STANDARD OPERATING PROCEDURE 34

Generation, Review and Approval of Study Specific Working Instructions

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Contents

Revision Chronology:	Effective date:	Reason for change:
Version 3.0	13 December 2024	Biennial review: Minor amends to text and updates to process flowchart.
Version 2.0	22 Sept 2022	Biennial review: Change to new format. Insertion of process flowchart.
Version 1.2	7 May 2020	Biennial review: Change to new format. Minor amends to text. Update to WCTU process for approving Working Instructions.
Version 1.1	21 February 2018	Biennial Review 2017/18: minor clarifications to the text. Updated to reflect use of Q-Pulse for approval. Removal of reference to Data Management Plans.
Version 1.0	25 November 2013	Biennial review November 2015: No changes required.

STANDARD OPERATING PROCEDURE 34

Generation, Review and Approval of Study Specific Working Instructions

1. Purpose and Scope

This Standard Operating Procedure (SOP) details the requirements for the generation, review and approval of study specific Working Instructions (WI) used in the conduct of clinical research studies. Although not mandated, application of the procedures within this SOP would be considered best practice for non-randomised research studies.

The SOP is applicable to any member of staff working on University of Warwick sponsored studies or staff working within WCTU on externally sponsored studies who are involved in the development of Working Instructions/guidance documents to aid study conduct.

2. Definitions

Working Instructions (WI)	A document that provides specific instructions to carry out an activity. Usually, a Work Instruction is a step-by-step guide to perform a single instruction/activity.

3. Background

In addition to the essential documents required by Good Clinical Practice (GCP) guidelines, research projects usually require specific WIs to be produced to provide staff (both at the coordinating centre and at study sites) with sufficient information or instructions to conduct study tasks.

Examples of study specific WIs include (but are not limited to): study physiotherapist manuals, sample collection manuals, procedures for drug ordering etc.

It is good practice to document who has produced study specific WIs and how each version has been reviewed and approved for use prior to implementation.

ICH GCP section 5.4.1 specifies that the study sponsor must utilise qualified individuals as appropriate throughout all stages of the study process, which includes the design of documents.

4. Procedure

4.1 Responsibilities

Chief Investigator (CI)	Responsible for ensuring that all study specific working instruction documents (and any subsequent amendments) are prepared, reviewed by appropriate staff and approved prior to their implementation.
Trial/Study Manager/Coordinator	Usually delegated the task of producing or overseeing the development of working instructions and facilitating appropriate review.

4.2 When?

Study specific Working Instructions should be produced during the study design or set up phase to ensure the approved documents are fit for purpose and ready for use as study procedures commence.

Production of further documents or amendments to current documents may be necessary as the study progresses and should be developed, reviewed and approved as required.

Approved documents should be reviewed e.g., after a protocol amendment or process/SOP change to ensure they remain valid. The review of any impact of the revised protocol or process should be documented e.g., in Trial/Study Management Group (T/SMG) meeting minutes, to detail who was involved in the review and made the decision as to whether the document remained valid or if changes were required.

4.3 How?

A Working Instruction template document – **T65**, is available via https://warwick.ac.uk/fac/sci/med/research/ctu/qa/templates/ and can be used to develop working instructions.

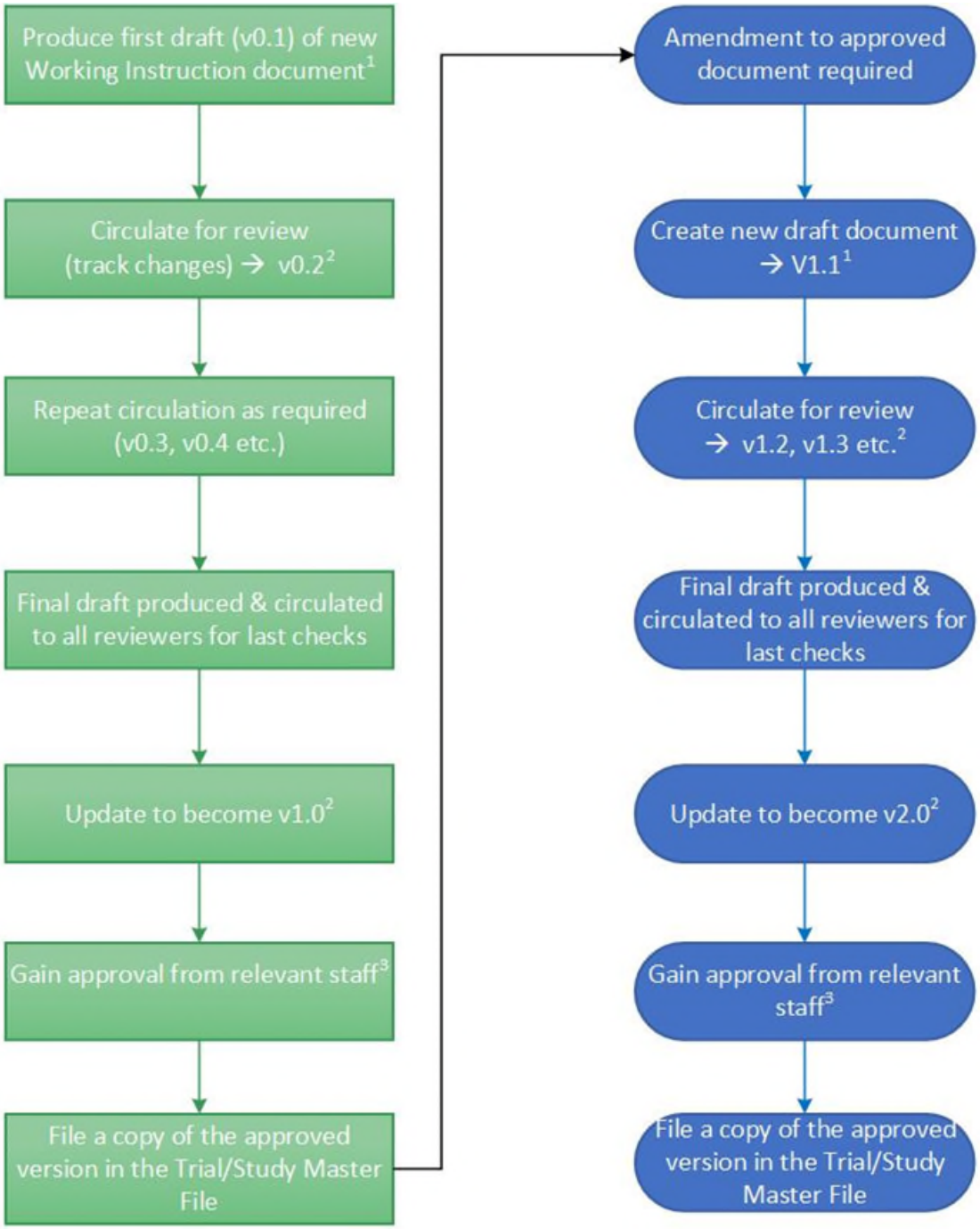
WIs are usually a step-by-step guide to perform an instruction/activity and can include flow charts, diagrams and signposting to other key documents.

WIs also play an important role in ensuring business continuity if people or systems are not available, and for handover and training purposes. Each WI should clearly state the author/s, reviewers and approvers and have a review date set. The flowchart below shows the creation and revision process.

Retain copies of each approved WI version in either the electronic or paper Trial/Study Master File.

Flowchart:

Generation, review and approval of new and amended documents



1. By someone with an appropriate level of knowledge and experience using Template T65.

2. Check any relevant SOP(s) to ensure consistency.
   N. B. Where SharePoint is being used version control will be automated.

3. Approval should be obtained via an appropriate method which provides an audit trail. E.g. via a confirmation email (see G33 email approval guidance), completion of form T39: Review/Approval of Working Instructions or within SharePoint.
WIs may be approved by SPM, TM/TC as appropriate.

See SOP 45 'Document Management' for details of document naming conventions

List of Abbreviations

CI	Chief Investigator
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
QA	Quality Assurance
R&IS	Research & Impact Services
SOP	Standard Operating Procedure
T/SMF	Trial/Study Master File
T/SMG	Trial/Study Management Group
WCTU	Warwick Clinical Trials Unit
WI	Working Instruction

Associated Documents

T39	Review and Approval of Working Instructions Form
T65	Template Working Instruction
G33	Email approval guidance

Q-Pulse Instructions – Document Management