The [Study Title] Trial Steering Committee Charter

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| --- | --- |
| **Study Title:** |  |
| **Chief Investigator:** |  |
| **EudraCT Number:** |  |
| **Sponsor:** | University of Edinburgh & NHS Lothian |

*This Trial Steering Committee (TSC) charter template will be used for studies that are sponsored or co-sponsored by the University of Edinburgh and/or NHS Lothian only.*

*As a template, sections may be adapted to suit the requirements of each study and some sections may not apply to all studies and can therefore be removed.*

Approval Signatures:

The following individuals, by providing their signatures, indicate their understanding of and willingness to comply with the roles and responsibilities assigned to them in this Charter.

1. TSC Chair:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_ \_ / \_ \_ /\_ \_ \_ \_

PRINT NAME SIGNATURE DATE

1. Prepared by (Role):

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_ \_ / \_ \_ /\_ \_ \_ \_

PRINT NAME SIGNATURE DATE

1. Chief Investigator:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_ \_ / \_ \_ /\_ \_ \_ \_

PRINT NAME SIGNATURE DATE

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# Introduction

* Objectives of trial, including interventions being investigated from the protocol
* Outline of scope of charter. Illustrative example;

*The Charter will define the primary responsibilities of the TSC, its membership, and the purpose and timing of its meetings. The Charter will also provide the procedures for ensuring confidentiality and proper communication, decision making, reporting and after trial publications.*

# Roles and Responsibilities

* A broad statement of the aims of the committee.
* Terms of reference
* Specific roles of TSC. Illustrative example;

*The TSC will provide oversight for the trial on behalf of the Sponsor/funder. The specific roles of the TSC include; monitoring recruitment rates and encouraging the TMG to develop strategies to deal with recruitment issues, review regular reports of the trial, review adverse events and serious adverse events blind to treatment allocation and assess the impact and relevance of any accumulating external evidence. It should also provide advice through its independent Chair to the Trial Management Group (TMG) on all aspects of the trial.*

*The TSC will be responsible for promptly reviewing the DMC recommendations, to decide whether to continue or terminate the trial, and to determine whether amendments to the protocol or changes in study conduct are required.*

# Before or early in the trial

* Whether the TSC will have input into the protocol. All potential TSC members should have sight of the protocol/outline as early as possible. Before recruitment begins the trial will have undergone review by the funder/Sponsor (e.g. peer review for public sector trials), scrutiny by other trial committees and a research ethics committee. Therefore, if a potential TSC member has major reservations about the trial (e.g. the protocol or the logistics) they should report these to the CI and may decide not to accept the invitation to join. TSC members should be independent and constructively critical of the ongoing trial, but also supportive of aims and methods of the trial.
* Members of the TSC will not be asked to formally sign a contract but should formally register their assent by confirming (1) that they agree to be a member of the TSC (2) that they agree with the contents of this Charter by signing.
* The TSC Charter should be signed by members prior to Sponsor Authorisation to Open (SATO) being issued.
* Any other issues specific to the trial (e.g. Phase I studies, dose escalation communication plan to the Sponsor and Investigator Team(s), and if applicable relevant trial committees e.g. DMC/TMG).

# Composition

* Membership and size of the TSC. The TSC chair must have experience of serving on previous TSC(s). Illustrative example;

*The Chair of the TSC will be independent of the trial. The TSC will comprise of mixed independent and non-independent members. The Chief Investigator (CI) is an important member of the TSC and no major decision should be made without their involvement. The members of the TSC are listed below. As stated in the preamble, this template applies to University of Edinburgh/NHS Lothian sponsored or co-sponsored studies only.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Member** | **Role in TSC** | **Responsibility** | **Independent** |
| *[Insert name]* | Chair of TSC | *[Insert basic responsibility]* | *[Y/N]* |
| *[Insert name]* | Chief Investigator | *[Insert basic responsibility]* | *[Y/N]* |
| *[Insert name]* | Trial Manager | *[Insert basic responsibility]* | *[Y/N]* |
| *[Insert name]* | *[Other members of TSC]* | *[Insert basic responsibility]* | *[Y/N]* |

# Relationships

* Advisory and executive bodies. The TSC is the oversight of the study. The DMC is advisory to the TSC.
* Any payments to TSC members (e.g. travel/accommodation)
* The need for TSC members to disclose information about any competing interests
* Definition of independence. See funder’s policy.

# Organisation of TSC Meetings

* Expected frequency of TSC meetings. It is recommended that the TSC meet formally at least once a year. At the request of the TSC, interim meetings, in person or by teleconference, will be organised. Major trial issues may need to be dealt with between meetings, by phone or by email. TSC members should be prepared for such instances.
* How TSC meetings will be organised, especially regarding open and close sessions, including who will be present in each session.
* Attendance at meetings. Illustrative example;

*Effort will be made to ensure that all members can attend. The CI must try to attend all meetings, especially if major actions are expected. Members who cannot attend in person should be encouraged to participate by teleconference. Presence will usually be limited to the TSC members however other attendees may be invited for all or part of the meeting by the TSC. If the report is circulated before the meeting, TSC members who will not be able to attend the meeting may pass comments to the TSC Chair for consideration during the discussion.*

# Trial Documentation and Procedures to Ensure Confidentiality and Proper Communication

* Intended content of material to be available during meetings.
* Who will be responsible for identifying and circulating external evidence (e.g. from other trials/systematic reviews)
* Whether reports to the TSC be available before the meeting or only at/during the meeting. It is usually helpful for the TSC to receive reports at least 1-2 weeks before any meetings.
* What will happen to the confidential papers after the meeting

# Decision Making

* What decisions will be open to the TSC. Illustrative example;

*Possible decisions by the TSC include:*

* + *Trial continues as planned*
  + *Early termination of the trial*
  + *Stopping recruitment within a subgroup*
  + *Extending recruitment or extending follow-up*
  + *Sanctioning or proposing protocol changes*

*The TSC is jointly responsible with the DMC for safeguarding the interests of participating patients and for the conduct of the trial. Recommendations to amend the protocol or conduct of the study made by the DMC will be considered and accepted or rejected by the TSC. The TSC will be responsible for deciding whether to continue or to stop the trial based on the DMC recommendations. The DMC will be notified of all changes to the protocol or to study conduct. The DMC concurrence will be sought on all substantive recommendations or changes to the protocol or study conduct prior to their implementation.*

* The role of formal statistical methods, specifically which methods will be used and whether they will be used as guideline or rules. This should include or provide reference to the planned interim analyses and statistical guidelines, i.e. the DMC should review and agree any interim analysis plan and note this in their report to the TSC if necessary.
* How decisions or recommendations will be researched within the TSC. Issues to be specified include the process of decision making, including whether there will be voting or other formal methods of achieving consensus.
* When the TSC is quorate for decision-making. The minimum number of attendees should be specified before the TSC is quorate for decision making. At least two independent members of the TSC should be present.
* Any specific issues relating to the trial design that might influence the proceedings, e.g. cluster trials, equivalence trials, multi-arm trials, phase I trials, Sponsor and Investigator(s) oversight of dose escalations.

# Reporting

* To whom the TSC will report their recommendations/decisions, and in what form. A timescale should be specified.
* Whether minutes of the meeting be made and, if so, by whom and where they will be kept. Illustrative example;

*The TSC Chair/other designated TSC member will prepare minutes of the TSC meetings. The minutes will describe the proceedings of the TSC meeting, and will summarize all decisions by the TSC. The draft minutes will be circulated for comment to those TSC members who were present at the meeting. The TSC Chair will sign off the final version of the minutes to send to all attendees and <Funder>.*

*Copies will be kept by the Sponsor for retention in the Trial Master File or Sponsor File and archived at the time of study closure.*

* What will be done if there is disagreement between the TSC and other trial committees.

# After the Trial

* Publication of results
* The information about the TSC that will be included in published trial reports
* Any constraints on TSC members divulging information about their deliberations after the trial has been published