Standard Operating Procedure (SOP)

PRODUCTION AND MANAGEMENT OF RESEARCH PROCEDURAL DOCUMENTS DEVELOPED BY RESEARCH & DEVELOPMENT

SETTING Research & Development (R&D)

AUDIENCE All R&D staff

ISSUE To describe the process of creating, maintaining and approving R&D procedural documents to ensure that research within and/or sponsored by University Hospitals Bristol and Weston NHS Foundation Trust (UHBW) is of a high quality and is compliant with all applicable regulations.

QUERIES Contact R&D department: research@uhbw.nhs.uk

Document History

SOP number	SOP_001	**SOP version**	4.0
Effective date	28/APR/2026	**Cycle review date**	28/APR/2028

Review date	Version number	Version date	Author/ Reviewer	Authorised by	Effective date
Original SOP	V1.0	28/JUL/2015	Diana Benton	Diana Benton (on behalf of TRG)	17/AUG/2015
20/AUG/2015	V1.1	20/AUG/2015	Genna Nicodemi	Diana Benton (on behalf of TRG)	14/SEP/2015
21/DEC/2015	V1.2	21/DEC/2015	Jess Bisset	Diana Benton (on behalf of TRG)	16/MAR/2016
NOV/2016	V1.3	02/DEC/2016	Jess Bisset	Diana Benton (on behalf of TRG)	12/DEC/2016
21/SEP/2017	V2.0	15/NOV/2017	Trusha Rajgor	Diana Benton (on behalf of TRG)	14/FEB/2018
08/JAN/2019	V2.1	07/JAN/2019	Katharine Wale	Jessica Bisset	15/JAN/2019
27/APR/2020	V3.0	17/JUL/2020	Becky Lambert/Jess Bisset	Jess Bisset (on behalf of TRG)	13/AUG/2020
09/AUG/2021	V3.1	09/AUG/2021	Jess Bisset	Diana Benton	27/SEP/2021
FEB/2023	V3.2	15/FEB/2023	Lucy Riddolls	Jessica Bisset	01/APR/2023
SEP/2023	V3.3	11/SEP/2023	Jess Bisset	Margie Pavey	15/NOV/2023
10/JAN/2025	V 3.4	15/OCT/2025	Sandra Mulligan	Jess Bisset	15/10/2025
14/NOV/2025	V4.0	12/JAN/2026	Jess Bisset	Diana Benton (on behalf of TRG)	28/APR/2026

Version number	Reason for change
Original V1.0	N/A
V1.1	Minor – incorporate consultation feedback. Correction of typos and grammatical errors and inclusion of examples for clarification.
V1.2	Minor – updating links, clarifying process including use of standalone templates and inclusion of authorisation log.
V1.3	Minor revisions and clarifications/updates to the process
V2.0	Major update to add further clarifications to the process and use of the new SOP template
V2.1	Minor – incorporate definition of Quality Management System
V3.0	Major – Amendment to SOP approval process during substantial emergency pressures on the Trust. Typographical corrections and process updates also included
V3.1	Minor – clarification on which members of the R&D department can review and authorise procedural documents and other minor clarifications
V3.2	Departmental name changed from Research & Innovation to Research & Development. Updated throughout SOP as minor amendment
V3.3	Minor revisions and clarifications on processes as part of biennial review and in response to the QMS audit. Also, addition of Research Governance and Quality Officer within QMS processes (new post in R&D).
V 3.4	Minor revision to update the name of Trust document management system and other minor clarifications
V4.0	Major revision to include process for R&D policies, QMS meetings and addition of RGQO ability to authorise other procedural documents where applicable.

1. Introduction

For research conducted within and/or sponsored by UHBW, procedural documents are produced by R&D to describe a system or process. These documents should be followed to ensure that procedures are standardised and are compliant with all applicable regulations. The procedural documents collectively comprise the R&D Department's Quality Management System.

2. Purpose

This standard operating procedure (SOP) details how R&D procedural documents (including SOPs, guidance documents, work instructions, workflows and templates) relating to the trust-wide systems should be generated, updated and approved.

3. Scope

All procedural documents produced by R&D relating to the systems and processes for managing and conducting research within and/or sponsored by UHBW are in scope.

4. Responsibilities

All staff within R&D are responsible for identifying the requirement for new procedural documents and ensuring that they have read and understood procedural documents and any updates relevant to their post.
The Research Operations Manager is responsible for ensuring authorised procedural documents are disseminated appropriately.

5. Abbreviations and Definitions

Abbreviations	
CTIMP	Clinical Trial of an Investigational Medicinal Product
CQG	Clinical Quality Group
QMS	Quality Management System
PAG	Policy Assurance Group
R&D	Research and Development
RGQO	Research Governance and Quality Officer
RMF	Research Management Facilitator
SOP	Standard Operating Procedure
SMT	Senior Management Team
TRG	Trust Research Group
UHBW	University Hospitals Bristol and Weston NHS Foundation Trust
UoB	University of Bristol

Definitions	
Standard operating procedures (SOP)	Detailed, written instructions to achieve uniformity of the performance of a specific function.
Other procedural documents	For the purposes of this document, this refers to guidance documents, templates, work instructions and workflows
Senior Management Team (SMT)	The core team consists of the Head of Research & Development, Research Operations Manager, Joint UHBW/North Bristol Trust Commercial Research Manager, Research Grants Manager, Deputy Director of Research Nursing, Clinical Research Facility Operations Manager. The Research Projects Manager (Sponsored Trials) is an honorary member of the team and for the purposes of this SOP is considered an appropriate authoriser for procedural documents.

6. Procedure

6.1 Creation of new procedural documents

- New procedural documents may be requested by R&D staff. Requests should be directed to the Research Operations Manager, Research Management Facilitator (RMF) Team Leader or Research Governance and Quality Officer (RGQO).
- A suitable author with sufficient experience of the process should be assigned by the Research Operations Manager or RMF Team Leader to draft (a) procedural document(s).

- All procedural documents should be appropriately version controlled, including those in draft. Prior to the first release of a document, minor version numbers 0.X should be used with an increase in minor version numbers as required, and the prefix 'DRAFT'.
- For new **policies**, Trust template should be used which specified structure and formatting. The policy may refer to related procedural documents.
- For **new SOPs**, *TMPL_001 SOP template* should be used which specifies the structure and formatting to be followed. A SOP may make reference to a related SOP or template via its reference number (for example SOP_001) and all referenced documents should be listed at the end of each SOP. The *TMPL_001 SOP template* can be supplied from R&D on request.
- **New guidance documents, templates, workflows and work instructions** (other procedural documents) should be created alongside the SOP to which they are relevant wherever possible. These documents may be referenced within a relevant SOP (as applicable) but do not need to be appended to the SOP. There are no set templates for standalone templates, workflows, guidance documents and work instructions.

6.2 Peer review of new unapproved procedural documents

- Once drafted by a member of SMT, all new unapproved policy documents should be sent to the Director and Deputy Director of Research to review. Comments should be documented and sent to the author to be addressed.
- Once drafted, **all new unapproved SOPs should be assigned to a member of the R&D Senior Management Team (SMT) for review. If there is uncertainty on the necessity of the unapproved SOP, it should be brought to an SMT meeting to discuss and agree.** Where possible, the SMT reviewer should be different to the author. Comments should be documented and sent to the author to be addressed.
- All **new unapproved other procedural documents** should be sent to a member of SMT, the RMF Team Leader or the RGQO for review. It is recommended that the reviewer is different to the author however this is not always necessary and should be dealt with on a case by case basis.
- For **SOPs**, this peer review should be performed prior to submission of the SOP to Trust Research Group (TRG) which is described in section 6.3.

6.3 Authorisation of new procedural documents

- To authorise a procedural document, GD_029 electronic authorisation process for QMS should be followed. Where practical the authorising individual should be different to the person who authored the document (although this may not always be possible or necessary for non SOPs). The authoriser may be the same person who reviewed the document.
- New Policies should be approved by the Trust Policy Assurance Group (PAG) and by Clinical Quality Group (CQG). All comments and responses should be documented. Applicable approval dates from each group should be entered into the policy document prior to release. Any new policies should be provided to TRG for information only.
- **New SOPs** should be approved at a TRG meeting. The minutes of TRG meetings should confirm that authorisation has been given. Comments should be documented and addressed as required. In some circumstances the SOP may be circulated outside of the TRG meeting and a request for review from members within a required deadline. The Head of R&D should sign the authorisation log on behalf of TRG when all comments have been addressed or if no comments were provided. If the Head of R&D is unavailable, then a member of the R&D SMT should be delegated to authorise the SOP. If the SOP is created in response to an emergency demand on the Trust (e.g. to manage resource during a pandemic), with agreement from the R&D SMT, the SOP can be implemented ahead of TRG review and TRG approval should be sought as soon as possible following implementation.
- **Other new procedural documents** should be authorised by a member of R&D SMT,the RMF Team Leader or RGQO. Review of these documents by TRG is not required.

6.4 New procedural document administration

- Once authorised, each new procedural document produced by R&D should be issued with a unique reference number to identify the document and classify it. This reference number should have a prefix and suffix, which is separated by an underscore. The prefix is dependent on the type of document:

  GD = Guidance document
  P = Policy document
  SOP = Standard Operating Procedure
  TMPL = Template
  WI = Work instruction
  WF = Workflow

  The suffix is a 3 digit number and each new document should be allocated the next sequential number following the latest existing procedural document number, e.g. TMPL_002

- The document title should be structured as follows:
  Reference number (space) Title of document (space) UHBW (underscore) Version number (underscore) Version date (DD/MMM/YYYY).
  This title should be recorded as both the electronic document title and within the footer of the document. (Please note the date format for the electronic file name can be recorded as DD.MM.YY to keep file path names short for example 11.08.23 and the corresponding footer will read 11.AUG.2023 for clarity).

- The first published version should be named Version 1.0. Versions should be updated during redrafting using an applicable version number increase (e.g. v1.1). Clarification on how to identify and name major and minor document versions is given in sections 6.6. and 6.6.2 below.
- The version date is the last date that was used during the drafting process of the procedural document (i.e. usually the day it was sent to the reviewer).

6.4.1 The UHBW R&D Reference Log of Policies, the UHBW R&D Reference Log of SOPs and list of TMPL-GD-WI-WF log, held electronically on the shared drive in R&D in the QMS Documents Tracker folder, should be updated by the Research Operations Manager or delegated other to record the updated version and date. For SOPs, each column in the table for the applicable SOP should be completed.

6.4.2 New SOP and Policy administration

- Each SOP and Policy should be given a ‘version’ date, ‘effective’ date and a ‘review’/’date version effective to’ date:
  - The effective date should be the date that the SOP or Policy came into use and the review date/date version effective to date should be recorded as the date that the SOP/Policy should undergo cycle review. To note, the cycle review periods for SOPs are 2 years after effective date and Policy documents are 3 years after effective date, unless relevant legislation or guidance determines that an earlier review is required – see section 6.6.
  - These dates should be logged in the appropriate table on the front page of the document. Dates should be written as DD/MMM/YYYY.
- For SOPs the names of the author, reviewer and authorising personnel should be typed into the document.
- For Policies the trust template should be followed which advises which personnel/group should be inserted.

6.5 Dissemination of procedural documents

6.5.1 New (and updated) SOPs and Policies

- The Research Operations Manager is responsible for ensuring authorised SOPs and Policies (in PDF format) are uploaded to the Trust's designated document management system (MyStaffApp) in line with Trust policy, saved on the UHBW R&D shared drive and are uploaded to the R&D website. UHBW staff are expected to use the designated Trust document management system to access latest versions of SOPs and to check the R&D website regularly for updates, as communicated in *SOP_007 Research Training UHBW*
- Notice of new or amended SOPs and Policies that have undergone a major change should be given via the following routes:
    - Disseminated to R&D Operations team at weekly meeting
    - Inclusion in the R&D internal bulletin to core R&D staff
    - Direct email to Research Projects Manager in R&D for onward cascade to sponsored studies trial management teams for updates as applicable
    - Direct email to Research Leads, Research Unit Managers and Research Band 7 staff for onward cascade
    - Direct email to Chief Investigators of Clinical trials of Investigational Medicinal Products (CTIMPs) sponsored by UHBW
    - Direct email to the Head of Research Governance at the University of Bristol (as relevant).

- All staff within R&D are responsible for ensuring that they have read and understood procedural documents and any updates relevant to their post. This should be documented in line with *SOP_007 Research Training*.

6.5.2 New (and updated) other procedural documents

- All the latest versions of outward facing templates are available on the research section of the trust's website and all research teams are expected to refer to the website for latest versions.
- The latest versions of all procedural documents (including templates) should be saved in the R&D shared drive Quality System Documents folder. All R&D staff are expected to refer to the R&D website for latest versions. However, they may refer to the R&D shared drive if they wish to update the procedural documents in line with this SOP or for latest versions of procedural documents which are not outward facing. R&D staff are required to know where to access a list of the current procedural documents and ensure they are trained in those which are relevant to their role.

6.6 Cycle review of SOPs and Policies

- SOPs and Policies should be reviewed when the automatic reminder from the designated Trust document management system is received or sooner if an urgent review or amendment is required.
- The Research Operations Manager should assign the SOP/Policy cycle review to an appropriate member of the R&D department. This review should assess the content of the SOP/Policy and the related documents listed. All SOPs should be reviewed by a minimum of one member of staff from the R&D SMT,RMF Team Leader or RGQO with the relevant experience to properly assess the content.
- All SOPs under review should be placed in the 'For Review by R&D' folder in the SOP section of the R&D Quality Management System folders on the shared drive and the SOP document under review should also be given the prefix 'DRAFT'.
- All Policies under review should be placed in the 'For Review by R&D' folder in the Policies section of the R&D Quality Management System folders on the shared drive and the policy document under review should also be given the prefix 'DRAFT'.

- Any suggested changes made during the review must be done with tracked changes. The reviewer will liaise with the Research Operations Manager to determine whether the changes are major or minor if they are unclear. The following will be used as a guide for this decision:
    - **Major amendments** consist of an amendment to the document that will result in a change of practice.
    - **Minor amendments** consist of an amendment to the document that does not substantially alter the main body of the document, (e.g. additions to references, changes to specific people's names, small alterations to standard forms and clarifications).

6.6.1 Authorisation of major and minor SOP and Policy amendments

- Any **major** amendments to an SOP or Policy should be authorised in accordance with section 6.3 above (Authorisation of new procedural documents). SOPs therefore should be authorised by TRG and policies by PAG and CQG.
- A **minor** amendment to an SOP should be authorised by a member of the SMT and will be documented in the *R&D authorisation log (TMPL_002).*
- A minor amendment to a Policy should be authorised by either the Director or the Deputy Director of Research and documented in the *R&D authorisation log (TMPL_002)*
- If the SOP is amended in response to an emergency demand on the Trust, with agreement from the R&D SMT, the emergency update can be implemented ahead of TRG review and approval. TRG approval should be sought as soon as possible following implementation.

Review of other procedural documents

- Other procedural documents (existing templates, workflows or work instructions) do not have a set review date. These should be updated as required (e.g. where information becomes outdated or improved ways of working are identified) or should be reviewed as part of the related documents for an SOP.
- Any updates to these procedural documents should be reviewed and authorised by a member of the SMT,RMF Team Leader or RGQO as per section 6.3.

6.6.2 All amended procedural documents administration.

- All updated procedural documents should be formatted as described in section 6.4. The unique SOP, Policy or TMPL/GD number (etc) should remain the same. However, the version number should be amended:
    - New published versions with minor amendments should be updated with an increased minor version number (e.g. v1.2)
    - New published versions with major amendments should be updated with an increased major version number (e.g. v2.0).

- Once major or minor amendments to an **SOP** have been authorised, details of the date of change, new version numbers and a brief description of the change, should be documented in the document history section at the beginning of each SOP (*TMPL_001*).
- The UHBW R&D Reference Log of SOPs and UHBW R&D Reference Log of Policies should be updated for **all** SOPs and Policies as described in 6.4 above**.**
- Previous final electronic versions of the document should be moved to an appropriate file named 'final superseded versions' located on the R&D shared drive in the Quality System Documents folder. Previous draft electronic versions of the document should be moved to an appropriate 'superseded' folder. The previous final version should be removed from the website (as applicable) and the new version should be uploaded onto the website (as applicable) and disseminated as described in section 6.5.

6.6.3 SOP or Policy breaches

- Occasionally, the need may arise to deviate from an SOP or Policy. Alternatively, there may be situations where unplanned or accidental deviations from SOPs or Policies are discovered.
- In these cases, please refer to *SOP_018 Management of Breaches in Research UHBW.*

6.7 Oversight of the Quality Management System

Monthly meetings are held within R&D led by the Research Operations Manager to maintain oversight of all procedural documents in the R&D QMS. These meetings ensure updates are carried out either within their cycle review date or sooner if legislative, national or departmental updates are required.

7. Training

- This SOP should be disseminated to applicable research staff (including R&D) and will be available on the R&D Website.

Plan Elements	**Plan Details**
The Dissemination Lead is:	Research Operations Manager
Is this document: A – replacing the same titled, expired SOP, B – replacing an alternative SOP, C – a new SOP:	A – replacing the same titled, expired SOP
If answer above is B: Alternative documentation this SOP will replace (if applicable):	N/A
This document is to be disseminated to:	All applicable research staff (including R&D)
Method of dissemination:	For major updates to the SOP dissemination will be: 1. To Chief Investigators of UHBW Sponsored CTIMPs 2. Research Unit leads across UHBW 3. Head of Research Governance at UoB (where SOP is applicable) All updates (major and minor to the SOP) will be: 1. Updated on the trust MyStaffApp System 2. Updated on the R&D website 3. Cascaded in R&D communications
Is Training required:	All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP. The personal training log of the individual (and the Investigator Site File/Trial Master File if required) should be completed to document that the content of this SOP has been read and understood as described in *SOP_007 Research Training UHBW*

8. Related documents

RELATED DOCUMENTS AND PAGES	• TMPL_001 R&D SOP • TMPL_002 R&D authorisation log • SOP_007 Research Training UHBW • SOP_018 Management of Breaches in Research UHBW Latest versions of these are located on the Research & Development section of UHBW's website: http://www.uhbristol.nhs.uk/research-innovation/for-researchers/templates-and-sops/ • GD_029 Electronic authorisation of the QMS Latest version is located in the R&D shared drive in the QMS folders
AUTHORISING BODY	Trust Research Group
SAFETY	N/A
QUERIES AND CONTACT	Research & Development department via research@uhbw.nhs.uk
AUDIT REQUIREMENTS	R&D departmental Quality Management System audits are undertaken annually.