STUDY/TRIAL STEERING COMMITTEE (SSC/TSC) CHARTER

The Principal Investigator (PI)/Coordinating Principal Investigator (CPI) of a research project ("study/clinical trial") holds the primary responsibility for the scientific and ethical conduct of a study/clinical trial, but the approving HREC, RGO and the Sponsor also play a role in providing oversight. When planning your study/clinical trial, you should consider whether further oversight is needed for your study/trial (e.g. a Steering Committee and/or for clinical trials a Safety Monitoring Committee, Data Safety Monitoring Board, Endpoint Committee). In this document, we briefly review the role of the Steering Committee and provide a template Charter, which can guide the work of the Committee.

OVERVIEW OF THE STUDY/TRIAL STEERING COMMITTEE

A Study/Trial Steering Committee ("Committee") may be established for studies that are large, complex or potentially controversial, or where there is a need to include key stakeholders in oversight of the study/trial.

The Committee provides oversight and ensures that the study/trial is conducted to the required standards. However, as noted above, the primary responsibility for the study/trial and its day-to-day management remains the responsibility of the PI/CPI. The Committee, through the Committee Chairperson, provides advice to the PI/CPI.

The role of the Committee is to:

- focus on progress towards study milestones (e.g. recruitment) to maximise the likelihood of completion within the agreed time period
- review reports on data quality, completeness, losses to follow-up and protocol non-compliance
- review reports on participant safety and data from the Data Safety Monitoring Board (DSMB) in intervention studies where a DSMB has been set up to undertake such monitoring
- consider any new external information relevant to the study

The Committee may also include additional roles to (for example):

- provide mentoring to the principal investigators – particularly if the investigators are relatively inexperienced
- provide advice related to strategic or specific decisions including (but not limited to) funding opportunities
- act as an arbiter if there is disagreement amongst the investigators over strategic or specific decisions
- approve publication and authorship plans suggested by the principal investigators and to settle disputes related to these when raised by any of the study team

The Committee should include:

- a Chairperson (preferably independent of the investigators)
- at least two other independent members (independent members provide assurance of objectivity for the PI, study team and study participants)
- the PI/CPI.

The Committee may also include (where appropriate) representatives of the major funding body/sponsor or other stakeholders (e.g. a consumer representative). Study team members such as statisticians and study/trial coordinators should attend meetings where appropriate. If the study is multi-national, the Committee may consider including an investigator from each region. However, overly large committees should be avoided and the TSC should not simply duplicate the committee of principal investigators.

The Committee should be established prior to the study being submitted for HREC approval. Formalised procedures should be in place directing the formation and membership of the Committee as well as its agreed responsibilities. At its initial meeting, the Committee should review the study protocol and should approve the protocol prior to its submission to HREC. Note that any subsequent amendments to the protocol should also be tabled for the Committee for comment.

The Committee should meet at least annually, with more frequent meetings as needed; the responsibility for calling a meeting lies with the PI/CPI, but meetings may also be called by the Committee. The Committee should keep minutes of all meetings. Post-study/trial, all documents should be archived in the Study/Trial Master File with other essential documents.

This document refers to 'Study' (non-interventional research) and 'Trial' (research involving an intervention assigned by the researcher) – delete whichever term is not appropriate for your research).

How to use this template Charter

Instructions to researchers are in purple italics – instructions should be deleted once that section has been completed.

Suggested wording (optional) is highlighted in green italics.

TEMPLATE: STUDY/TRIAL STEERING COMMITTEE (SSC/TSC) CHARTER

This document refers to 'Study' (non-interventional research) and 'Trial' (research involving an intervention assigned by the researcher) – delete whichever term is not appropriate for your research).

Protocol Title:	
Protocol #:	
Protocol Version & Date this Charter is based on:	
Study Sponsor:	
Sponsor-Investigator (clinical trials only):	

REVISION HISTORY

Version No.	Date	Summary of Changes
1.0		Initial version

AGREEMENT

Name and Title	Role	Signature	Date
	Committee Chair		
	Add remaining members		

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TABLE OF CONTENTS

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1. CORE MEMBERSHIP

The Study/Trial Steering Committee membership will consist of:

Name and Title	Affiliation / Institution	Email
	PI / CPI	
<To be Confirmed>	*Parent Representative*	*<To be Confirmed>*

Additional invited attendees will be:

Name and Title	Affiliation / Institution	Email
<Study/Trial Manager / Coordinator / Administrative Assistant>		

1.1 Chair of the TSC

The Chair of the Committee is <Insert name here>.

2. RESPONSIBILITIES OF THE COMMITTEE

The Committee provides oversight and ensures that the study/trial is conducted to the required standards. The Committee, through the Committee Chairperson, provides advice to the PI/CPI; the primary responsibility for the study/trial and its day-to-day management remains the responsibility of the PI/CPI.

This Committee will have responsibility for monitoring study/trial progress with regards to:

1. Overseeing progress towards study/trial milestones (i.e. recruitment accruals, timelines etc.).
2. Reviewing adherence/compliance to the protocol and adherence/compliance to good clinical research practices.
3. Reviewing reports on participant safety and data (and acting on recommendations from the Data Safety Monitoring Board [DSMB] where this has been established).
4. Considering any new external information relevant to the study.

In addition, the TSC will also be responsible for (select as appropriate):

1. *Providing mentoring to the principal investigators, particularly for investigators who are relatively inexperienced.*

2. *Providing advice related to strategic or specific decisions including (but not limited to) funding opportunities.*
3. *Acting as an arbiter in the case of disagreement amongst the investigators over strategic or specific decisions.*
4. *Advising on funding for the trial/study. (delete here if referenced in point 2 above)*
5. *Developing, amending, and advising the study/trial protocol.*
6. *Advising on discontinuation or extension of recruitment.*
7. *Approving publication and authorship plans suggested by the principal investigators and settling of any associated disputes raised by any of the study team.*
8. *Reviewing manuscripts, manuscript author lists and/or order of authors, and providing final approval of any publication plans.*

3. DATA

At each scheduled meeting, the TSC will be provided with a report for review, containing the following data elements:

- Summary of progress to date, including site activation status, recruitment update, timeline update etc.
- Summary of protocol compliance i.e. protocol deviations, serious breaches etc.
- *Summary and any outcome/s and recommendation/s provided by the DSMB (where applicable)*
- *Summary and any outcome/s and recommendation/s provided by any other study/trial-related committee*
- *Site Monitoring update (where applicable)*
- *Summary of any upcoming manuscripts/abstracts*

4. FREQUENCY AND FORMAT OF MEETINGS

4.1 Meeting Frequency

The TSC will meet *<insert time frame>* via *<insert meeting method – face-to-face, teleconference, videoconference>* during the recruitment phase of the study. During the follow-up phase of the study, meetings will be held *<insert time frame>* via *<insert meeting method>.*

4.2 Ad Hoc Meetings

Additional ad hoc meetings of the TSC may be scheduled if requested by either the PI/CPI or the DSMB (i.e. where established).

4.3 Meeting Attendance and Quorum

The minimum number of members in attendance for the TSC to be quorate for decision-making is 50% of membership, being *<insert number, rounding up to higher number if required>* members. If at any time the number of members is less than a quorum, the Committee may meet only for discussion purposes.

If the report is circulated before the meeting, those TSC members unable to attend the meeting may pass comments to the TSC Chair for consideration during the discussions.

4.4 Meeting Deliberations

The Chair will facilitate and summarise discussions and will encourage decision-making via consensus. Meetings will be minuted and any decisions made electronically will be recorded in the form of meeting minutes and distributed to Committee members within 14 days of the meeting. All meeting agendas, data reports submitted to the Committee for review, meeting minutes generated, and other relevant documentation will be filed in the Study/Trial Master File (SMF/TMF).

The discussions of the Committee are confidential to its members.

5. CHARTER REVIEW

This Charter will be reviewed and updated annually, as required.

6. COMMUNICATIONS

At any time during the study/trial, regulatory authorities, the Human Research Ethics Committee, the DSMB or any other body or individual involved with the conduct of the study/trial may seek the advice of the SSC/TSC about any concern that they may have about the conduct, outcome or continuation of the study/trial. Any such requests should be forwarded in writing to the Committee Chairperson at the email address provided above.