STANDARD OPERATING PROCEDURE 12
GCP Defined Responsibilities

Part 2: Trial/Study Steering Committee

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Revision Chronology:	Effective date:	Reason for change:
Version 3.0	20 October 2023	Biennial review: Change of Title, linking SOP 12 parts 1, 2 and 3 for clarity. Minor amends to text.
Version 2.0	27 May 2021	Biennial review: Change to new format. Minor amends to text
Version 1.5	25 March 2019	Biennial review: Addition of reference to TSC Charter. Minor text amends.
Version 1.4	21 July 2016	Biennial review: Minor text amends for clarification. Change to new format.
Version 1.3	2 June 2014	Biennial review: Addition of TSC *agenda* template document. Minor text changes.
Version 1.2	29 July 2011	Amend TSC/DMC responsibilities and TMG meeting timings.
Biennial review April 2010		No changes.
Version 1.1	8 April 2008	Format change.
Version 1.0	March 2006	

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Part 2: Trial/Study Steering Committee

1. Purpose and Scope

The purpose of this Standard Operating Procedure (SOP) is to describe the responsibilities for members of Trial/Study Steering Committees (T/SSC) and how it operates.

The responsibilities of those involved in Trial/Study Management Groups (T/SMG) and Data Monitoring Committees (DMC) are covered in Parts 1 and 3 of this SOP respectively.

This SOP applies to all University of Warwick staff working on studies requiring independent oversight of activities. It is also applicable to research studies managed by WCTU who have an external sponsor where use of Warwick SOPs has been agreed.

2. Definitions

Oversight Committee	A group responsible for making sure that an activity is done correctly and legally.
Trial Steering Committee	A group which provides overall supervision for a project on behalf of the Project Sponsor and Project Funder to ensure that the project is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care, and the Guidelines for Good Clinical Practice (GCP).

3. Background

Trials/Studies should have a Trial/Study Steering Committee (T/SSC) to provide independence in oversight of the trial. It is part of the trial governance arrangements and provides assurance to the funder and Sponsor.

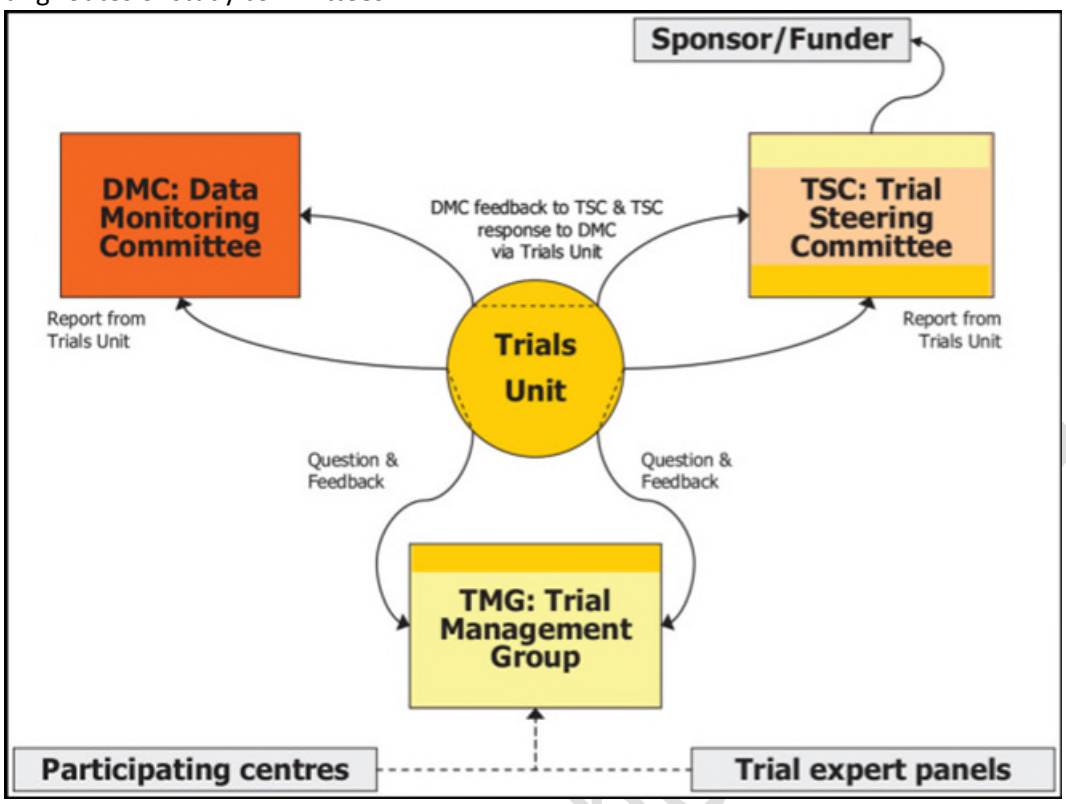
T/SSC's are a key part of a trial/study's overall Monitoring Plan. Membership of the T/SSC includes both independent members and members of the research team.

The funding body or sponsor may specify particular oversight arrangements, but even if they do not, some form of oversight is strongly recommended for all research studies, although the appropriate structures will vary according to the size, complexity and risks associated with the study.

Not all studies require a T/SSC, particularly small trials, or pilot studies. Large-scale randomised controlled trials are usually required to have a T/SSC.

The T/SSC interact with other oversight committees that have different responsibilities – see below:

Reporting routes of study committees:



4. Procedure

4.1 Responsibilities

Chief Investigator (CI) (or their delegate)	• Provide nominees to the funding body for membership of oversight committees. • Arrange oversight committee meetings at appropriate time points in the study. • Ensure members sign the committee Charter document
Trial Manager (TM)	• Assist T/SSC Chair / Chief Investigator in scheduling of oversight meetings. Liaise with committee members to determine availability for meetings. Circulate meeting invitations, as appropriate. • With input from Chief Investigator and Statistician develop/ collate materials to be presented during oversight committee meetings inc. TSC report, agenda and other documents as required. Ensure materials are circulated to committee members in advance of meetings. • Produce minutes and action points from each meeting, as required. • Liaise with committee members following the meeting to agree and confirm review of the meeting minutes. • Ensure that relevant observations/feedback are shared with the TMG and/or funder, as appropriate, with oversight of Chief Investigator.
Funding Body	• Review the nominees and appoint the committee Chairs and members. • Receive minutes from committee meetings.

T/SSC Chair	• Liaising with the Chief Investigator to arrange a meeting to finalise the protocol and to set up a schedule of meetings to align with the project plan • Establishing clear reporting lines to the Funder, Sponsor, etc. • Being familiar with relevant guidance documents and with the role of the DMC if appropriate. • Providing an independent, experienced opinion if conflicts arise between the needs of the research team, the funder, the sponsor, the participating organisations and/or any other agencies • Leading the Steering Committee to provide regular, impartial oversight of the study, especially to identify and pre-empt problems • Ensuring that changes to the protocol are debated and endorsed by the Steering Committee; letters of endorsement should be made available to the study team when requesting approval from the funder and sponsor for matters such as changes to the protocol • Being available to provide independent advice as required, not just when Steering Committee meetings are scheduled • Commenting on any extension requests and, where appropriate, providing a letter to the funder commenting on whether the extension request is supported or otherwise by the independent members of the Committee. • Commenting in detail (when appropriate) regarding the continuation, extension or termination of the study.
T/SSC members	• To provide expert advice that is independent of the investigators and make recommendations, through its Chair, to the study's funder, sponsor, Chief Investigator, host institution, and contractor • To monitor the study's progress, adherence to the protocol, and patient safety, and to consider new information of relevance to the research question • To uphold the rights, safety, and well-being of the participants: these are the most important considerations and should prevail over the interests of the research • To ensure appropriate ethical and other approvals are obtained in line with the project plan • To agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments • To consider recommendations from the Data Monitoring Committee (DMC) • To provide advice to the investigators on all aspects of the study

4.2 When?

Nominations for membership of a T/SSC should be made as early as possible in the set-up phase of a study. Where it is a requirement of the funding body to set up oversight committee(s) e.g., National Institute for Health and Care Research (NIHR), the Chief Investigator (CI) should nominate individuals who will then be formally approached by the funder to invite them to join the relevant committee.

Other funding bodies may have alternative procedures and the CI must understand and abide by their requirements.

T/SSC meetings should be scheduled regularly throughout the lifetime of the trial/study.

Meeting 1 (Before the start of the trial): This should be organised by the Chief Investigator (or coordinating trials unit) to approve the final protocol. Ideally this meeting should take place prior to Ethics Committee review. This may be an open meeting jointly with the DMC.

Regular meetings (During the trial): These should take place at least once per year. More frequent meetings may be requested by the Chair of the TSC or the Chief Investigator and organised by the trial team. The frequency of the meetings is usually determined in relation to the trial risk assessment. More regular meetings are typically required during key stages of the trial such as trial set up. Additional meetings may be held at appropriate timepoints relating to the data collection or in response to critical milestones.

Frequency of the meetings should be agreed between the Chief Investigator and TSC Chair and should be documented in the study protocol. Meetings may be in person or online/remote via MS Teams

4.3 How?

4.3.1 Remit and procedures of a T/SSC

The overarching responsibilities of the TSC are listed in section 4.1

For all trial oversight meetings, it is good practice to use an agenda and produce minutes with clearly defined decision and action points. A template T/SSC agenda document is available (Template T60) to aid in the production of relevant meeting agendas.

Meeting papers should be circulated by the trial team well in advance of the meeting.

An accurate minute of the meeting should be prepared by the Chief Investigator (or their delegate) and agreed by all members, including the sponsor and funder representatives. At the start of each meeting, the minutes of the previous meeting should be accepted and formally approved.

The agenda and minutes of all meetings should be filed in the Trial/Study Master File (T/SMF)

No unblinded information should be presented to the TSC, unless recommended by the independent Data Monitoring Committee (DMC). If the DMC recommends the T/SSC be unblinded to the accumulating comparative data, the independent members should initially review the information to protect the trial team from viewing unblinded data. If the independent members agree, then the non-independent members (or other attendees) can be shown the information.

4.3.2 Constitution of the T/SSC

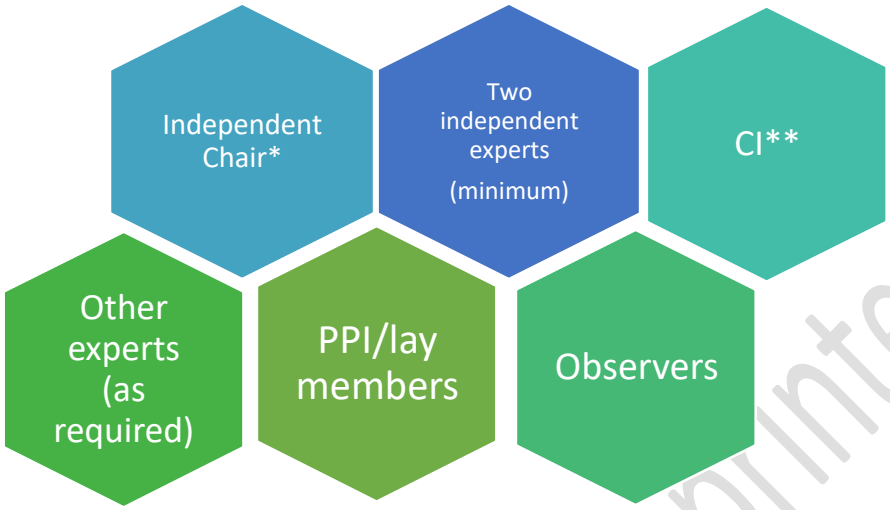
Membership will vary from study to study according to the requirements of the funding body.

Full details of the constitution, composition, Chair's role and quoracy can be found here and good practice guidelines on the recruitment of public members is available here.

Patient & Public Involvement (PPI) representatives should be invited to join an oversight committee to provide input from a lay persons/patient perspective. An Introduction for PPI Contributors

document is available (T45), which explains the remit and procedures of committees and may be useful for new PPI representatives for information.

Membership:



Observers may be invited from the funding organisation/sponsor and Host Institution if permission to attend is granted by the Chair.

** Independence is defined by the NIHR as follows (but be aware that other funders may differ):*

- *Not part of the same institution as any of the applicants or members of the project team.*
- *Not part of the same institution that is acting as a recruitment or investigative centre, including Patient Identification Centres (PIC), identifying and referring patients to a recruitment or investigative centre.*
  (In both cases above 'not part of the same institution' means holding neither a substantive nor honorary contract with said institution).
- *Not related to any of the applicants or project team members.*
- *For the Chair only; not an applicant on a rival proposal.*
- *It is recognised that independence status may change during the duration of the trial.*

*** N.B. If you have co-CIs, it is advisable to have one as a non-independent member of the committee and the other as an observer (if agreed by the Chair) as this may affect the requirements to have at least 75% of independent members. Consider how the committee is set up as there may be issues around quoracy in terms of numbers attending the meeting.*

In the event the Chair is unable to attend, and the meeting cannot be rearranged, then the meeting should go ahead with an 'Acting/Deputy Chair' from the remaining members of the committee, if quoracy is obtained.

A template Charter for the T/SSC (Template T37) is available which specifies the membership of the Committee, the tasks for which they will be responsible, and procedures to ensure confidentiality and

proper communication. A signed copy of the T/SSC Charter should be obtained from all members and filed in the Trial/Study Master File (T/SMF).

At the discretion of the Chair, observers may be allowed to attend by invitation. Observers will be required to sign the Confidentiality Statement for Oversight Committee Observers (Template T61)

4.3.3 T/SSC Reports

The primary Steering Committee reporting line is via the Chair to the relevant funding body's Programme Director; however, communication is likely to be between the Chair and the Programme Research Manager who has day to day responsibility for the study. Reports produced from T/SSC meetings should be produced and filed in the T/SMF and shared with the TMG where appropriate.

List of abbreviations

CI	Chief Investigator
Co-CI	Co-Chief Investigator
DMC	Data Monitoring Committee
GCP	Good Clinical Practice
NIHR	National Institute for Health & Social Care Research
PPI	Patient & Public Involvement
QA	Quality Assurance
R&IS	Research & Impact Services
SOP	Standard Operating Procedure
TM	Trial Manager
T/SMF	Trial/Study Master File
T/SMG	Trial/Study Management Group
T/SSC	Trial/ Study Steering Committee
WCTU	Warwick Clinical Trials Unit

Templates

TemplateT60	T/SSC Agenda
Template T37	T/SSC Charter
Template T61	Confidentiality Statement for Oversight Committee Observers