STU-SOP-TS-002 – Standard Operating Procedure on Requirements for Trial Steering Committees, and Data Monitoring Committees in trials

Version No:	5	**Effective Date:**	27-Mar-2026
Description of changes:	SOP reviewed in light of clinical trial regulations 2025 and GCP updates. Specific references to QPulse as the QMS have been removed. We now only refer to a QMS system.		

List of Abbreviations	
AD	Associated Documents
CI	Chief Investigator
DM	Data Manager
DMC	Data Monitoring Committee
HRA	Health Research Authority
MHRA	Medicine and Healthcare Products Regulatory Agency
QMS	Quality Management System
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
SU	Swansea University
TMG	Trial Management Group
TM	Trial Manager
ToR	Terms of Reference
TS	Trial Statistician
TSC	Trial Steering Committee

1. Purpose

This Standard Operating Procedure (SOP) describes the procedure of creating and managing research project oversight committees as required by the UK Policy Framework for Health and Social Care Research 2017, the Medicines for Human Use (Clinical Trials) Regulations 2025 and the requirement of sponsors and funders.

This SOP also outlines committee reporting requirements for both Clinical Trials of an Investigational Medicinal Product (CTIMP) and other trials which require Trial Steering Committees (TSCs), and Data Monitoring Committees (DMCs).

Trial Management Groups (TMGs) and other operational committees required for all research projects are outlined in STU-SOP-TS-003 Research Project Operational Committees.

2. Background

Where appropriate for trials, TSCs, and DMCs are set up to provide independent oversight and provide advice to support and resolve problems that might occur. It is part of the governance arrangements and provides assurance to the funder and Sponsor who may stipulate specific oversight arrangements. Where there are no formal/legal requirements, consideration should still be given to establishing appropriate oversight arrangements.

It is the responsibility of the sponsor to establish these groups, but this is usually delegated to the Chief Investigator (CI) who is also responsible for reporting to the committees in a timely manner using high quality data.

It is a requirement to develop Charters or Terms of Reference (ToR) for the individual groups so that they understand their role and how they will interact with each other.

3. Roles and Responsibilities

The **Sponsor** has overall responsibility for defining the requirement for project TSCs, and DMCs, but will usually delegate this role to the CI. The sponsor via a risk assessment shall ensure that appropriate oversight groups are defined and shall assess the requirement for sponsor representation.

The **Funder**, where required, has responsibility for approving the oversight committee membership.

The **Chief Investigator (CI)** has delegated responsibility for setting up and managing TSCs, and DMCs, but will usually assign this role to the Trial Manager (TM). The CI will provide advice on suitable candidates to be invited to the TSC and DMC.

The **Trial Manager (TM)** will invite members to the relevant group, draft charters for review at the inaugural meeting and manage the groups throughout the trial. They will also produce key outputs for discussion in meetings and ensure relevant feedback is shared as appropriate.

For larger trials with a **Data Manager (DM)**, the CI may delegate the role of organising and managing the DMC to that person. The DM may also be delegated the task of producing data-related outputs for meetings by the TM.

The **Trial Statistician (TS)** is responsible for performing any statistical analyses to be reported to any meetings and to liaise with the Independent Statistician as appropriate.

An **Independent STU Statistician** may be needed by some trials for creating unblinded reports and assessing the analyses provided, and for generating the authorisation to unblind data when required.

The **Unblinded Researcher(s),** where required, is responsible for managing any unblinded data for a trial when the TM and DM are also blinded. They will assist the independent STU statistician with preparing any unblinded analyses and can attend the closed DMC.

The **Chairperson** of the TSC or DMC will be an independent member and responsible for representing the committee's views in communications with other groups as part of the trial reporting structure.

The **TSC** provides overall supervision of the trial and ensures research is conducted safely, ethically, with scientific integrity, and according to the protocol. The TSC will convene at least annually to review progress and conduct of the research. The TSC is independent of the sponsor, funder and CI, except for non-independent members defined in the Charter/ToR.

The **DMC** monitors accumulating research data to make recommendations to the Sponsor and TSC on whether there are any ethical or safety issues with the primary aim of protecting patient safety. In a blinded trial, the unblinded report produced shall be discussed by the DMC in a

'closed session' with only independent members and the unblinded STU statistician present. After each meeting, the DMC will provide the CI and the TSC with written recommendations regarding research modification, continuation or termination. The TSC will consider and act, as appropriate, upon the recommendations of the DMC and ultimately carries the responsibility for deciding whether a trial needs to be stopped on grounds of safety or efficacy.

External use of SOP: This SOP and Associated Documents (AD) may be used for research projects not adopted by STU where Swansea University (SU) staff and associated NHS organisations require guidance. In such instances, oversight responsibility for any associated tasks will not be the responsibility of STU.

4. Procedure

4.1 Setting up a TSC or DMC

The Sponsor should decide whether the study requires both a TSC and DMC or whether they can be combined. This will be determined from the complexity and risks associated with the research project, and in accordance with funder requirements, where required

High risk CTIMPs, device trials and adaptive designs always require a DMC and a TSC.

The CI proposes the membership of the TSC and DMC for the trial, for approval by the Sponsor and the funder, where required. Once agreed, the CI, or funder (as appropriate), will approach and formally appoint members. The research protocol stipulates the requirement for each committee.

Membership will depend on the design of the research project, but Table 1 illustrates a typical example:

Role	TSC	TSC (closed)	DMC	DMC (closed)
Chairperson	✓	✓	✓	✓
Independent clinicians	✓	✓	✓	✓
[*Independent medical experts depending on trial design e.g. radiologist, paramedic, surgeon, pharmacist*]	✓	✓	✓	✓
Lay representatives (2 per group, where possible)	✓	✓	✓	✓
Independent statistician	✓	✓	✓	✓
Chief Investigator	✓		✓	
Trial Manager	✓*		✓*	
Data Manager			(✓)*	
Trial Statistician	✓		✓	
Health Economist	✓		✓	
Independent STU statistician	✓	(✓)*	✓	(✓)*
Unblinded researcher	(✓)*	(✓)*	(✓)*	(✓)*
Independent STU representative	✓	(✓)*	(✓)*	(✓)*
Other representative(s) from the trial e.g. clinician, laboratory lead	(✓)		(✓)	

Sponsor representative	✓			
Funder representative (to be invited)	✓			
Trial location PIs / other delegated local staff	(✓)			
Ad hoc independent expert	(✓)	(✓)	(✓)	(✓)

Table 1: Example of members for each group for a trial.
Notes:
(✓) indicates that this member is optional or may be requested to attend individual meetings.
** Indicates that this member may also be asked to be the secretary for the group.*

A TSC and/or DMC must be fully constituted and established prior to enrolment of participants into a research project.

4.2 Committee Charters

Template Charters are available for both TSC (STU-AD-TMP-010) and DMC (STU-AD-TMP-011) to be adapted for each trial according to its bespoke requirements. Where the two committees are merged into one, the Charters for each should also be merged.

The Charter should be ratified at the first TSC or DMC meeting.

Charters should be reviewed annually or as required. Revised Charters must be signed by all independent members.

4.3 Committee meetings

4.3.1 Timing of meetings

The frequency of meetings will be determined by the committee Chairperson in discussion with the CI and funder if required and will be detailed in the Charter. Each committee will meet at least annually.

4.3.2 Meeting organisation

The TSC and DMC meetings should allow for a closed session during the main meeting where independent members discuss unblinded aspects of the trial in privacy. Only the independent STU statistician for the trial may attend to discuss unblinded data in detail. Meetings are typically organised with an initial open session to update on the study, then a closed session to discuss an unblinded report or have confidential conversations, followed by an open session where the Chairperson summarises these discussions in a blinded manner and issues the recommendations of the independent committee members.

4.3.3 Meeting documentation

Minutes of committee meetings, along with documentation indicating actions to address recommendations made by the TSC or DMC will be held in the TMF. However, minutes from 'closed sessions' of the TSC and DMC must be held separately and securely by an unblinded STU representative to avoid unblinding. The structure of the unblinded TMF is detailed in STU-AD-GDN-005 Essential Documents Index. Contents of the unblinded TMF will be merged at the end of the trial.

The CI or TM will send open minutes from the TSC and DMC, and documentation of actions taken, to the Sponsor and the Trial Management Group as required.

Further guidance is available in STU-AD-GDN-010 TSC/DMC Guidance.

5. References

- Damocles DMC Charter template located at https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(05)17965-3/fulltext
- Health Research Authority website (HRA) - http://www.hra.nhs.uk/
- Medicine and Healthcare products Regulatory Agency website (MHRA) - https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information
- NIHR Project Oversight Groups Guidance https://www.nihr.ac.uk/about-us/who-we-are/policies-and-guidelines/research-governance-guidelines
- UK policy framework for health and social care research (2017) - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- UK Medicine for Human Use (Clinical Trials) Regulations 2025 - https://www.legislation.gov.uk/uksi/2025/538/contents

It is assumed that by referencing the principal regulations that all subsequent modifications are included in this citation.

6. Associated Documents

Number	Title	Location
STU-AD-TMP-010	TSC charter template	QMS
STU-AD-TMP-011	DMC (Damocles charter template)	QMS
STU-AD-GDN-010	TSC/DMC Guidance	QMS
STU-AD-GDN-005	Essential Documents Index	QMS