

STANDARD OPERATING PROCEDURE 1

SOP Development and Approval for Warwick-Sponsored Studies

Version:	5.0
Approval Date:	17/12/2025
Effective Date:	31/12/2025
Review Date:	31/12/2027
Review Lead:	Greg Scott, QA Support Officer, WCTU
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Sponsor Reviewers:	Mathew Gane, Research Governance & QA Manager, R&IS
WCTU approval:	Natalie Strickland, Head of Operations, WCTU
Sponsor approval:	Carole Harris, Associate Director Research Culture, Governance and Compliance

Revision Chronology:	Effective date:	Reason for change:
Version 5.0	31 Dec 2025	Biennial review. Removed references to Q-Pulse. Updated processes for approval, making change requests, versioning and archiving in line with move to SharePoint. Simplified text throughout. Added sections for specific tasks for clarity. Changed to and updated text in line with new template.
Version 4.0	08 Nov 2023	Procedures amended to reflect new acknowledgement process for SOPs. Slight amends to flow chart on SOP review process.
Version 3.0	15 November 2022	Biennial review. Change to new template. Minor amends to text only.
Version 2.2	21 July 2020	Change to new template. Inclusion of Contents page.
Version 2.1	16 August 2019	Change to new template. Change to review and approval process. Procedure for proportionate review of minor amendments added.
Version 2.0	4 September 2018	Change to review and approval process, new process flowchart included.
Version 1.8	20 July 2017	Change to new template. Change to review process: Use of Q-Pulse system and addition of R&IS staff as reviewers and approvers.
Version 1.7	21 March 2016	Addition of new SOP review process within WCTU. Change to new format.
Version 1.6	16 February 2015	Biennial review; minor text amends only. Change to named WCTU approver
Version 1.5	9 January 2013	Addition of sign-off procedure by Sponsor.
Version 1.4	13 February 2012	Web site link updated. Format changed to comply with SOP.
Version 1.3	28 January 2010	WMSCU abbreviation changed to WCTU. Website address updated.
Version 1.2	30 January 2008	Addition of section 1 to comply with SOP template. Addition of text to clarify SOP review process.
Version 1.1	20 Dec 2006	Addition of cover page for revised SOPs to state author and approver.
Version 1.0	March 2006	

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1 Purpose and Scope

To define the process for developing, approving, and controlling all SOPs related to clinical research activities conducted on behalf of UoW. This includes studies sponsored or co-sponsored by UoW in accordance with the UK Policy Framework for Health & Social Care Research (2017) and the Medicines for Human Use (Clinical Trials) Regulations 2025.

This SOP applies to:

- All University staff involved in preparing, reviewing, and approving SOPs for Warwick-sponsored/co-sponsored studies,
- Staff working on externally sponsored studies where use of Warwick SOPs is agreed
- Research activities requiring adherence to Warwick SOPs.

2 Abbreviations

GC	Governance Committee
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
MHRA	Medicines and Healthcare products Regulatory Agency
QA	Quality Assurance
R&IS	Research & Impact Services
SOP	Standard Operating Procedure
UoW	University of Warwick
WCTU	Warwick Clinical Trials Unit

3 Definitions

SOP	Detailed written instructions to achieve uniformity of the performance of a specific activity
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4 Background

UoW SOPs cover key areas of research study management and aim to ensure that all University sponsored, and co-sponsored studies conform to the standards of ICH GCP and all applicable research governance and legal requirements.

SOPs will form the basis for any audit/inspection by internal or external bodies. It is essential that all staff are familiar with the procedures and work according to the directions given.

5 Responsibilities

WCTU QA Managers/R&IS Research Governance Team	<ul style="list-style-type: none"> • Coordinate biennial reviews of Warwick SOPs relating to research activities • Update SOPs in between the biennial review process if new requirements/systems/processes arise • Keep WCTU SOP web pages up to date (WCTU QA team only)
WCTU Governance Committee	<ul style="list-style-type: none"> • Review and approve new/revised SOPs (the committee includes staff representing R&IS)
All staff	<ul style="list-style-type: none"> • Read all SOPs required by their role • WCTU staff must acknowledge they have read and understood new or revised SOPs via the MS Team 'WCTU Personal Development' • Submit a change request if an update to an existing SOP is required

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6 When

SOPs are reviewed every two years by an appropriate lead following the process in section 7.3. Updates are made as needed, and new versions are issued with a revised effective date. If no changes are required, the version number and date are still updated, and a note confirming no changes is added to the revision chronology table.

If significant changes occur during the two-year period between reviews, the relevant SOP(s) will be updated and approved following the procedure described in section 7.5.

New SOPs should be produced to detail the requirements of any task, process or procedure requiring a controlled, systematic approach to its completion.

7 How

7.1 Format and content

SOPs will include a cover page documenting the Review Lead, and who reviewed and approved the SOP. It will also state the effective date and the next review date.

SOPs will comply with the standard template attached as Appendix 1, including the header, footer, contents page etc.

SOPs will have separate pagination with the version number and effective date in the footer of each page.

Each SOP must be written logically and concisely, using short sentences and avoiding repetition. All abbreviations and acronyms should be defined in a table located in section 2.

Whenever reference is made to another activity covered by a SOP, the instruction: see SOP number 'xx, <Short title>' should be included.

7.2 Circulation and distribution

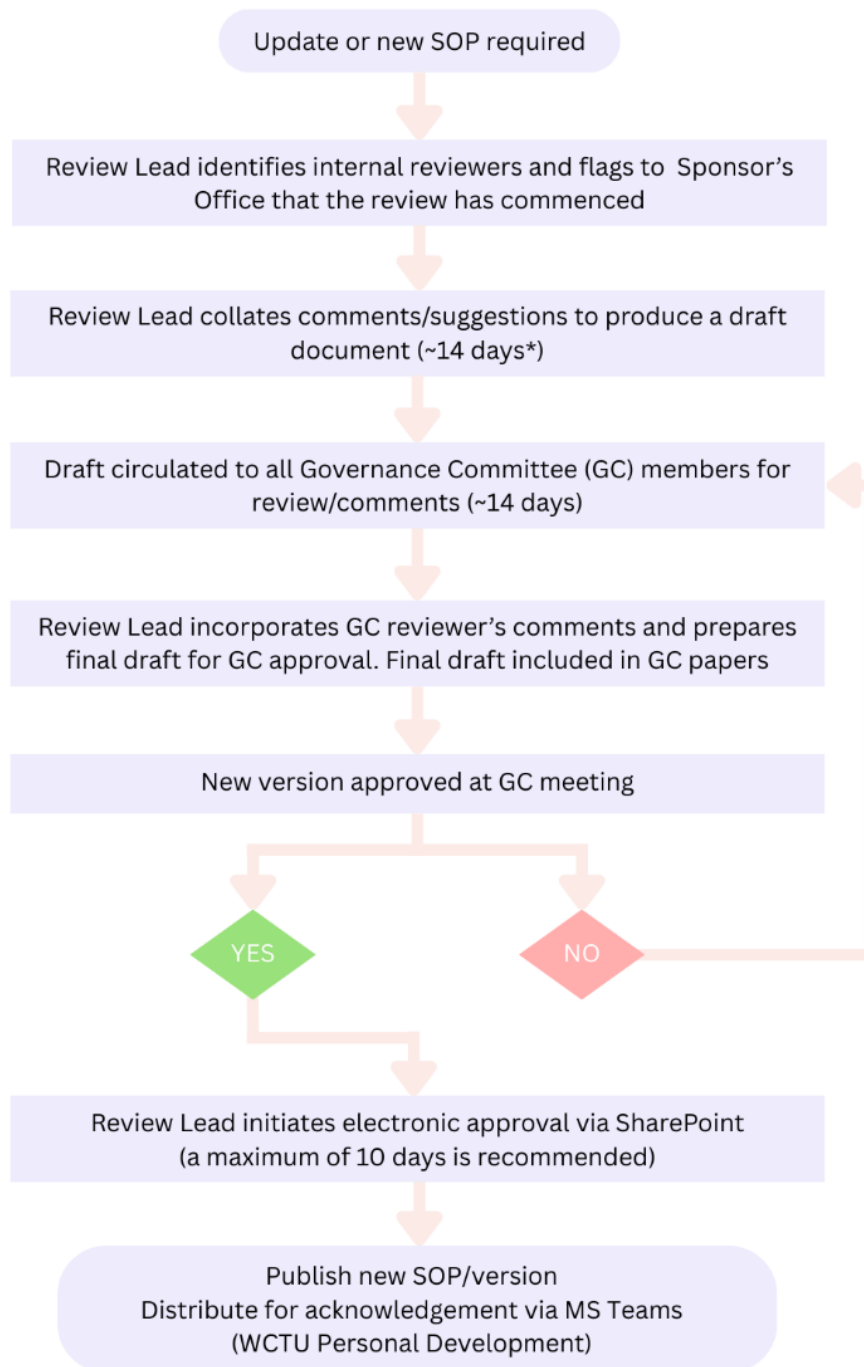
The University maintains a master copy of all current approved SOPs and associated reference documents in the WCTU QA Team's SharePoint site. An electronic read-only copy of the latest version of all SOPs are available here:

- WCTU website: <https://warwick.ac.uk/fac/sci/med/research/ctu/ctuintranet/qa/sop>
- Via a link on the R&IS website: <https://warwick.ac.uk/services/ris/research-integrity/apply-sponsorship/>

Staff should not use saved or printed copies to ensure they follow the latest version. Current SOP PDFs display a watermark: "Uncontrolled when printed" as a reminder to check the website.

7.3 Preparation, review and approval process

Preparation of new SOPs and subsequent reviews will be led by the named Review Lead with input from other Nominated Reviewers, including specialist input where required (e.g., statisticians, health economists, programmers, R&IS staff) following the process flow below:



**If a major re-write is required, timelines may vary. Where this occurs, deadlines should be internally agreed and documented with justification which should be reported at GC*

The WCTU QA team maintains documentation to detail the effective and review dates for each SOP.

7.4 Version Control

When a new SOP is created in draft form, it should be designated as version 0.1. Subsequent revisions to the draft document should be designated as version 0.2, 0.3 etc. Once agreement on final content has been reached, the draft document will be named version 1.0 upon approval.

All draft documents revised during the review period will amend the number after the decimal point. E.g., version 1.0 of a document undergoing review will be named as v1.1, v1.2 etc. and then be named as v2.0 when the review process is complete, and the new version is approved.

The revision chronology section of each SOP should detail any changes made, if it replaces a previous version, and, if so, which version.

7.5 Updates to SOPs

If an urgent amendment is required (e.g., changes to processes, guidance or legislation) the revised document may be approved directly by the Governance Committee without the need for input from multiple reviewers to avoid delay in implementation. The version number should be increased in accordance with the instructions detailed in section 7.4.

Any non-urgent amendment, such as a minor inaccuracy or typographical error, will be added to the change request log and implemented in the next biennial review.

7.6 Change requests

Staff who identify an update, error, or discrepancy for a SOP can raise this via the '[Make a SOP change request](#)' form. Alternatively, they should contact the Review Lead named on the SOP cover sheet, and either the WCTU's QA team via: wctuqa@warwick.ac.uk or the Research Governance Team in R&IS via: researchgovernance@warwick.ac.uk to flag as required.

7.7 Archiving

Superseded versions of all SOPs are archived electronically within the SOP Library in the WCTU QA team's SharePoint site as previous versions of the current document. Versions in place prior to the use of the SOP Library are saved on the WCTU shared drive. Evidence of approvals are recorded in the Governance Committee minutes and on the archived Q-Pulse system stored on Warwick servers.

8 Appendix 1: Template SOP

Laid out below is the expected content for these SOPs. A copy of the latest SOP template is available from the WCTU QA team on request.

SOP Title

Cover Page: as for this SOP

Header: as for this SOP

Footer: as for this SOP

Contents

Main text:

1. Purpose and Scope

Detail the reasons why the SOP has been written, to which staff and the setting in which it is applicable, and what needs to be achieved.

2. Abbreviations

Include as applicable

3. Definitions

Include as applicable

4. Background

Briefly discuss the background to the procedure, referring to legal requirements and national or international guidance as applicable. Consider the driving forces or why the procedure is necessary.

5. Responsibilities

Define the individual responsibilities of each person, team or committee involved.

6. When

Describe at what stage of study activity the SOP applies.

7. How?

Step-by-step description of the procedure to be followed. Include relevant sub-sections as required to describe each step

8. Templates/Associated documents

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Include a list of any templates or associated documents referred to in the SOP.

9. Appendices

Appendices should be included as necessary.