be sent a draft Charter based on the MRC template (link below) and the current version of the protocol. The Study Project manager will normally act as the Committee co-ordinator.

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 should also agree the TSC Charter and Terms of Reference. The Medical Research Council's CTU template for the TSC Charter (<https://www.ctu.mrc.ac.uk/our-research/other-research-policy/regulatory-information/toolkits-templates>), including a Competing Interests statement, should be used unless otherwise defined by the funder. The signed Charters should be stored as hard copies in the Trial Master File (TMF).

5.2 Role of the TSC in Trial conduct

The TSC should 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. They should 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 should also provide any information agreed with the TSC in the Charter for each meeting. If the TSC recommend that a trial be stopped they should inform the Sponsor immediately. Documentation and minutes of TSC meetings, indicating actions taken by the CI to address recommendations, shall be held in the TMF.

5.3 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.

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 amendment required to the research outputs now 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 DMC if applicable) should be appropriately acknowledged in the final report and/or any papers.

6. Referenced Documents

- SOP 51.023 - Sponsor Process for an IDMC
- Form 51.036A - Letter of Invitation to TSC member GG&C sole Sponsor
- Form 51.036B - Letter of Invitation to TSC member GG&C/UoG co-sponsor
- MRC CTU Template TSC Charter and Annexes (<https://www.ctu.mrc.ac.uk/our-research/other-research-policy/regulatory-information-toolkits-templates>)

7. Related Document

- MHRA Good Clinical Practice Guide

8. Document History

Version	Date	Description
Draft 1.0	04/01/2019	Process development
1.0	25/06/2020	Scope, purpose and procedures updated. URL link to MRC included. Author, Approver and Released by updated.
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

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