Joint Research Management Office Standard Operating Procedure for:			
Trial Committees			
SOP Number:	**47**	Version Number:	**5.0**
Effective Date:	**8th April 2025**	Review Date:	**8th April 2028**

Authorship:		**Signature and Date:**
Author and Reviewer:	Rebecca Carroll, Quality Assurance Manager	Rebecca Carroll Digitally signed by Rebecca Carroll Date: 2025.03.25 13:03:12 Z

Authorisation:		**Signature & Date:**
Name/Position:	Mays Jawad, Research Governance Operations Manager	Dr Mays Jawad Digitally signed by Dr Mays Jawad Date: 2025.03.25 14:57:15 Z

Purpose and Scope:

The role of trial committees is to give independent and expert oversight of the conduct of clinical trials. The purpose of this Standard Operating Procedure (SOP) is to define which committees are necessary and provide procedural guidance on the set-up and conduct of study committees for studies that are sponsored by Barts Health NHS Trust (Barts Health) or Queen Mary University of London (Queen Mary).

This SOP also gives guidance on trial committee composition/ definitions and committee charters. See *Associated Document 1 Further guidance for Trial Committees* for details.

This SOP is mandatory for Clinical Trials of Investigational Medicinal Products (CTIMPs), Advanced Therapy Investigational Medicinal Products (ATIMPs), and Clinical Investigation Trials sponsored by Barts Health or Queen Mary.

This SOP should be considered best practice for all Queen Mary and Barts Health sponsored research and should be applied proportionately to other types of clinical research that do not fall within the scope above.

Abbreviations:

ATIMP	Advanced Therapy Investigational Medicinal Product(s)
Barts Health	Barts Health NHS Trust
CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
DMC	Data Monitoring Committee
GCP	Good Clinical Practice
JRMO	Joint Research Management Office
MHRA	Medicines and Healthcare Regulatory Agency
NIHR	National Institute for Health Research
Queen Mary	Queen Mary University of London
SOP	Standard Operating Procedures
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

SOP Text:		
	Responsibility	**Activity**
1.	Chief Investigator (CI)	**All MHRA Regulated Studies must have a Trial Steering Committee (TSC).** All CTIMPs, ATIMPs and Clinical Investigations must have a TSC. For details of the TSC purpose, composition and general guidance *see* *Associated Document 1 Further guidance for Trial Committees .* It is the CI's responsibility to set-up a TSC. All TSCs should include a non-voting Joint Research Management Office (JRMO) Governance section member as a Sponsor representative (for CTIMPs, ATIMPs and Clinical Investigation Trials this is usually a Good Clinical Practice (GCP) and Governance manager). For further detailed guidance, see the *National Institute for Health Research (NIHR's) Trial Steering Committee and Study Steering Committee Guidance*
2.	CI and named study statistician	**Assess the need for a Data Monitoring Committee (DMC).** For all CTIMPs, ATIMPs and Clinical Investigations, a justification from the named statistician and CI should be provided at the study design stage to ascertain if a DMC is needed. The CI should consider whether the funder has any requirements during this decision-making process. For details of the DMC purpose, composition and general guidance *see* *Associated Document 1 Further guidance for Trial Committees .* For Clinical Investigations, the decision of whether to include a DMC should be based on the study risk assessment. This should be discussed with the allocated GCP and Governance manager at study design stage.
3.	CI	**All CTIMPs, ATIMPs and Clinical Investigations require a Trial Management Group (TMG)**. It is the CI's responsibility to set-up a TMG. For details of the TMG purpose, composition and general guidance see *Associated Document 1 Further guidance for Trial Committees* and *Template 1 Trial Management Group Remit*.
4.	CI	**Trial committees must be documented within the protocol.** All CTIMPs, ATIMPs and Clinical Investigations must outline their trial committees within the protocol. Individuals should not be named but committee roles (i.e. Chair, Statistician, etc.) should be indicated in the protocol. For all committees convened the following should be produced and retained: • Charter (*Associated Document 2*); located within Sponsor Over-sight File and the Trial Master File (TMF) • Conflict of Interest Declarations from all members and attendees (*Associated Documented 3 Competing Interests Form*); located within Sponsor Oversight File and TMF • CV and GCP training (all members with the exception of any consumer / public / patient representatives on the committee); located within TMF only.

5.	CI	**Committees should be set up prior to study activation.** Membership of committees should be agreed, the charter drafted, and first meeting scheduled ideally prior to the sponsor issuing confirmation of sponsorship with permission to activate sites. The CI will provide copies of signed finalised charters to the sponsor immediately after the first meeting. Committees should continue to meet until the End of Trial Notification is submitted, in accordance with the protocol and charter.
6.	CI	**All members of any committee should receive appropriate/proportionate GCP training**. This can be the JRMO's GCP training or the NIHR's online GCP course. Barts Health and Queen Mary committee members are welcome to attend the JRMO training at no cost. For Clinical Investigations, committee members should have appropriate ISO 14155 training. (See the *JRMO website* for booking details or email: research.governance@qmul.ac.uk) It is the CI's responsibility to ensure all committee members are appropriately trained. **EXCEPTION:** Any consumer / public / patient representatives on the committee do not need to attend a certified GCP/ISO14155 course, but the CI should ensure they are given a level of understanding of the research environment and GCP/ISO14155. This training should be documented within the TMF.
7.	CI or delegate	**All meetings and critical decisions must be documented.** All meetings (blinded sections and unblinded), discussions and decision-making must be documented and retained in the TMF. Blinded reports, and discussions surrounding blinded reports, must be retained by the independent committee chairman until the study team is formally unblinded. After this point, the chairman must ensure the blinded documentation is added to the TMF prior to archiving. For CTIMPs, ATIMPs and Clinical Investigation *only*, minutes should be sent to the GCP team. The timing of this will vary depending on the type of reporting a team is performing. Minutes will either be attached to quarterly reports and/or disseminated as part of the main minutes distribution list.
8.	Clinical Trial Monitors	**Minutes should be chased, reviewed (where appropriate), saved and filed appropriately (As per *SOP 27 Filing*).** The timing of the distribution/receipt of minutes should be agreed at the final governance meeting or when confirmation of sponsorship is issued. Minutes will be chased at each monitoring visit and/or on receipt of summary monitoring reports. Failure to submit minutes will be escalated and/ or items from minutes via GCP manager to the Sponsor Oversight Group. Where possible, or where concerns are raised, minutes will be reviewed by a member of the GCP team.

Change control

This section outlines changes from version 4.0 to version 5.0

Section changed	Summary and description of changes
Definitions	Moved to guidance document
Relevant SOPs	Removed and replaced with hyperlinks
Section 3	Trial Management Group Remit moved to a template format
Section 5	Addition of requirement to provide signed charter copies following the first meeting

List of appendices

There are no appendices

List of associated documents

Document number	Document name
Associated Document 1	Further Guidance for Trial Committees
Associated Document 2	Sample DMC Charter template
Associated Document 3	Competing Interests Form

Templates

Template number	Template Name
Template 1	Trial Management Group Remit