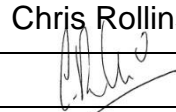


## Standard Operating Procedure

Please refer to <https://www.plymouthhospitals.nhs.uk/research-sops> to ensure the latest version of this document is in use. Printed copies are uncontrolled.

Title:	Preparing, approval and review of SOPs and WIs		
Approver	Document No:	QA1	
Name:	Chris Rollinson	Version No:	6.0
Signature:		Effective Date:	Jan-2022
Date:	11-Jan-2022	Review Date:	Jan-2025

### 1. Purpose

To describe the procedure for developing a new Standard Operating Procedure (SOP) and Work Instruction including the revision and review process of an existing SOP and WI.

SOPs are a controlled document of written methods (who, what, where and when) necessary to achieve a consistent approach to a process and provide a platform for training, monitoring compliance with applicable guidance and regulation, and assessing quality.

WIs are a description of the processes, how to perform a task.

### 2. Scope

This SOP applies to individuals involved in SOP or WI drafting and authorisation.

### 3. Responsibilities

Research Governance Manager (RGM) or in their absence the Assistant Clinical Trials Manager will authorise SOPs. R&D Directors and the R&D Lead Research Nurse may also authorise SOPs in the event of absences.

An SOP/ WI author maybe anyone who has experience of performing, or currently performs a particular task.

### 4. Documents needed for this SOP

- SOP Template
- WI Template
- Document Control List

### 5. Related documents

- Electronic Signature Policy TRW.CGV.POL.1292.1

## 6. Acronyms

**CI:** Chief Investigator

**ISF:** Investigator Study File (the study site file)

**PI:** Principal Investigator

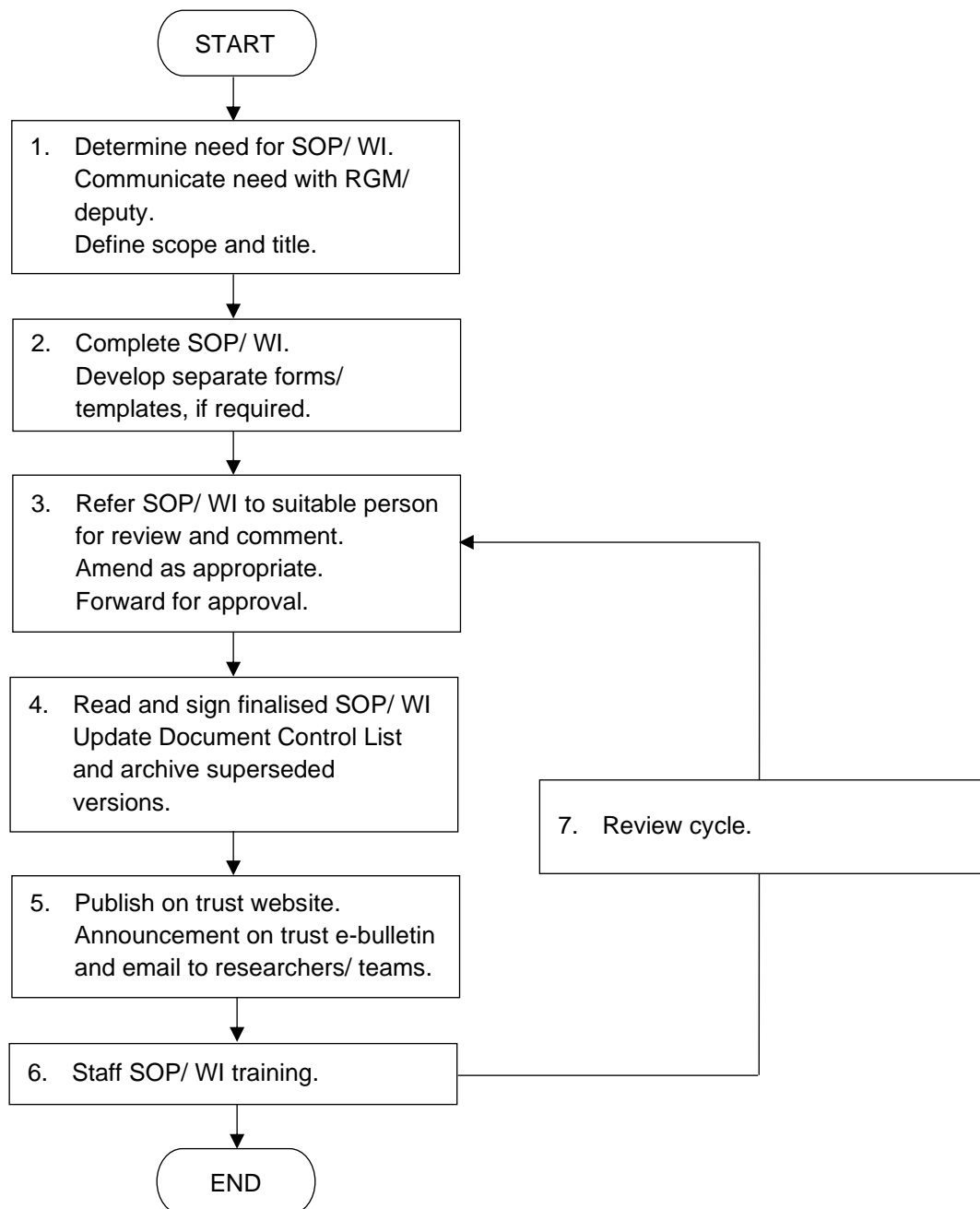
**R&D:** Research and Development

**RGM:** Research Governance Manager





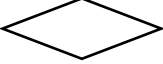




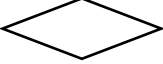




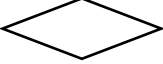
**SOP:** Standard Operating Procedure

**WI:** Work Instruction

## 7. Process map(s)/ flow chart(s)



## 8. Procedure

Step	Action	Responsibility																		
1	<p>Determine need for a new SOP/ WI.</p> <p>Communicate identified gaps in listed procedures/ tasks to the RGM or their deputy. For WIs this may be communicated to line manager.</p> <p>Define scope, purpose and title of SOP/ WI.</p> <p>Verify if any other SOP/ WI for similar procedure/ task in R&amp;D exists or is under development to avoid duplication or divergence. A list of current SOPs, WIs and templates are maintained by the RGM/ their deputy or administrator as delegated.</p> <p><u>Note:</u> study or department specific SOPs/ WI are the responsibility of the CI/ PI or the department manager respectively and maintained locally.</p>	Research staff and RMG.																		
2	<p>Complete all sections of SOP/ WI template provided by R&amp;D to document the defined process or task. Author should not deviate from the template and use template font and size.</p> <p>Assign SOP/ WI document number, major version number including draft number e.g. version 1.0, draft 1.0 to each new drafted SOP/ WI. Each time the draft is updated assign a new draft number e.g. version 1.0, draft 2.0.</p> <p>During the revision of an existing SOP/ WI assign a new major number and draft number.</p> <p>Create a workflow diagram using the appropriate symbols defined below to map process steps for the procedure/ task to be documented.</p> <table border="1"> <thead> <tr> <th>Symbol</th> <th>Name</th> <th>Function</th> </tr> </thead> <tbody> <tr> <td></td> <td>Start/ end</td> <td>An oval represents a start or end point.</td> </tr> <tr> <td></td> <td>Arrow</td> <td>A line is a connector that shows the relationship between the representative shapes.</td> </tr> <tr> <td></td> <td>Input/ output</td> <td>A parallelogram represents input or output.</td> </tr> <tr> <td></td> <td>Process</td> <td>A rectangle represents a process.</td> </tr> <tr> <td></td> <td>Decision</td> <td>A diamond indicated a decision.</td> </tr> </tbody> </table>	Symbol	Name	Function		Start/ end	An oval represents a start or end point.		Arrow	A line is a connector that shows the relationship between the representative shapes.		Input/ output	A parallelogram represents input or output.		Process	A rectangle represents a process.		Decision	A diamond indicated a decision.	Author.
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Step	Action	Responsibility
	<p>Describe the procedure/ task in clear concise steps, based on the flow chart using active verbs. Refer to documents required for the procedure/ task, using document number. Provide full details (document number, title, version and date) and their location or member of staff who can provide access in the related documents (and equipment in the case of WI) section of the SOP/ WI.</p> <p>Refer to responsible persons by role or group(s) only.</p> <p>Ensure that all functions identified as responsible for specific actions described in the SOP/ WI have been consulted in the drafting of the document.</p> <p>Save SOP/ WI version in the SOP or WI-specific folder on the G-Drive, or send to the RGM/ their deputy for saving as the drive has restricted access.</p> <p>Develop template/ forms in parallel to the SOP/ WI if required for the described procedures/ task.</p>	Author and RGM.
3	<p>Refer draft SOP/ WI and templates/ forms to at least one suitable person for review and comment prior to submission for authorisation. The author may set a timeline for these reviews.</p> <p>Incorporate all comments into the SOP/ WI.</p> <p>Forward electronic copy of SOP/ WI, <i>via</i> email to the RGM or their deputy for approval.</p>	Author.
4	<p>Read finalised SOP/ WI.</p> <p>Insert SOP/ WI effective date and review date.</p> <p>Remove draft version number, keeping the major version number.</p> <p>Sign the electronic master copy and save as a doc. (word) and PDF version. The electronic signature must be in line with the Trusts Electronic Signature Policy located in Trust Documents &gt; Corporate Governance.</p> <p>Update SOP/ WI list (Document Control List) and electronically archive any superseded versions.</p>	RGM.
5.	<p>Publish the PDF version of the new and revised SOP and where applicable WI on the trust website.</p> <p>Notice of a new or amended SOP/ WI that has undergone a major amendment will be given <i>via</i> the Trust e-bulletin Vital Signs and direct email to researchers and or teams.</p>	RGM and administrator

<b>Step</b>	<b>Action</b>	<b>Responsibility</b>
6.	<p>List core SOPs/ WIs per job title/ role as essential reading.</p> <p>Read and understand the SOP/ WI content where applicable.</p> <p><u>Note:</u></p> <ul style="list-style-type: none"> <li>• Anyone can recommend a SOP/ WI to be withdrawn by notifying the RGM. Withdrawn electronic master copies should be archived.</li> <li>• In rare cases a deviation from an SOP or WI may be required; this must be documented as a planned deviation and details filed in the ISF.</li> </ul> <p>Deviations from an SOP and or WIs that impacts participant rights or safety and/ or the outcome of the study will be reported on DATIX and to the RGM.</p>	Line managers and all staff.
7.	<p>Review cycle is every 3 years or sooner in the case of regulatory/ guidance updates, changes to personnel structure/ responsibilities or current practice. An appropriate person will be nominated by RGM to review and revise the SOP/ WIs.</p>	RGM

## **8. Changes from last revision**

SOP template change and to incorporate WIs.