York and Scarborough Teaching Hospitals NHS Foundation Trust R&I Department
Standard Operating Procedure
R&D/S72

Oversight Committees for Research Studies

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SOP Reference:	R&D/S72
Version Number:	6.0
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Implementation date of current version:	13th May 2026

Approved by:	Name/Position:	Lydia Harris, Head of R&D
	Date:	16th April 2026
	Name/Position:	Sarah Sheath, SOP Controller
	Date:	15th April 2026

This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Reviewers	Details of significant changes
1.0	7th November 2011		
2.0	24th March 2014		Removal of references to the North and East Yorkshire R&D Alliance. Removal of Head of R&D and inclusion of Director of ALAR for urgent recommendations.
3.0	24th August 2017		Two year review, no changes necessary
4.0	22nd July 2019		Change of link to R&D website.
5.0	7th December 2022		Minor changes only. Link to MHRA website added and HRA website removed.
6.0	13th May 2026	Monica Haritakis	Updates SOP title. Included information about TSCs

Contents

1 Introduction, Background and 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 2004 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 research studies that require Trial Steering Committees (TSCs) and/or Data Monitoring Committees (DMCs).

Where appropriate for research studies, TSCs, and DMCs are set up to oversee the conduct of that project and to provide advice and resolve any issues that might occur.

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.

Each committee should have their own charters or terms of reference so that they understand their role and how they will interact with each other.

2 Who Should Use This SOP

This SOP is aimed at:

- Chief Investigators (CIs), trial co-ordinators, and other professional or administrative research staff, in the investigator team or in support departments, working on clinical trials sponsored or co-sponsored by the Trust;
- R&I Department personnel;
- Members of the R&I Group;
- Members of DMCs and TSCs for Trust sponsored or co-sponsored clinical trials.

3 When this SOP Should be Used

This SOP should be used when establishing a DMC and TSC for a Trust sponsored or co-sponsored trial and throughout the conduct of that trial.

4 Procedue(s)

4.1 Data Monitoring Committees (DMCs)

The need to establish a Data Monitoring Committee (DMC) depends on the nature of the trial and is not a legal requirement. Guidance on DMCs is available from a number of sources, in particular:

- The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA) has published guidelines at: https://www.ema.europa.eu/en/

- Guidance from the Medicines and Healthcare Products Regulations Agency (MHRA) is available at: https://www.gov.uk/government/publications/oversight-and-monitoring-of-investigational-medical-product-trials/oversight-and-monitoring-activities

Sponsors are strongly recommended to establish DMCs for certain kinds of clinical trial, for example those with predicted high morbidity or mortality, or double-blind trials with unknown or uncertain risks.

4.1.1 The role of the DMC

The Data Monitoring Committee's main role is as follows:

- In the case of a study with blinded/masked data, the DMC is the only body involved that may have access to the unblinded comparative data. For other study types it has oversight of any primary data collected from participants, including qualitative data
- The role of DMC members is to monitor these data and make recommendations to the TSC on whether there are any ethical or safety reasons why the study should not continue
- The DMC should uphold the safety, rights and well-being of the study participants: these are paramount considerations
- The DME should consider the need for any interim analysis advising the TSC regarding the release of data and/or information
- The DMC may be asked by the TSC, Study Sponsor or Study Funder to consider data emerging from other related studies
- There are also rare occasions when the DMC chair might be asked by the Study Funder, through the chair of the TSC, to provide advice based on a confidential interim or futility analysis if serious concerns are raised about the viability of the study or if the research team are requesting significant extensions
- Criteria should be agreed (where appropriate) relating to the point at which continuation of the study is considered futile, and in the case of a randomised trial, the DMC would only indicate if these had been passed or not as this would limit the potential for un-blinding.

4.1.2 Requirement to establish a DMC

The R&I Group and study funder will be responsible for determining whether a DMC is required for a trial sponsored or co-sponsored by the Trust. The Risk Assessment (R&D/S18) will help to inform this decision.

4.1.3 Who should establish a DMC

If a DMC is required to be established, then this will be the responsibility of the appropriate Sponsor representative and study CI. The membership and terms of reference of the DMC will be informed by the nature of the trial.

4.1.4 Membership of the DMC

The DMC will usually be made up of 3-7 members who are independent of the trial. A minimum of 3 members should be appointed. Membership will include as a minimum (i) a statistician (ii) a clinical expert in the field of the research,

and (iii) an experienced researcher. Additional individuals may be invited by the DMC Chairperson to attend to inform DMC meetings as necessary.

4.1.5 The Role of the Sponsor

The Sponsor will not be represented on the DMC but a Sponsor representative may attend meetings (as requested by the DMC Chairperson) to inform or assist the Committee. Sponsor representatives must not attend closed sessions where unblinded data may be reviewed or discussed.

4.1.6 DMC Terms of Reference

The trial DMC will 'meet' prior to participant recruitment where possible to agree Terms of Reference and to finalise membership. An example DMC Terms of Reference is available (see section 5). A Chairperson will be appointed (if not already agreed). The agreed Terms of Reference will be signed by all members of the DMC and filed in the Sponsor File.

4.1.7 DMC Meeting Schedule

At the initial meeting of the DMC the Committee will agree the proposed timing of meetings for the duration of the trial. The proposed schedule can be adapted as required. The trial sponsor representative may request that the DMC meets at any point during the trial as a result of any concerns it may have. Such a meeting may need to be convened immediately, and the DMC members must be responsive to such a request.

4.1.8 DMC Meetings

The Sponsor representative will liaise with the Investigator team and DMC Chairperson to ensure that meetings are held in a timely fashion. The Sponsor representative (or delegate) will assist with organising logistical arrangements for the meeting and providing information to inform meetings as requested by the DMC. The Sponsor representative may minute meetings where he/she attends by agreement with the DMC Chairperson. Where Sponsor representative presence is not appropriate, then a DMC member will be responsible for taking minutes and the DMC Chairperson is responsible for retaining these confidentially until the close of the trial, whereupon they will be returned to the Sponsor.

4.1.9 Review of Unblinded Trial Data

Should the DMC be required to review unblinded data during the trial then the sponsor must approve the unblinding. Although the request must be made by the Sponsor on behalf of the DMC, the code break(s) must be supplied directly to the DMC Chairperson and not to the Sponsor.

4.1.10 Communication following DMC Meetings

The Sponsor Representative and TSC (if applicable) will be informed of any recommendations by the DMC in writing within 10 working days of the meeting. Recommendations received by the R&I Unit (on behalf of the Sponsor) will be communicated to the R&I Group at the next scheduled meeting (for non urgent recommendations) and to the investigators.

Any urgent recommendations following a DMC meeting must be informed within 2 working days to the Head of R&I and the Sponsor Representative. The Head of R&I (or in his/her absence the Research Adviser or Sponsor Representative) must take necessary action without delay. The DMC recommendations and remedial action taken must be communicated with the Chairperson of the R&I Group and the Investigators as soon as possible and to

the R&I Group at the next scheduled meeting. All such communications must be documented and filed in the Sponsor File.

4.1.11 Carrying out DMC Recommendations

Where there is no TSC, the R&I Group will usually take on the role of Trial Steering Committee for trials sponsored or co-sponsored by the Trust. The R&I Group will therefore, on behalf of the Sponsor, receive recommendations from the DMC and act accordingly. All recommendations and resulting actions will be fully documented in the Sponsor File.

4.2 Trial Steering Committees

4.2.1 The role of the TSC

The role of the Steering Committee is to provide overall supervision for a project on behalf of the study's Sponsor and Funder and to ensure that it is conducted to the rigorous standards set out in the UK Policy Framework for Health and Social Care and the Guidelines for Good Clinical Practice.

The main features of the Steering Committee are as follows:

- To provide advice, through its Chair, to the study's funder, sponsor, Chief Investigator, host institution, and contractor
- To concentrate on the study's progress, adherence to the protocol, and patient safety (where appropriate), and to consider new information of relevance to the research question
- To uphold the rights, safety and well-being of the participants: these are the most important considerations and should prevail over the interests of the research
- To ensure appropriate ethical and other approvals are obtained in line with the project plan
- To agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments
- To provide advice to the investigators on all aspects of the study

4.2.2 Requirement to establish a TSC

The R&I Group and study funder will be responsible for determining whether a TSC is required for a trial sponsored or co-sponsored by the Trust. The Risk Assessment (R&D/S18) will help to inform this decision.

4.2.3 Who should establish a DMC

If a TS is required to be established, then this will be the responsibility of the appropriate Sponsor representative and CI. The membership and terms of reference of the TSC will be informed by the nature of the trial.

4.2.4 Membership of the TSC

The TSC will usually be made up 5 members some of who are independent of the study. Membership will include as a minimum (i) an independent Chair (ii) a independent statistician (iii) at least one public member, preferably independent (iiii) others with clinical or other expertise relevant to the project, such as in health economics, social care, public health etc. a clinical expert in the field of the research.

Ideally, the Steering Committee should invite observers, including representatives of the sponsor and research network to meetings

4.2.5 The Role of the Sponsor

The Sponsor will not be represented on the TSC but a Sponsor representative may attend meetings (as requested by the TSC Chairperson) to inform or assist the Committee.

4.2.6 TSC Terms of Reference

The trial TSC will 'meet' prior to participant recruitment where possible to agree Terms of Reference and to finalise membership. A Chairperson will be appointed (if not already agreed). The agreed Terms of Reference will be signed by all members of the TSC and filed in the Sponsor File.

4.2.7 TSC Meeting Schedule

At the initial meeting of the TSC the Committee will agree the proposed timing of meetings for the duration of the trial. The proposed schedule can be adapted as required. Although there may be periods when more frequent meetings are necessary, the Steering Committee should meet at least annually. Where a Data Monitoring Committee (DMC) is required, Steering Committee meetings should be scheduled to follow shortly after their meetings so that reports from the DMC can be considered if appropriate

4.2.8 TSC Meetings

The Sponsor representative will liaise with the Investigator team and TMC Chairperson to ensure that meetings are held in a timely fashion. The Sponsor representative (or delegate) will assist with organising logistical arrangements for the meeting and providing information to inform meetings as requested by the TMC. The Sponsor representative may minute meetings where he/she attends by agreement with the TSC Chairperson. Where Sponsor representative presence is not appropriate, then a TSC member will be responsible for taking minutes and the TSC Chairperson is responsible for retaining these confidentially until the close of the trial, whereupon they will be returned to the Sponsor.

4.2.9 Communication following TSC Meetings

The Sponsor Representative and funder (if applicable) will be informed of any recommendations by the TSC in writing within 10 working days of the meeting. Recommendations received by the R&I Unit (on behalf of the Sponsor) will be communicated to the R&I Group at the next scheduled meeting (for non urgent recommendations) and to the investigators.

Any urgent recommendations following a TSC meeting must be informed within 2 working days to the Head of R&I and the Sponsor Representative. The Head of R&I (or in his/her absence the Research Adviser or Sponsor Representative) must take necessary action without delay. The TSC recommendations and remedial action taken must be communicated with the Chairperson of the R&I Group and the Investigators as soon as possible and to the R&I Group at the next scheduled meeting. All such communications must be documented and filed in the Sponsor File.

4.2.10 Carrying out TSC Recommendations

The Sponsor and funder (if applicable) will receive recommendations from the DMC and act accordingly. All recommendations and resulting actions will be fully documented in the Sponsor File.

5 Related SOPs and Documents

R&D/S18	Clinical Trial Risk Assessment
R&D/T27	DMC Terms of Reference Template