STANDARD OPERATING PROCEDURE 1
Preparation, Review and Approval of Standard Operating Procedures for University of Warwick Sponsored and Co-Sponsored Studies

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Author:	Claire Daffern, Quality Assurance (QA) Manager, Warwick Clinical Trials Unit (WCTU)		
WCTU Reviewers:	Jo Grumett, QA Manager, WCTU Kerry Raynes, Clinical Trial Manager, WCTU		
Sponsor Reviewers:	Mathew Gane, Research Governance & QA Manager, Research & Impact Services (R&IS)		
WCTU approval:	Natalie Strickland, Head of Operations, WCTU		
Sponsor approval:	Carole Harris, Assistant Director, R&IS (Systems & Strategic Projects) & Head of Research Governance		
Review Lead:	WCTU QA Team		

Contents

Revision Chronology:	Effective date:	Reason for change:
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	WMSCTU 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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Preparation, Review and Approval of Standard Operating Procedures for University of Warwick Sponsored and Co-Sponsored Studies

1. Purpose and Scope

The purpose of this Standard Operating Procedure (SOP) is to define the format, approval, issue and control of all SOPs for studies where the University of Warwick (University) undertakes the role of sponsor or co-sponsor as defined either by the UK Policy Framework for Health & Social Care (2017) or The Medicines for Human Use (Clinical Trials) Regulations (2004), as appropriate. This SOP applies to all University staff who are involved in the preparation, review and approval of SOPs for University of Warwick sponsored and co-sponsored studies. It also applies to staff working on any externally sponsored studies where the use of Warwick SOPs has been agreed.

2. Definitions

Standard Operating Procedure (SOP)	Defined by the International Conference for Harmonisation on Good Clinical Practice (ICH GCP) section 1.55 as "*detailed written instructions to achieve uniformity of the performance of a specific function*".

3. Background

Section 2.13 of ICH GCP states that *"systems with procedures that assure the quality of every aspect of the trial should be implemented".*

The University's 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 GCP and all applicable research governance and legal requirements.

SOPs will form the basis for any audit/inspection by regulatory bodies such as the Medicines and Healthcare products Regulatory Agency (MHRA), thus it is essential that all staff are thoroughly familiar with the procedures and work according to the directions given.

4. Procedure

4.1 Responsibilities

WCTU QA managers/R&IS Research Governance Team	• To coordinate the biennial reviews of all Warwick SOPs relating to research activities • To update SOPs in between the biennial review process if new requirements/systems/processes come into force. • To keep WCTU SOP web pages up to date
WCTU Governance Committee	• To review and approve all new/revised SOPs (the committee includes staff representing R&IS)

All Research active staff	• To 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'.

4.2 When?

SOPs are dynamic documents and need to be reviewed regularly. An overall review will be carried out on each SOP every two years by an appropriate review lead following the process detailed on the flowchart in section 4.3.3 (the review lead will be documented on the cover sheet).

SOPs will be updated as required at their biennial review date, and a new version will be approved and issued with a new effective date. If no changes are required at the point of the biennial review, the version number of the document will still be changed (along with the effective date), and a statement to confirm that no changes were required will be added into the revision chronology table.

If significant changes occur during the two-year period between reviews which will affect any SOP, the relevant SOP(s) will be updated and approved following the procedure described below.

If an urgent amendment is required for compliance to be maintained (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 any delay in implementation. The version number should be increased in accordance with the instructions detailed in section 4.3.4.

If a minor amendment only is required i.e., to correct a minor inaccuracy, this may also be amended and taken to the Governance Committee for approval.

If a typographical error is noted and flagged, this will be amended with no change to the version number. The amended version will be uploaded to the relevant websites and on the Q-Pulse system to indicate it is the current implemented version.

Any member of staff who feels that a particular SOP needs updating, or who finds a perceived error, discrepancy or inconsistency, should contact the Lead Reviewer set out on the SOP cover sheet, and either the WCTU's Quality Assurance (QA) team via: wctuqa@warwick.ac.uk or the Research Governance Team in R&IS via: researchgovernance@warwick.ac.uk to flag as required. Alternatively, a 'change request' can be made on the relevant document record in the Q-Pulse system for those staff who have access.

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

4.3 How?

4.3.1 Format and content

New and revised SOPs will include a cover page documenting who has authored, reviewed and approved the SOP. It will also state the effective date and the date when the next biennial review is due.

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

Each SOP 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 on their first appearance and referenced at the end of the document.

Whenever reference is made to another activity covered by a SOP, the instruction: see SOP number 'xx' entitled 'xxx' should be included at the relevant point.

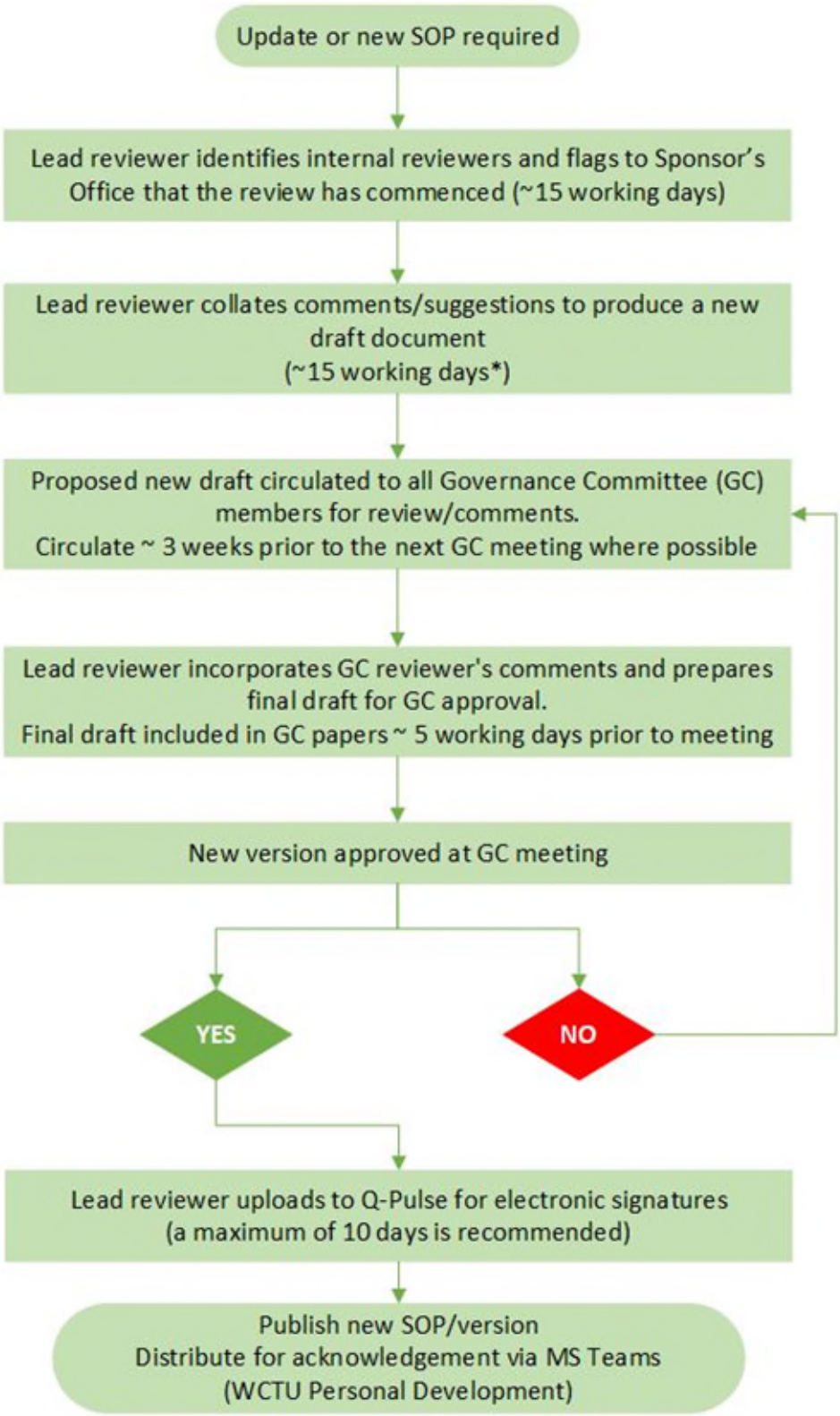
4.3.2 Circulation and distribution

The University maintains a master copy of all current approved SOPs and associated reference documents in the University's electronic quality management system (Q-Pulse), and an electronic read-only copy of the latest version of all SOPs are available on the WCTU website: https://warwick.ac.uk/fac/sci/med/research/ctu/ctuintranet/qa/sop and via a link on the R&IS website: https://warwick.ac.uk/services/ris/research_integrity/sponsorship/ .

Members of staff should always refer to the online published versions of SOPs via the links above, rather than previously saved or printed copies to ensure they are working from current versions. PDF versions of the current version will include a watermark to state 'uncontrolled when printed' to prompt researchers check the website to ensure they are referring to the current version.

4.3.3 Preparation, review and approval process

Preparation of new SOPs and their subsequent reviews will be led by the named Lead Reviewer 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 within Q-Pulse to detail the effective and review dates for each SOP.

4.3.4 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 as version 1.0 for approval.

Subsequent reviews of SOPs must follow document management processes outlined in SOP 45: Document Management.

All draft documents which are 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 ready for approval.

All current versions will be published with the version number as a whole integer irrespective of the significance of the changes.

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

4.3.5 Archiving

Superseded versions of all SOPs will be archived electronically within the Q-Pulse system. Versions in place prior to the use of the Q-Pulse system are saved on the WCTU shared drive.

List of 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
WCTU	Warwick Clinical Trials Unit

Appendix 1: Template SOP

Cover Page: as for this SOP

Header: as for this SOP

Footer: as for this SOP

Main text:

Title

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. Definitions

Include as applicable

3. 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.

4. Procedure

4.1 Responsibilities

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

4.2 When?

Describe at what stage of study activity the SOP applies.

4.3 How?

Step-by-step description of the procedure to be followed.

List of Abbreviations

Templates/Associated documents