STU-SOP-TS-003 – Standard Operating Procedure on Requirements for Research Project Operational Committees

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	
CI	Chief Investigator
DM	Data Manager
DMC	Data Monitoring Committee
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
TM	Trial Manager
TMG	Trial Management Group
ToR	Terms of Reference
TSC	Trial Steering Committee

1. Purpose

This Standard Operating Procedure (SOP) describes the procedure of creating and managing research project operational committees as required by 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.

2. Background

Some trials require the establishment of operational committees to facilitate a process or monitor an action(s). It is the responsibility of the Sponsor to decide whether any such groups are necessary and if so, how they should be set up and managed. Certain funders may also have requirements for these committees. The responsibility for establishing committees is usually delegated to the Chief Investigator (CI).

It is common for most trials to have a Trial Management Group (TMG) but the membership of the group will differ according to the requirements of the trial and its remit.

Some more complex trials may have operational groups tasked with organising a specific work package (sometimes called a task and finish group) which are short-lived but nonetheless need clear guidance on how they are to be run.

It may also be necessary to develop terms of reference (ToRs) for the individual groups so that they understand their purpose within the trial and each member's individual roles.

3. Roles and Responsibilities

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

The **Chief Investigator (CI)** has overall responsibility for setting up and managing operational committees, but will usually assign this role to the Trial Manager (TM). The CI will provide advice on the membership of any operational committees and may elect to chair them or nominate a chairperson from the members list.

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

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

Other members of any operational groups will have their roles and responsibilities defined by the ToR and will act in accordance with that document.

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 an operational group

The CI will usually decide whether an operational or task and finish group is required for a particular task or role in the trial.

For example, for low-risk trials there may be no requirement for a Trial Steering Committee (TSC) or Data Management Committee (DMC) but there should be another committee in place with a similar role of overseeing the trial. Additionally, trials using an electronic data capture system e.g. REDCap may require a task and finish group consisting of the Trial Statistician, Trial Manager, Data Manager and IT Manager for the period of setting up and developing the database which will be dissolved thereafter.

The CI will define the membership of any operational group in accordance with its proposed role. For example, a TMG may have members of the trial office team, a Sponsor representative, trial location representatives and external advisors. For task and finish groups, it is advisable to have the minimal number of members to facilitate discussions and decision making, all of which should play a key role in the purpose of the group.

4.2 Drafting a Terms of Reference

For some trials not needing formal oversight committees they may allocate the role to their TMG. The TSC charter (STU-AD-TMP-010 TSC Charter Template) can be adapted if their role is to oversee the trial.

For bespoke ToRs there should be sections covering:

- Committee name
- Remit
- Roles and responsibilities
- Membership (including chairperson and secretary)
- Meeting arrangements
- Meeting organisation and structure (including standing agenda items)
- Relationship with other groups
- Decision making
- Reporting

A template ToR document is available for adaptation in line with the operational group's remit (STU-AD-TMP-012 ToR Template).

4.3 The inaugural and further committee meetings

At the inaugural meeting, the charter or ToR drafted for a group, should be discussed and any amendments approved. For long standing groups there may be a requirement to review this document as the trial evolves. This should be documented in the ToR.

Meetings should be scheduled in accordance with the remit of the group so that it delivers its actions in a timely manner. For example, a TMG may be held monthly or quarterly whilst operational groups to develop a bespoke database may be held weekly.

Decisions and actions made by an operational group will be reported to another relevant group in writing using pre-agreed reporting structures and templates.

Groups may be dissolved once a task or role has ended for a trial. This will usually be identified in the ToR.

5. References

- 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#page=DynamicListMedicines
- 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 - http://www.legislation.gov.uk/uksi/2004/1031/contents/made

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

6. Associated Documents

Number	Title	Location
STU-AD-TMP-010	TSC Charter Template	QMS
STU-AD-TMP-012	ToR Template	QMS