ECTU Central Office SOP ECTU_TM_08: Preparing for Trial Steering Committee Meetings

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1.0</td>
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<td>2.0</td>
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<td>Updated after use by trial management team and scheduled review to provide more detailed guidance and to include TSC Charter (appendix 1). Sections 3.1-3.4 added</td>
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<tr>
<td>3.0</td>
<td>4th Sept 2017</td>
<td>Updated after scheduled review. Changes to wording in section 1 and 2. Reference to ACCORD SOP and TSC template added to sections 3.4.2 and 4. ECTU TSC Charter removed form appendix (as advised at audit) and held as separate template. PPI Advisor details moved to section 4 and INVOLVE website address added. Minor changes to text throughout document.</td>
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1. PURPOSE

The Trial Steering Committee (TSC) is the completely independent committee which provides overall supervision of a trial on behalf of the research Sponsor, providing advice on the trial design (through the trial protocol and data collection tools) and agreeing proposals for substantial protocol amendments. The TSC will provide advice regarding trial progress, ensuring ethical and other approvals are obtained, and maximising the chances of completion within the proposed time scale.

The remit of a TSC is to ensure the delivery of the trial considering patient safety, resources and operational aspects of the trial. The committee should meet at regular intervals throughout the trial, or upon request if a significant issue is identified and guide the Chief Investigator appropriately. The Data Monitoring Committee (where applicable) typically has a duty to keep the TSC informed of their findings so will hold their meeting prior to the TSC.

This Standard Operating Procedure (SOP) provides instruction on the organisation and operation of TSC meetings.

2. SCOPE

This SOP should be used for all studies managed by ECTU where a TSC will operate. This SOP should be used by the Trial Manager or designee who has been delegated the responsibility of overseeing the operation of the TSC.

3. PROCEDURE

3.1 TSC Members
The membership should include an independent Chair (not involved directly in the trial other than as a member of the Trial Steering Committee), no fewer than two other independent members, the Principal Investigator with additional experts if required. The majority of members should be independent. The trial manager/coordinator, trial statistician etc. should attend meetings. An observer from the Host Institution, or sponsoring organisation if different, should be invited to attend all Trial Steering Committee meetings.

The funder and/or sponsor may have specific requirements when convening the TSC and throughout the duration of the trial. Stipulations may relate to the timing of meetings, the TSC charter template and the proportion of independent versus non independent members on the committee and a definition of what constitutes independence. The funder may also wish to approve and formally invite members onto the TSC. Where this does not apply, consider who will invite the members to join - this will usually be the Chief Investigator, with input from the Chair once appointed.

In addition to the relevant skill set, independence from the trial and expertise, consider how practical it will be for potential members to join the TSC in terms of their availability and where the meetings are mostly held in person, how practical it will be for the TSC member to travel to the meeting. Some funders stipulate that TSC members cannot be based overseas.

3.2 TSC Chairperson
The Chairperson will have specific roles and responsibilities as part of their membership and is directly answerable to the funder. Their responsibilities should be defined in the charter and be in line with the funder policy. The funder may also ask for this to be formalised in a contract.

3.3 Patient Representatives
Potential patient representatives can be identified through several channels including clinics, patient support groups and charities associated with the condition relevant to the trial.
The Edinburgh Clinical Research Facility have a Patient and Public Involvement Advisor who can arrange for an advert to be posted on their website for PPI members from your patient group of interest (see section 4 for contact details). General information for patients and researchers about Patient and Public Involvement in research is available on the Edinburgh Clinical Research Facility website (see section 4 for website details).

In selecting a patient representative consider their health needs and whether the venues will be suitably accessible. Consider also whether the patient representative may fall into the eligible category for the trial and whether taking on such a role will be appropriate. Some trials have funding to cover modest payments to patient representatives and going rates can be obtained from organisations such as INVOLVE.

3.4 Preparing for the meeting
3.4.1 General meeting preparation
The TSC chair will be responsible for arranging the inaugural meeting and the Trial Manager will usually facilitate this. Trial Manager should ensure that the date, time and suitable venue for the meeting has been finalised and that all committee members are aware and have confirmed their availability. It should be ensured before a meeting is conducted that there are enough independent vs non-independent members attending to achieve a quorate for decision making (as defined in the charter). If there is not, the meeting should be rescheduled.

3.4.2 Preparations prior to the first meeting
The TSC Charter should be prepared in advance of the meeting by the Trial Manager or designee on behalf of the CI. For UoE/NHSL sponsored studies, a Charter template and SOP is available from ACCORD. For all other studies, and ECTU TSC Charter template is available if the funder does not provide their own template.

The Charter should then be circulated to the TSC members and the Sponsor (if required, please check specific Sponsor guidance) in advance of the first meeting for review. Once agreed, the signature pages should be collected from the members at , or before, the first meeting.

A summary of the trial timelines should be prepared and circulated along with a copy of the protocol and a meeting agenda.

The TSC can be asked what information they would like to see on the trial report, at each of the Trial Steering Committee meetings.

3.4.3 Preparations prior to all meetings
The CI will prepare a Trial Report for committee review. This is a progress report on the trial. The information for the TSC review can include recruitment and publicity plans, statistical analysis reports, trial logistics and funding reports, safety reports, planned protocol amendments and any other trial specific requirements. This information may be part of the CI Trial Report or provided as separate documents. The format for presenting the information may be dictated by the individual funder’s requirements.

The Trial Manager will prepare an agenda and any related documents for the meeting as directed by the Chair and CI. These should be circulated to the Chair in the first instance for comment. Conflicts of Interest should be included on the agenda as a standing item. A copy of the minutes for the previous meeting (if applicable) should also be circulated.

The Trial Manager or designee will usually take the minutes but a proportion of the meeting may be held in private for the Independent members. An alternative minute-taker should be arranged for this section of the meeting if required. The minutes from this section of the meeting will be included in the overall minutes unless the content should remain private to the independent members. In such situations, a separate set of minutes will be produced for those members.

3.4.4 Arrangements for members who cannot attend the meeting in person
TSC members who are not able to attend in person can participate via conference call if this is practical. The Trial Manager or designee should arrange the teleconference details and circulate the dial-in numbers to those who wish to do so.
3.5 After the meeting
Once the minutes have been transcribed they should be sent to the Chair for approval before being circulated to the other members of the committee. The minutes should also be circulated to the funder and sponsor if necessary by the Trial Manager or designee. The Trial Manager or designee should also check that the Chair has sent their copy of the minutes from the independent members to the funder if any part of the meeting was private.
Where the funders have electronic reporting, the Trial Manager or designee may need to upload the minutes and related documents as required.
A date for the next TSC should be discussed at the meeting as an agenda item and included in the minutes.
The Chair should ensure that all action points raised at the meeting are followed up prior to the next meeting and any unresolved issues should be added to the next agenda. It is likely the Trial Manager or designee will facilitate this.

3.6 Expenses
Expenses should be paid to cover reasonable travel and subsistence costs and can be charged against the grant for the trial (if costed for in the budget). Where practical, the travel arrangements should be made by the relevant team member at ECTU. Otherwise, TSC members should be asked by the Trial Manager or designee to retain their receipts for expenses claims and provide a University of Edinburgh Claim for Expenses form to complete. Expenses claims should abide by the University and/or funder policy (eg. no first class travel etc.)

4. RELEVANT DOCUMENTS

**ACCORD SOP CR015 Data Monitoring Committee and Trial Steering Committee Charters**
(available online at [www.accord.scot](http://www.accord.scot))

**ECTU TSC Charter Template (on shared drive)**
ECTU Unit/SOPs/Finalised SOP and WPD/TM/SOP and WPD Documents/

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**Edinburgh Clinical Research Facility**

**NIHR INVOLVE**
[www.invo.org.uk](http://www.invo.org.uk)