Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Ariennir gan **Lywodraeth Cymru**
Funded by **Welsh Government**

Standard Operating Procedure: SOP number: QA1

Title: Production, Review and Approval of all-Wales SOPs.

Version No:	**Version 1.0**					
Compliance	**Mandatory**		**Advisory**		**Template**	
Implementation Date:	**1st July 2018**					
Supersedes:	**N/A**					

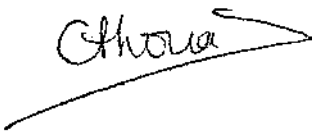
AUTHOR: Kathy Malinovszky DATE: 22/4/18

JOB TITLE: Head of Research Delivery (SWW)

APPROVAL: DATE: .8/6/18
(Chair NHS R&D Delivery Board)

If printed this SOP is only valid at time of printing. Please sign and date if using a printed version of this SOP. Any copies should be destroyed after 24 hours.

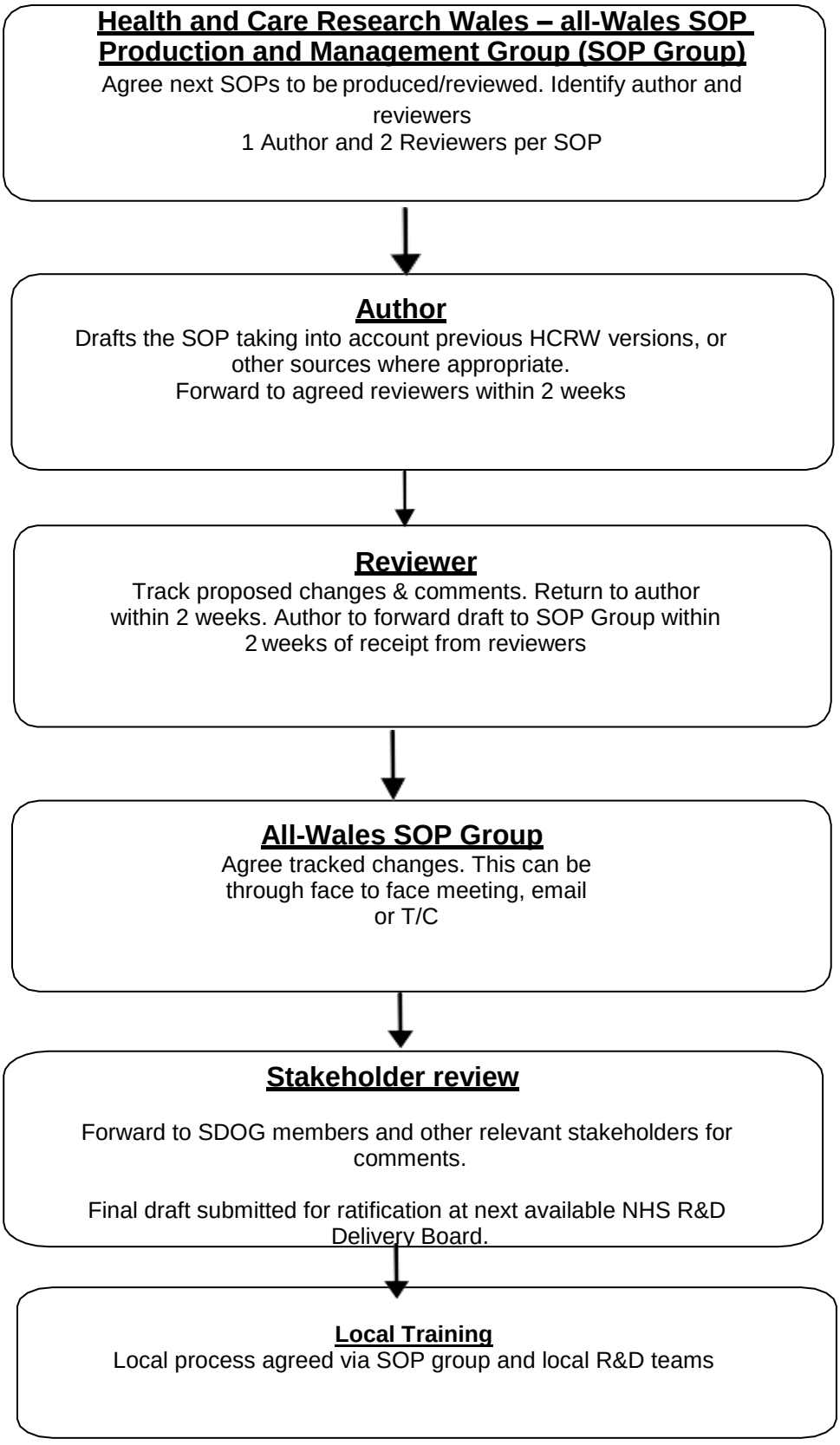
Signed



Date 14.06.2018

Version Record		
Version Number	**Effective Date**	**Reason for Change**
0.1	**31/7/2017**	
0.2	**22/04/2018**	**Reviewer comments and updates**
1.0	**7/6/18**	**Final Version following ratification at NHS R&D Delivery Board**

Contents


Health and Care Research Wales – all-Wales SOP Production and Management Group (SOP Group)
Agree next SOPs to be produced/reviewed. Identify author and reviewers
1 Author and 2 Reviewers per SOP
Author
Drafts the SOP taking into account previous HCRW versions, or other sources where appropriate.
Forward to agreed reviewers within 2 weeks
Reviewer
Track proposed changes & comments. Return to author within 2 weeks. Author to forward draft to SOP Group within 2 weeks of receipt from reviewers
All-Wales SOP Group
Agree tracked changes. This can be through face to face meeting, email or T/C
Stakeholder review
Forward to SDOG members and other relevant stakeholders for comments.
Final draft submitted for ratification at next available NHS R&D Delivery Board.
Local Training
Local process agreed via SOP group and local R&D teams

1. Purpose

1.1. This document describes the process for the production, review, approval, distribution and revision of Health and Care Research Wales Support & Delivery all-Wales Standard Operating Procedures (SOPs).

2. Background

1.1. Standard Operating Procedures (SOPs) are a necessary constituent of establishing quality systems with regards to Research Governance and ICH Good Clinical Practice (GCP) and should be designed to ensure consistency and quality. In addition to being a legal requirement in many existing regulations, SOPs are expected to:

- Disseminate best practice within an organisation and standardise an approach to specific procedures
- Communicate these requirements to employees and provide an up-to-date and accurate training reference
- Create an environment for process improvement by leading to the development of systems for monitoring and reviewing quality and compliance (of SOPs)

3. Scope

3.1. All- Wales SOPs relate to Health and Care Research Wales Support & Delivery activities.

3.2. Some of the all-Wales SOPs produced will be advisory, some will provide a template and others will be mandatory.

3.3. Each organisation will be responsible for incorporating these all-Wales SOPs into their own quality management systems as appropriate.

3.4. At the time of implementation this SOP was compliant with all applicable UK legislation. Should new legislation come into force it will supersede the current SOP. The SOP will be updated to take account of the new legislation at the earliest opportunity.

4. Responsible Personnel

- Health and Care Research Wales all-Wales SOP Production and Management Group (SOP Group): responsible for development and management of all-Wales SOPs.

- SOP Author: responsible for production of new SOPs.
- SOP Reviewer: responsible for reviewing and revising both new and existing SOPs.
- Chair of Health and Care Research Wales NHS R&D Delivery Board: Responsible for approving SOPs recommended by the SOP Group.

5. Abbreviations

GCP	Good Clinical Practice
ICH	International Conference for Harmonisation
SOP	Standard Operating Procedure
TSF/ISF	Trial Site File/Investigator Site File
RDM	Research Delivery Manager
CTIMP	Clinical Trial of an Investigational Medicinal Product

6. Procedure

New all-Wales SOPs

6.1. New SOPs will be drafted and approved as and when required in the standard format (Appendix 1).

6.2. SOPs will be drafted to incorporate the requirements implicit in ICH GCP (1996) the UK Policy Framework for Health and Social Care Research (2017) and in accordance with Medicines for Human Use (Clinical Trials) Regulations (2004) and amendments for application in Clinical Trials of Investigational Medicinal Products (CTIMPs).

6.3. Under certain exceptional circumstances an agreed waiver of a procedure in an SOP will be acceptable which will be documented.

6.4. Reasons for SOP violations and actions will be documented in the relevant Trial Site File (TSF).

SOP Author

6.5. The Health and Care Research Wales SOP Production and Management Group (SOP Group) will be responsible for ensuring Health and Care Research Wales Support & Delivery activities are supported by appropriate SOPs.

6.6. Each SOP will be written by a person with direct practical experience of the procedure or by a member of the SOP Group in collaboration with the people who have direct practical experience of the procedure.

Format

6.7. All SOPs will follow the structure below:

Front sheet	See Appendix 1.
Second page:	Process Map with SOP relationships if appropriate
Section 1:	PURPOSE: The purpose of the SOP.
Section 2:	BACKGROUND: A description of why it is considered the SOP is needed.
Section 3:	SCOPE: The areas covered/not covered.
Section 4:	RESPONSIBLE PERSONNEL: Those who must follow the

procedure/ those involved in the procedure.

Section 5: DEFINITIONS AND ABBREVIATIONS: Optional for definition; all abbreviations used in the SOP.

Section 6: PROCEDURE: Who does what, when and how?

Section 7: REFERENCES: If applicable.

Section 8: SOP LINKS: Links to other SOPs

Section 9: APPENDICES: Any documents appended to the SOP

6.8. SOPs will be formatted following the Health and Care Research Wales Communications Good Practice Guide section headers will be in bold Arial typeface size 14, the subheadings will be in bold Arial typeface size 12, and the remainder of the document will be Arial typeface size 12. Standard headers and footers are used to ensure the document style is consistent within and between SOPs.

SOP Numbering

6.9. The draft SOP has a number in accordance with the current versions of the SOP classification (please refer to Document Management & Control SOP DM1).

Production and Approval Process

6.10. The SOP should be clearly marked as ‘draft’ until its final approval and sign off by the Health and Care Research Wales NHS R&D Delivery Board. Full details in Document Management & Control SOP DM1).

6.11. The SOP Group review which SOPs require writing /rewriting and identify authors and reviewers and ensure the formatting of the draft SOP is consistent with the standard SOP format. The SOP Group circulates any existing versions of the SOP to the author and gives timelines for initial draft.

6.12. The SOP Author drafts the SOP and sends to a minimum of two reviewers for comment. The SOP Group will be copied in on all correspondence between author and reviewer in order to maintain version control and offer advice, if needed.

6.13. The SOP Reviewers are defined as those with knowledge and experience of the procedure requirements. Reviewers will annotate the draft SOP with comments, ensuring all changes are tracked. The SOP will be returned to the SOP Group and Author within the specified time frame. If no comments are received by the specified date it will be assumed that there are no comments.

6.14. The SOP Author incorporates changes recommended by the reviewers and into the draft SOP and amends version number in line with Document Management and Control SOP DM1. If the author has any queries regarding the reviewer’s comments, these can be addressed with the reviewer or SOP Group.

6.15. If required, a meeting of the SOP Group is arranged with reviewers and the author to discuss issues and agree the final version of the SOP.

6.16. The SOP will then be circulated for wider comment, likely to members of the

Support & Delivery Operational Group and others as appropriate.

6.17. The SOP Group Lead will sign off the SOP final draft as ready for ratification by the NHS R&D Delivery Board.

6.18. The NHS R&D Delivery Board should ratify each SOP based on assurance that an appropriate review process has been followed. Members of the NHS R&D Delivery Board should have had the opportunity to provide comment on the content of any SOPs that are directly related to their work as part of the earlier stages of SOP production.

Distribution

6.19. The SOP controller will upload a PDF copy of the final signed SOP onto the document management system . Access to the SOPs will be via the Health and Care Research Wales website. In addition advice will be given on the destruction of any superseded versions. This will ensure that staff access and use the most up-to-date versions of the documents. The SOP Group will maintain a master file of all SOPs in development and/or approved for reference.

6.20. The SOP Group will determine any training that may be necessary for implementation of the SOP. The requirement for training and who receives it will be dependent on the nature of the SOP, impact on research staff and the relevance to individual roles. Any training needs will be addressed and rolled out as part of the SOP's implementation.

Review and Revision of existing all-Wales SOPs

Types of review

6.21. Triggered review**:** May occur as a result of substantial changes to legislation or governance which require urgent implementation or as the result of identified poor practice or non-compliance.

6.22. Routine review: A review of each SOP will take place every two years or more often if required. If necessary a new version will be written and issued.

Review Process

6.23. The SOP group will identify which SOPs are due for routine biennial review and identify authors and reviewers,

6.24. The Amendment Tracking Log (appendix 3) can be used between routine reviews to log suggested revisions to the SOP. The outcome of the review and whether the SOP needs redrafting can be documented on the SOP Review and Amendment Record (Appendix 2). If the amendment requires immediate implementation, as is the case for a triggered review, then this would be discussed and agreed by the SOP Group prior to the quarterly meeting if necessary.

6.25. When a new version of the SOP is needed either as a result of a triggered or

routine review it would follow the production, review and approval process documented in Section 6. A copy of the SOP review and amendment record and the amendment tracking log would be filed in the master file held by the SOP Group on the document management system.

Implementation of all-Wales SOPs

6.26. The SOP Group will make recommendation to the NHS R&D Delivery Board about whether the SOP is advisory or mandatory. SOPs will be implemented in a variety of ways:

- Advisory: NHS organisations incorporate the new SOP into their own suite of SOPs/ Quality Management System if they do not have a suitable SOP in place.
- Mandatory SOPs: NHS organisations must adopt the SOP and incorporate it into their quality management systems. This may require other local SOPs to be updated.

SOP Violations

6.27. All staff are required to discuss any violations of SOPs with the person indicated within the specific SOP Document, documenting any actions taken and file in the relevant trial site file. The Principal Investigator and Sponsor should be informed as appropriate and the violation reported to the SOP Group for assessment of whether SOP needs review.

7. References

ICH-GCP (1996)

The UK Policy Framework for Health and Social Care Research (2017) Medicines for Human Use (Clinical Trials) Regulations SI 2004/1031 and Amendment Regulations

North and East Yorkshire R&D Alliance SOPs

8. All-Wales SOP Links

9. Appendices

Appendix 1 - Health and Care Research Wales SOP Standard Front Sheet
Appendix 2 - Health and Care Research Wales SOP Review Form
Appendix 3 - Health and Care Research Wales Proposed SOP Amendment Tracking Log
Appendix 4 – SOP training log.

Appendix 1:
Standard front Sheet

Standard Operating Procedure: SOP number: **Title:**						
Version No:						
Compliance:	Mandatory		Advisory		Template	
Implementation Date:						
Supersedes:						
AUTHOR: …….DATE:……..…… JOB TITLE: ……..……..…….…… APPROVAL: ……..DATE:.…….…… (Chair NHS R&D Delivery Board)						
If printed this SOP is only valid at time of printing. Please sign and date if using a printed version of this SOP. Any copies should be destroyed after 24 hours. Signed …… Date ……						

Version Record		
Version Number	**Effective Date**	**Reason for Change**

Appendix 2: Health and Care Research Wales SOP Review and Amendment Record

This form is to be used for the review of existing SOPs

SOP Title	
SOP Number	
SOP Version	
SOP Date	
Reviewer 1 Name	
Reviewer 1 Job Title	
Date review required by	
Date returned by	
Reviewer 2 Name	
Reviewer 2 Job Title	
Date review required by	
Date returned by	
Name/reviewer	
Job Title	
Review and Formatting	
Date sent to Comms Team	
New version of SOP required? (Y/N)	
SOP new version Number	
Date new version of SOP approved.	
Date new version of SOP implemented.	

Appendix 3: Proposed Amendment Tracking Log

Date	Proposed Amendment	Signature

Amendments incorporated into version:

Date:

Signature:

Appendix 4: Standard Operating Procedure Training Log

Name: **Line Manager:**
Role:

Please file this form in your Training File

SOP Title	Version	Date Assessment Completed	Your Signature Once Completed	Line Manager/Training Facilitator Signature and Date