UNIVERSITY OF WARWICK

STANDARD OPERATING PROCEDURE 12

GCP Defined Responsibilities

Part 1: Trial/Study Management Group and day-to-day activities

Version:	5.0
Approval Date:	20/08/2026
Effective Date:	03/09/2026
Review Date:	02/09/2028
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Revision Chronology:	Effective date:	Reason for change:
Version 5.0	3 September 2026	Biennial review: Updated to new template and aligned with current regulations. Replaced Co-CI with Co-I, clarified CI/Co-I responsibilities and delegation arrangements, strengthened TMG requirements, added guidance on blinded/unblinded data sharing and unblinding responsibilities, and updated trial delegation of responsibilities procedures. Further minor amendments throughout.
Version 4.0	5 June 2024	Amend image in 4.3.2.1 to clarify amendment type for change of PI.
Version 3.0	20 October 2023	Change of Title, linking SOP 12 parts 1, 2 and 3 for clarity. Addition of Co-CI considerations. Minor amends to text.
Version 2.0	12 May 2022	Biennial review: Change to new format. Minor amends to text.
Version 1.6	22 January 2020	Biennial review: Change to new format. Minor amends to text throughout.
Version 1.5	24 October 2017	Biennial review. Updated web links. Format changes. Addition of TMG charter template. Addition of information regarding the delegation of responsibilities where there are two PI's.
Version 1.4	17 June 2015	Addition of procedures to follow on the loss or change of a Chief Investigator
Version 1.3	2 June 2014	Amendments to trial team responsibilities. Addition of TMG information.
Version 1.2	7 May 2012	Updated web links. Format change only.
Biennial review April 2010 Version 1.1		No changes.
Version 1.0	March 2006	Format change.

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1 Purpose and Scope

The purpose of this SOP is to detail common roles and appropriate allocation of day-to-day responsibilities for research team members, including the TMG, to help ensure the smooth running of a clinical research trial.

There are also other groups who have responsibility for the trial, but who are not involved on a day-to-day basis with the running of the trial. These are called oversight committees and include the TSC and DMC. Responsibilities of these groups are covered in Part 2 and Part 3 of this SOP, respectively.

It is applicable to any member of staff working on a University of Warwick sponsored research trial. Staff working on trials with external sponsors must ensure they are following their sponsor's requirements.

2 Acronyms

API	Associate Principal Investigator
CDMS	Clinical Data Management System
CI	Chief Investigator
Co-I	Co- Investigator
CRF	Case Report Forms
CtQ	Critical to Quality
DMC	Data Monitoring Committee
DMP	Data Management Plan
EAP	Employee Assistance Programme
GCP	Good Clinical Practice
HEAP	Health Economic Analysis Plan
PI	Principal Investigator
QA	Quality Assurance
RAMP	Risk Assessment, Monitoring Plan
REC	Research Ethics Committee
R&IS	Research and Impact Services
SAP	Statistical Analysis Plan
SOP	Standard Operating Procedure
SPM	Senior Project Manager
TC	Trial Coordinator
TM	Trial Manager
TMG	Trial Management Group
TSC	Trial Steering Committee
WCTU	Warwick Clinical Trials Unit

3 Definitions

Clinical Trial/Study*:	Any prospective evaluation of a health care intervention involving human participants, including the administration of a treatment or type of management, diagnosis, or the provision of lifestyle (e.g., dietary) advice.
TMG	The TMG includes individuals responsible for the day-to-day management of the trial, such as the CI, Statistician, TM, Health Economists, Data Manager etc. The role of the group is to monitor all aspects of the conduct and progress

	of the trial, ensure that the protocol is adhered to and take appropriate action to safeguard participants and the quality of the trial itself.
CI:	The healthcare professional who takes primary responsibility for the conduct of the trial, whether or not they are an investigator at any particular trial location. An investigator assigned responsibility for the coordination of investigators at different trial locations participating in a multicentre trial.
Co-I	For regulatory purposes there must be one single healthcare professional who has overall responsibility. Trials may include Investigators that have extensive responsibilities and input and are subsequently called Co-Is. It is important to distinguish between CI and Co-I roles.
Coordinating Centre:	The centre involved in managing the trial
Investigator/Principal Investigator:	A person responsible for the conduct of a trial at a trial location. If a trial is conducted by a team of individuals at a trial location, the investigator is the responsible leader of the team.
Sponsor:	An individual, company or organisation which takes responsibility for the initiation, management and/or financing of a trial.
Essential documents:	Documents which must be signed by the CI with overall responsibility: Protocol (and any associated amendments) Coordination centre delegation log CRFs Patient Information Sheet(s) and Consent Form(s) DMP RAMP Regulatory and REC submissions (including amendments)

**Throughout the SOP 'Trial' will be used, but can be interchanged with 'Study'*

4 Background

GCP guidelines state that prior to initiating a trial, the sponsor (delegated to WCTU for WCTU-managed trials) should define, establish, and allocate all trial related duties and functions and that each individual involved in conducting a trial should be qualified by education, training, and experience to perform their respective task(s).

It is essential that all staff involved are aware of the anticipated extent of their involvement and limits to their authority.

It is a requirement for all Warwick staff involved in research to read the University of Warwick Research Code of Practice which is available on the R&IS website. This informs staff of good practice for day-to-day involvement in research at Warwick.

5 Responsibilities

Sponsor	• Liaise with CI (and Co-I where applicable) to agree division of responsibilities • Completion of the applicable Delegation of Responsibilities form (see section 7.2.2)
CI	• Overall oversight (safety and scientific integrity)

	• Application and signatory for the REC opinion. • Liaise with Sponsor's Office to agree trial responsibilities and document appropriately. Delegate tasks to trial team and document on Coordinating Centre Signature & Delegation Log • Chair TMG meetings and ensure meetings have clearly documented minutes and action logs • Approval of essential records • Ensure all unblinding events are assessed/discussed for impact on the trial and documented at TMG meetings
Co-Investigator	• Any CI-related tasks other than overall oversight, delegation of CI activities and ethical and regulatory submission approval. The delegated activities must be clear on the Coordination Centre Signature & Delegation Log.
All staff	• Ensure familiarity with Good Clinical Practice (GCP) principles • Ensure relevant training applicable to role is completed (to include reading and acknowledging all relevant SOPs)

6 When

Individual trial-related duties and functions should be defined, established and allocated prior to green light and reviewed throughout the lifetime of the trial.

7 How

An outline of some key responsibilities of each role/committee is given below. Details of some responsibilities may vary according to the trial, and the make-up of the team will vary depending on trial design. For WCTU managed trials, the CI will work with their SPM to allocate roles and create an appropriate team.

7.1 TMG Meetings

Constitution:
The TMG normally includes those individuals responsible for the day-to-day management of a trial at the coordinating centre. Membership usually comprises of the CI, SPM, TM (or TC), Statistician, Health Economist and others as appropriate for the stage of the trial.

Frequency:
The TMG should meet regularly, as appropriate for the phase of the project. Meetings are generally held monthly, however, the frequency should be reviewed and agreed throughout the lifecycle of the trial and may be adjusted according to the level of trial activity and associated risks.

Remit:
The TMG is responsible for monitoring the conduct and progress of the trial, to ensure protocol compliance, safeguard participants and maintain trial quality. The TMG should identify and periodically review the trial's CtQ factors and associated risks, ensuring that risks are appropriately managed and mitigated. Trial oversight should focus on participant safety, trial integrity and the reliability of trial results. See SOP 18 Risk Assessment & Monitoring for further details.
Prior to each meeting, a summary report should be circulated to attendees. Trials using a CtQ-based approach should use the TMG report and meeting slide set (Template **T79**), to provide oversight of key CtQ indicators, associated risks and trial progress. For legacy trials, or trials where CtQs have not yet

been formally defined, the TMG agenda template (**T28**) and other appropriate summary reports may be used.

For blinded trials, care must be taken to ensure that information shared with TMG members does not compromise blinding. TMG reports should normally contain aggregated or appropriately blinded data. Any unblinded data should only be shared with individuals authorised to review such information, as defined in the trial-specific procedures and governance documentation.
Comprehensive minutes should be recorded for each meeting to document key discussions, actions, and decisions (see list of templates below). A copy of the agenda, minutes and associated report(s) should be filed in the TMF. It is good practice to maintain a decision and action log to document decisions made by the TMG and track completion of associated actions.

TMG Charter:
A TMG Charter should be established using template (**T27**). The Charter should define the membership, roles and responsibilities, Chair, quoracy requirements, conduct, decision-making processes and arrangements for declaring and managing conflicts of interest.
The CI is responsible for reviewing all declared conflicts of interest and ensuring that any required mitigations or escalations are managed appropriately. Confirmation of the review and any resulting actions should be documented in the TMG minutes.
Where Co-Is are appointed, the Charter should clearly define accountability, including the individual with final decision-making authority where required.

7.2 CI and Co-I

7.2.1 CI and Co-I Responsibilities

The CI is the lead investigator taking responsibility for the overall conduct of the trial and for the safety of trial participants. The CI should be a healthcare professional who is appropriately trained and has relevant experience to undertake this role. For further guidance on who can be a CI, refer to the HRA website.
Several funders also allow the listing of Co-Is. Where Co-Is are appointed, their roles and responsibilities must be clearly documented and approved by the Sponsor prior to trial commencement. Any responsibilities that may be undertaken by a Co-I in exceptional circumstances must be predefined and documented. Such arrangements should only apply where the CI is unavailable and an urgent decision or action is required. Examples may include the review and approval of essential trial records or other time-critical trial activities. Overall accountability for trial conduct remains with the CI.

7.2.2 Documentation of Responsibilities

The Sponsor, in collaboration with the CI (and Co-I where applicable) shall ensure that trial-related responsibilities are appropriately allocated and documented using the relevant Delegation of Responsibilities document identified through the Delegation of Responsibilities Toolkit. See SOP 03 Sponsorship for further details.

The selected document should clearly document delegated activities, oversight arrangements, and accountability between participating organisations. For blinded trials, responsibilities relating to blinding and unblinding must also be explicitly documented, including responsibility for authorising, performing and documenting any unblinding events (see SOP 41 Blinding and Unblinding in Research Studies). Clear

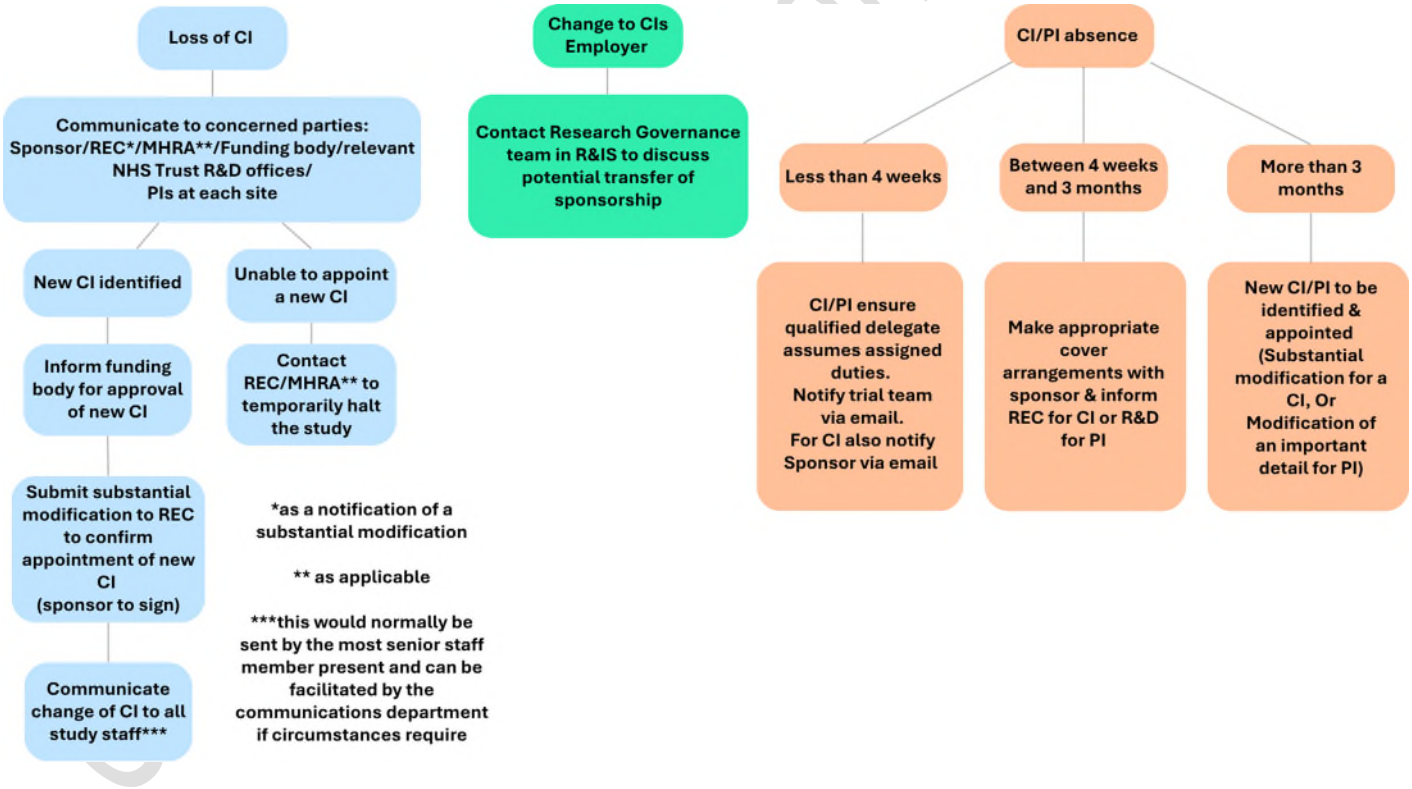
allocation of these responsibilities is essential to maintain trial integrity, minimise the risk of unnecessary unblinding, and ensure participant safety.

7.2.3 Trial Activation and Delegation Documentation

Once all required approvals/contracts are in place, the CI or their delegate should follow the guidance in SOP 26 Clinical Research Study Activation, Site Selection and Initiation and sign the 'Clinical Study Green Light' Form, (**T18**). For WCTU managed trials, the WCTU QA team will review the form and confirm all the required elements are in place via an email to the trial team and sponsor's office prior to submission for approval signatures.

Roles and responsibilities of staff at the coordinating centre should be delegated as appropriate and documented using the Coordinating Centre Signature & Delegation Log form (Template **T23**). Electronic versions of delegation logs may be used where staff are working remotely, and the CI may approve via email (follow **G33**, email approval guidance). For trials that have an eTMF via SharePoint this form is inbuilt into the system, therefore delegation and CI sign off can be managed via SharePoint.

7.2.4 Procedures required on the change, loss, or absence of trial CI/PI



If the circumstances around the loss or change of a CI are in any way distressing and staff are upset by the news, the University has a counselling service available via Wellbeing Support Services. Alternatively, staff can access the university's Employee Assistance Programme (EAP) - a confidential support service that provides help to deal with personal and professional problems that could affect home or work life, or health and general well-being.

7.3 PI

The PI is responsible for the trial at their site. They should nominate appropriately qualified/trained and experienced staff, for example research nurses, to assist in the recruitment and follow-up of participants and to provide specific expertise if required. Roles and responsibilities of site staff should be documented using the Site Signature and Delegation Log (**T22**), alternatively, the delegation functionality within the CDMS may be used, which enables delegated tasks to be assigned and aligned automatically with the relevant database user roles.

If there is change of PI at any point, it may be necessary to arrange for the site agreement to be updated and re-signed by the site team. Contact the contracts team in R&IS to obtain advice.

See the process flowchart above for details of how to manage loss, absence or change of a PI.

The NIHR have an Associate PI scheme, details of which can be found here. The scheme is a six month in-work training opportunity, providing practical experience and mentorship for healthcare professionals starting their research career. Where an API is involved, the site delegation log should state their responsibilities.

7.4 TM/TC

The day-to-day conduct of the trial is usually the responsibility of the TM or TC. Additional support may be provided from a SPM to ensure that trial milestones are met and further operational/administrative support e.g., DEC(s). Recruitment Facilitators may be required to help with day-to-day activities.

Main duties for a TM or TC include:

- Planning and coordination of trial activities using project management and administrative expertise to ensure recruitment targets are met
- Responsibility for submission of all relevant applications for approval on behalf of the CI
- Ensuring adherence to GCP, SOPs, University policies and relevant regulatory requirements
- Acting as main point of communication between CI, funders, regulatory agencies, and clinical teams
- Creation and maintenance of trial documentation
- Reports to and minutes from the TMG and other related materials
- Management of trial data
- Line management of trial team and ensuring training needs are met
- Ensuring adherence to trial contracts and/or agreements.

7.5 Senior Project Managers

The SPM role is to provide high level project management input across a portfolio of clinical trials to ensure that projects are delivered on time, within budget and in accordance with the protocol, contracts and agreements and all relevant regulations.

7.6 QA Team

The QA role is to provide oversight to ensure that all trials are conducted in compliance with the relevant regulatory requirements and legislation. This includes oversight of appropriate training for the staff concerned and monitoring of trial processes and procedures. See SOP 19 ‘Quality Control’, SOP 24 ‘Essential Training and Training Records’, SOP 25 ‘Auditing’ and SOP 31 ‘Handling non-compliances’ for further details.

7.7 Programmer

The Programmer leads the development, creation, validation, and maintenance of the bespoke CDMS to comply with the legal and regulatory obligations to safeguard clinical trial data. Further information regarding the activities of the programming team is provided in SOP 14 'Clinical Trial Software Development' and SOP 42 'Clinical Data Management System (CDMS) Planning & Maintenance'.

7.8 Statistician

The Statistician should be involved in all phases of the trial, from the research proposal and funding application to the analysis and reporting stage. Their main responsibilities include development of the protocol, CRFs, development of the trial database, SAP and analysis, reporting and publication of the results. Further information is provided in SOP 8 'Statistical Considerations' and SOP 21, 'Statistical Analysis Plan'.

7.9 Health Economist

The Health Economist is responsible for the economic evaluation alongside a trial. They are responsible for assisting with developing the protocol, relevant CRF development, preparing a HEAP, managing the health economic data as it is received and analysis, reporting and publication of the results. Further details are available in SOP 33 'Economic Evaluation Considerations'.

8 Associated Templates and Documents

T18	Permissions Required to Commence a Randomised Controlled Trial Form (Green Light)
T22	Site Signature and Delegation Log
T23	Coordinating Centre Signature and Delegation Log
T28	Trial Management Group Agenda Builder
T27	Trial Management Group Charter
T31	Minute writing template
T29	Decision and action log
T79	TMG Meeting Report
G33	Email approval guidance