Standard Operating Procedure

AUTHORSHIP, REVIEW, REVISION AND APPROVAL OF RESEARCH PROCEDURAL DOCUMENTS PRODUCED BY RESEARCH & INNOVATION

SETTING Research & Innovation (R&I)

FOR STAFF R&I staff; preparing and maintaining procedural documents which have a trust-wide remit.

ISSUE This SOP relates to the authorship, review, revision and approval of procedural documents produced by R&I that apply to the systems and processes for the conduct of research within and/or sponsored by UHBristol.

Standard Operating Procedure (SOP)

Author:	Diana Benton	Head of Research & Innovation
Approved by:	Trust Research Group	
Date for Review:	November 2017	

Review Date	Version Number	Version Date	Effective Date	Reason for change	Author/Responsible person	Authorised by
Original SOP	V1.0	28/07/2015	17/08/2015	n/a	Diana Benton	Diana Benton
20/08/2015	V1.1	20/08/2015	14/09/2015	Minor – incorporate consultation feedback. Correction of typos and grammatical errors and inclusion of examples for clarification.	Genna Nicodemi	Diana Benton
21/12/15	V1.2	21/12/15	16/03/2016	Minor – updating links, clarifying process including use of standalone templates and inclusion of authorisation log.	Jess Bisset	Diana Benton
November 2016	V1.3	02/12/15	12/12/2016	Minor revisions and clarifications/updates to the process	Jess Bisset	Diana Benton

1. Purpose

The purpose of this document is to describe the process by which procedural documents produced by R&I relating to the trust-wide systems and processes for research conducted within and/or sponsored by UHBristol are generated, updated and approved.

2. Scope (areas/people in and out of scope should be defined)

In scope: procedural documents produced by Research & Innovation (R&I) relating to the systems and processes for managing and conducting research within and/or sponsored by UHBristol.

3. Definitions/Abbreviations

CTIMP	Clinical Trial of an Investigational Medicinal Product
DMS	UHBristol Trust Document Management System
SOP	Standard Operating Procedure: 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 work instructions, workflows, templates and forms.

4. Audience

The audience for this SOP is R&I staff with a responsibility for writing or controlling procedural documentation to support the conduct and management of research within and/or sponsored by UHBristol.

5. Creation and authorisation of new procedural documents and standalone templates

New **standard operating procedures** will be reviewed and agreed via Trust Research Group. This may be done electronically or via a full meeting. Comments will be documented and addressed as required. SOPs will be authorised by the Head of Research & Innovation or an individual within the R&I Senior Management Team. All SOPs will use the R&I SOP template (see Appendix 1).

Other new procedural documents will be appended to the SOP to which they are relevant, as applicable, and will be reviewed and agreed via the R&I Senior Management Team. This may be done electronically or via a full meeting. Comments will be documented and addressed as required. Other new procedural documents will be authorised by the Deputy Director of Research or an individual within the R&I Senior Management Team.

Standalone templates will not be appended to the SOP to which they are relevant but may be referenced within the SOP. These templates will be version controlled. A new template and major or minor amendments to an existing template, will require review and authorisation via an R&I Senior Manager prior to implementation. This authorisation will be documented on the R&I authorisation log (Appendix 2). Templates will not need to be reviewed by Trust Research Group or the Deputy Director of Research.

6. Update and authorisation of existing procedural documents

All updated procedural documents will be reviewed by a minimum of two members of staff from the R&I Senior Management Team with the relevant experience to properly assess the content. The reviewers will determine whether the changes are major or minor.

6.1 Major changes consist of an amendment to the document that will result in a change of practice.

6.2 Minor changes

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 and small alterations to standard forms).

One of the reviewers may be the authorising member of staff. Major changes will be reviewed and agreed in accordance with section 5 above (creation and authorisation of new procedural documents). Minor changes will be incorporated and a new version of the document will be authorised by the Head of Research & Innovation or delegated individual from the Senior Management team. Details of dates of change, new version numbers, a brief description of the change, the author who made the changes and authorising individual will be inserted on the title page of the procedural document.

Example:

Review date	Version number	Version Date	Effective Date	Reason for change	Author/Responsible person	Authorised by
-	1.0	29/6/2015	15/07/2015	Original Policy	Personnel name	Personnel name
29/06/2016	2.0	29/06/2016	05/07/2016	Annual review	Personnel name	Personnel name
30/08/2016	2.1	30/08/2016	09/09/2015	Minor – incorporate consultation feedback	Personnel name	Personnel name

Previous final electronic versions of the document will be moved to a file named 'final superseded versions' located on the R&I shared drive in the Quality System Documents folder. Previous draft electronic versions of the document will be moved to an appropriate 'superseded' folder. Outdated final hard copy versions will be crossed through and filed in a folder marked 'superseded SOPs' in the Research & Innovation department.

7. Process for authorisation of procedural documents

To authorise a procedural document the appropriate personnel (see sections 5 and 6) will complete and sign the authorisation log (appendix 2). Where authorisation is obtained from Trust Research Group, the Deputy Director of Research will sign the authorisation log on behalf of the group. The minutes of Trust Research Group meetings will confirm that authorisation has been given. The author and approver of the document will insert their name and role electronically on the title page of the document.

The authorised version of the SOP will then be uploaded as a .pdf into the DMS, saved on the UHBristol R&I shared drive and onto the UHBristol Research & Innovation website.

Hard copy final SOPs will be filed by the Research & Innovation Management Assistant in the Research & Innovation department.

8. Documenting authorisation of procedural documents

The UH Bristol R&I Reference Log of Procedural Documents will be updated by the personnel in R&I initiating the change to the procedural document. This will be communicated to the Management Assistant and Research Operations Manager who will complete the relevant sections of the log in accordance with tasks they have completed in their role (e.g. the Management Assistant to upload the document to DMS and the Research Operations Manager to disseminate major updates to relevant personnel as described in 8).

9. Dissemination of procedural documents

9.1 New SOPs and new versions of existing SOPs: The Research Operations Manager will be responsible for ensuring authorised SOPs are uploaded to the DMS in line with Trust policy and on the R&I website as described in section 7. Internal Trust staff are expected to use the DMS to access latest versions of SOPs and to check the website regularly for updates; as communicated in the Training SOP.

Notice of new or amended procedural documents that have undergone a major change will be given via the following routes:

- Inclusion in the R&I e-bulletin (monthly);
- Direct e mail to Research Leads, Research Unit Managers and Band 7 staff for onward cascade;
- Direct email to Chief Investigators of CTIMPs sponsored by UHBristol;
- Direct email to the Head of Research Governance at the University of Bristol (as relevant).

10. Review of procedural documents

Documents will be reviewed when the automatic reminder from the DMS is received (on an annual basis) or sooner if an urgent review and amendment is required.

11. Effective and expiry dates

Each procedural document will be given an 'effective' date and a 'review' date, which will be recorded in the appropriate table on the front page of the document.

12. Training

All staff within R&I are responsible for ensuring that they have read and understood procedural documents and any updates relevant to their post. This will be documented.

13. Control & Referencing

Each SOP produced by Research & Innovation will be issued with a unique number to identify the origin of the document. For example, the reference number for this SOP is 001/UHBristolR&I. A log of document references will be managed by the R&I Management Assistant and held electronically on the shared drive in R&I in the Quality Systems Document folder. As other procedural documents will be appended to a relevant SOP, the reference and version number and date of that SOP will apply to the SOP and all appendices.

Version numbers and dates will be used to control procedural documents as follows:

- For final published versions the version date will be incorporated into the file name, using the format dd_mm_yyyy (i.e. XXX/UHBristolR&I v1 dd/mm/yyyy).
- For redrafting, the date of the latest version for comment will be incorporated into the file name, using the format dd_mm_yyyy.
- Prior to the first release of a document, minor version numbers 0.X will be used, with an increase in minor version numbers as required, and the suffix 'DRAFT'.
- The first published version will be named Version 1.0.
- Versions will be updated during redrafting using an applicable version number increase (e.g. v1.1).
- New published versions with major amendments will be updated with an increased major version number (e.g. v2.0).
- New published versions with minor amendments will be updated with an increased minor version number (e.g v1.2)
- Draft documents will be watermarked DRAFT.

14. Appendices

Some supplementary documents referred to within an SOP (e.g workflows, templates, checklists, forms) will be attached as an appendix to the SOP and numbered sequentially. They will contain the SOP footer and will also be stored separately as a word document for ease of use in a controlled electronic folder on the R&I shared drive.

A number of standalone templates will be created for specific purposes and due to the likely frequency of review required will not form appendices but where applicable will be referred to by the relevant SOP.

15. Archiving

Procedural documents will be archived in accordance with Trust Policy.

16. List of Appendices

- **Appendix 1 - R&I SOP Template**
- **Appendix 2 – R&I Authorisation log**

IMPORTANT NOTE:

This procedure has been screened for equality impact; it was not assessed as having adverse effects on any section of the community.

QUERIES Contact R&I department Ext 20233 or research@uhbristol.nhs.uk

Standard Operating Procedure

TITLE – IF POSSIBLE KEEP TO 1 LINE MAX

SETTING Suggest you choose between Trustwide / Hospital / Division / Dept / Ward

AUDIENCE Make it clear to what staff this SOP applies – i.e. who will use and follow it.

ISSUE If relevant, make it clear to what issue or group this SOP applies. Take care to be explicit. This is particularly important where the SOP if used on the 'wrong' group could lead to harm.

[Please read then delete this text within the square brackets before filling in the template: This SOP template was developed and reviewed within R&I based on the Trust's SOP template. It was finalised by the Head of R&I and the Research Operations Manager for use by R&I staff for R&I SOPs on 29 June 2015.]

Standard Operating Procedure (SOP)

Author:	Name	Role:	
Approved by:	Trust Research Group		
Date for review:			

Review date	Version number	Version Date	Effective Date	Reason for change	Author/Responsible person	Authorised by

THIS IS WHERE YOU BEGIN YOUR TEXT

You are free to place your SOP within this space between the green lines. This cell will grow and spill over to additional pages as necessary.

Use straightforward plain text as much as possible. Keep to this standard font (Arial). Be very cautious about using colour or underlining.

The following may be useful sub-headings to help structure your SOP:

1. **Purpose**
2. **Scope (areas/people in and out of scope should be defined)**
3. **Definitions/Abbreviations [Please delete after reading: definitions/abbreviations are to be inserted into the table provided below]**

4. **Procedure**
5. **Dissemination and training in the SOP**

5.1 Dissemination of this SOP

5.1.1 New SOPs and new versions of existing SOPs: The Research Operations Manager will be responsible for ensuring authorised SOPs are uploaded to the DMS in line with Trust policy and on the R&I website as described in the SOP "Authorship, review, revision and approval of research procedural documents produced by Research & Innovation". Internal Trust Staff are expected use the DMS to access latest versions of SOPs and to check the website regularly for updates, as communicated in the Training SOP.

Notice of new or amended procedural documents that have undergone a major amendment will be given via the following routes:

- Inclusion in the R&I e-bulletin (monthly);
- Direct email to Research Leads, Research Unit Managers and Band 7 staff for onward cascade ;
- Direct email to Chief Investigators of CTIMPs sponsored by UHBristol;
- Direct email to the Head of Research Governance at the University of Bristol (as relevant).

5.2 Training in this SOP

5.2.1 All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP.

5.2.2 The training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the content of the SOP and its amendments.

6. **Appendices (include flowcharts, work instructions, templates and forms referred to in the body of the SOP. NB only the document types listed here should be used – this template must be amended formally if additional document types are to be added).**

If you want to use tables, adapt the example below.

TABLE HEADING		
Some short text		
Keep adding rows below as necessary		
You can	split table cells	If necessary

Don't forget to update the footer of the document so that the appropriate details are correct.

THIS IS WHERE YOU END YOUR TEXT

IMPORTANT NOTE:

Depending on the nature of the SOP, it may be necessary to complete an Equality Impact Assessment form for this procedure. This can be found on HR Web under "Equality Impact Assessment"

RELATED DOCUMENTS	Name of document DMS address i.e. http://nww.avon.nhs.uk/dms/download.aspx?did=nnnn
AUTHORISING BODY	Name of committee or group that authorised this document
SAFETY	If there are unusual or unexpected safety concerns (to staff or patient), emphasize them here
QUERIES	Contact xxxx ' Ext nnnn / Bleep nnnn – this does not need to be the author, but whoever might be best placed (particularly 24/7) to answer a query.

Appendix 2 – R&I Authorisation log

Procedural document/ standalone template title	Version number and date	Author	Authorised by	Signature	Date