





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

Version No:	7.0
Issue Date:	04 Jun 2024
Effective Date:	24 Jun 2024

Authorship and Approval			
Name and Designation	Author/Reviewer /Approval/ Authorisation	Date	Signature
Denise Cranley, Trial Manager	Author	04-Jun-2024	
Lorna Dewar, Trial Manager	Reviewer	31-May-2024	
Gina Cranswick, Senior Trial Team Manager	Approver	03-Jun-2024	 <small>Gina Cranswick (Jun 3, 2024 10:32 GMT+1)</small>
Tanya Tharakan, QA Manager	QA Authorisation	04-Jun-2024	 <small>Tanya Tharakan (Jun 4, 2024 08:49 GMT+1)</small>

Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	14 th June 2012	Initial creation
2.0	18 th June 2015	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
3.0	4 th Sept 2017	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 from 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.

The user of this document is responsible for ensuring it is the current version.

4.0	4 th Sept 2019	Updated at scheduled review. Document moved to new SOP template. Minor changes throughout, updated links and contacts in section 4.
5.0	23 Feb 2022	SOP has been transferred onto new SOP template. SOP has been updated and changed extensively throughout.
6.0	16 Mar 2022	Section 4.1.3 and 4.2.6 updated to reflect current processes.
7.0	24 Jun 2024	Updated at scheduled review. Reviewer name updated. Clarification of (i) the signature process for the TSC charter, (ii) the process of minute taking if the TSC has a combined DMC role.

The user of this document is responsible for ensuring it is the current version.

1.0 PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to provide instruction on the preparation required for a Trial Steering Committee (TSC) meeting.

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 (CI) appropriately.

2.0 SCOPE

Preparation for Trial Steering Committee (TSC) meetings is the overall responsibility of the CI, but this can be delegated. This SOP applies to studies managed by ECTU where the planning of the TSC meetings has been delegated to the Trial Management team (typically within the table of responsibilities).

3.0 RESPONSIBILITIES

It is the responsibility of the delegated Trial Management team member to ensure that:

- The TSC meetings are convened according to any sponsor, funder or contractual obligations.
- The TSC meetings follow the procedures laid out in the TSC Charter, including consideration for quorate requirements of a meeting.
- Ensure they are familiar with relevant SOP's.
- Ensure the timely and accurate distribution of reports and minutes for a meeting.

4.0 PROCEDURE

4.1 General TSC meeting Requirements

- 4.1.1 A TSC should be convened according to sponsor, funder and contractual requirements. Membership details should be collated and stored within the trial master file (TMF, Section 10) to aid meeting preparations.
- 4.1.2 It is the responsibility of the CI to identify and invite an individual to take up the role as TSC Chair. The TSC Chair or CI will then be responsible for identifying potential committee members. In some instances, the funder will invite members to join (e.g. NIHR) otherwise the CI should invite members. Members should be provided with a protocol.
- 4.1.3 The TSC Charter should be drafted in advance of the first meeting by the trial management team and circulated to the TSC members. Once finalised, all signature pages should be collected from all members and filed in the TMF. In the case of

The user of this document is responsible for ensuring it is the current version.

studies which have undergone combined risk assessment, the signature pages should be signed and collected prior to Sponsor Authorisation to Open (SATO). This is in accordance with the ACCORD SOP ([CRO15 Data Monitoring Committee and Trial Steering Committee Charters, section 5.2.9](#)) Once finalised, signature pages should be collected from the members prior to Sponsor Authorisation To Open (SATO) and filed in the TMF. For studies that have not undergone combined risk assessment the signature pages should be collected prior to starting recruitment.

- 4.1.4 Attendance at TSC meetings must meet any quorate agreement (independent vs non-independent members) as stated within the TSC Charter. If quorum requirements are not met, the meeting must be rescheduled.
- 4.1.5 Meetings can be held via video/teleconference. In person meetings can be convened if there is sufficient funding to cover travel and subsistence costs, either from within the award or if identified by the CI from another source. Expenses should be claimed using the University of Edinburgh Claim for Expenses form and abide by the current ECTU, University and/or funder policies. Consideration should also be given to the University of Edinburgh Sustainable Travel Policy (2021). (see section 5.0)

4.2 Preparations prior to all meetings

- 4.2.1 As directed by the Chair and/or CI an agenda should be prepared by the TM with the following standard items:
- Attendance / apologies
 - Review of last minutes
 - Update since last meeting
 - Conflicts of Interest
 - Date of next meeting
- 4.2.2 A report will be prepared (co-ordinated by the TM) in order to provide the TSC with details of the trial progress (e.g. recruitment against milestones, publicity plans, statistical analysis reports, trial logistics and funding reports, safety reports, planned protocol amendments).
- 4.2.3 A copy of the minutes from the previous meeting (if applicable) should be circulated with the CI report and any other supporting documentation before the meeting. Minutes should be taken by the TM (or designee) during the meeting and then sent to the Chair for approval prior to circulation to the members. Minutes should be held within the TMF (section 10).
- 4.2.4 Action points should be followed up prior to the next meeting with any unresolved issues being added to the next meeting agenda. This will be facilitated by the TM (or designee).
- 4.2.5 In some cases the TSC charter may stipulate that the TSC committee will have a combined Data Monitoring Committee role for oversight of data. In the event of a

The user of this document is responsible for ensuring it is the current version.

closed session for data review being required, an alternative minute taker would need to be identified (typically the unblinded statistician) These minutes must be held separately by the unblinded trial statistician in a restricted access folder of the TMF (until archiving when these minutes will be filed within the TMF, section 9).

- 4.2.6 Where a trial has both a Trial Steering Committee and a Data Monitoring Committee (DMC), the TSC should be convened after the DMC, in order for the TSC to consider any issues that have been raised by the DMC. This would not apply to the inaugural meetings of both committees.

5.0 RELEVANT DOCUMENTS AND REFERENCES

- [ACCORD SOP CR015 Data Monitoring Committee and Trial Steering Committee Charters](#)
- [ECTU TSC Charter Template](#) (on shared drive)
- [University of Edinburgh Sustainable Travel Policy 2021](http://www.ed.ac.uk/sustainability/topics/travel/sustainable-travel-policy-2021) -
www.ed.ac.uk/sustainability/topics/travel/sustainable-travel-policy-2021
- [University of Edinburgh Expenses Policy](#)

The user of this document is responsible for ensuring it is the current version.











ECTU_SOP_TM_08 Preparing for Trial Steering Committee Meetings v7.0

Final Audit Report

2024-06-04

Created:	2024-05-31 (British Summer Time)
By:	Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAXxc32SWMgCDAWjpydglb6SgsJiHIV_55

"ECTU_SOP_TM_08 Preparing for Trial Steering Committee Meetings v7.0" History


-  Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
2024-05-31 - 11:56:26 GMT+1- IP address: 192.41.114.230
-  Document emailed to Denise Cranley (denise.cranley@ed.ac.uk) for signature
2024-05-31 - 12:00:50 GMT+1
-  Document emailed to Lorna Dewar (lorna.dewar@ed.ac.uk) for signature
2024-05-31 - 12:00:50 GMT+1
-  Document emailed to Gina Cranswick (gina.cranswick@ed.ac.uk) for signature
2024-05-31 - 12:00:51 GMT+1
-  Document emailed to Tanya Tharakan (tanya.tharakan@ed.ac.uk) for signature
2024-05-31 - 12:00:51 GMT+1
-  Email viewed by Lorna Dewar (lorna.dewar@ed.ac.uk)
2024-05-31 - 13:12:47 GMT+1- IP address: 104.47.11.254
-  Document e-signed by Lorna Dewar (lorna.dewar@ed.ac.uk)
Signature Date: 2024-05-31 - 13:13:08 GMT+1 - Time Source: server- IP address: 192.41.114.228
-  Email viewed by Gina Cranswick (gina.cranswick@ed.ac.uk)
2024-06-03 - 10:29:47 GMT+1- IP address: 104.47.11.62
-  Document e-signed by Gina Cranswick (gina.cranswick@ed.ac.uk)
Signature Date: 2024-06-03 - 10:32:37 GMT+1 - Time Source: server- IP address: 5.181.59.56
-  Email viewed by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
2024-06-03 - 12:27:37 GMT+1- IP address: 192.41.114.230

 Email viewed by Denise Cranley (denise.cranley@ed.ac.uk)

2024-06-04 - 08:23:11 GMT+1- IP address: 104.47.11.254

 Document e-signed by Denise Cranley (denise.cranley@ed.ac.uk)

Signature Date: 2024-06-04 - 08:23:18 GMT+1 - Time Source: server- IP address: 192.41.114.230

 Document e-signed by Tanya Tharakan (tanya.tharakan@ed.ac.uk)

Signature Date: 2024-06-04 - 08:49:30 GMT+1 - Time Source: server- IP address: 192.41.114.230

 Agreement completed.

2024-06-04 - 08:49:30 GMT+1