Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Creation, Control, Amendment and Storage of Standard Operating Procedures for Research Governance**		
SOP Reference Number:	QUB-RGEI-001	Version Number:	FINAL v1.0
Revision Date:	15 September 2021	Review Date	15 September 2024

	Name and Position	Signature	Date
Author:	Research Governance, Ethics and Integrity Team	----------	----------
Reviewed and Approved by:	Chair, Research Governance, Ethics and Integrity Committee	----------	----------

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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number

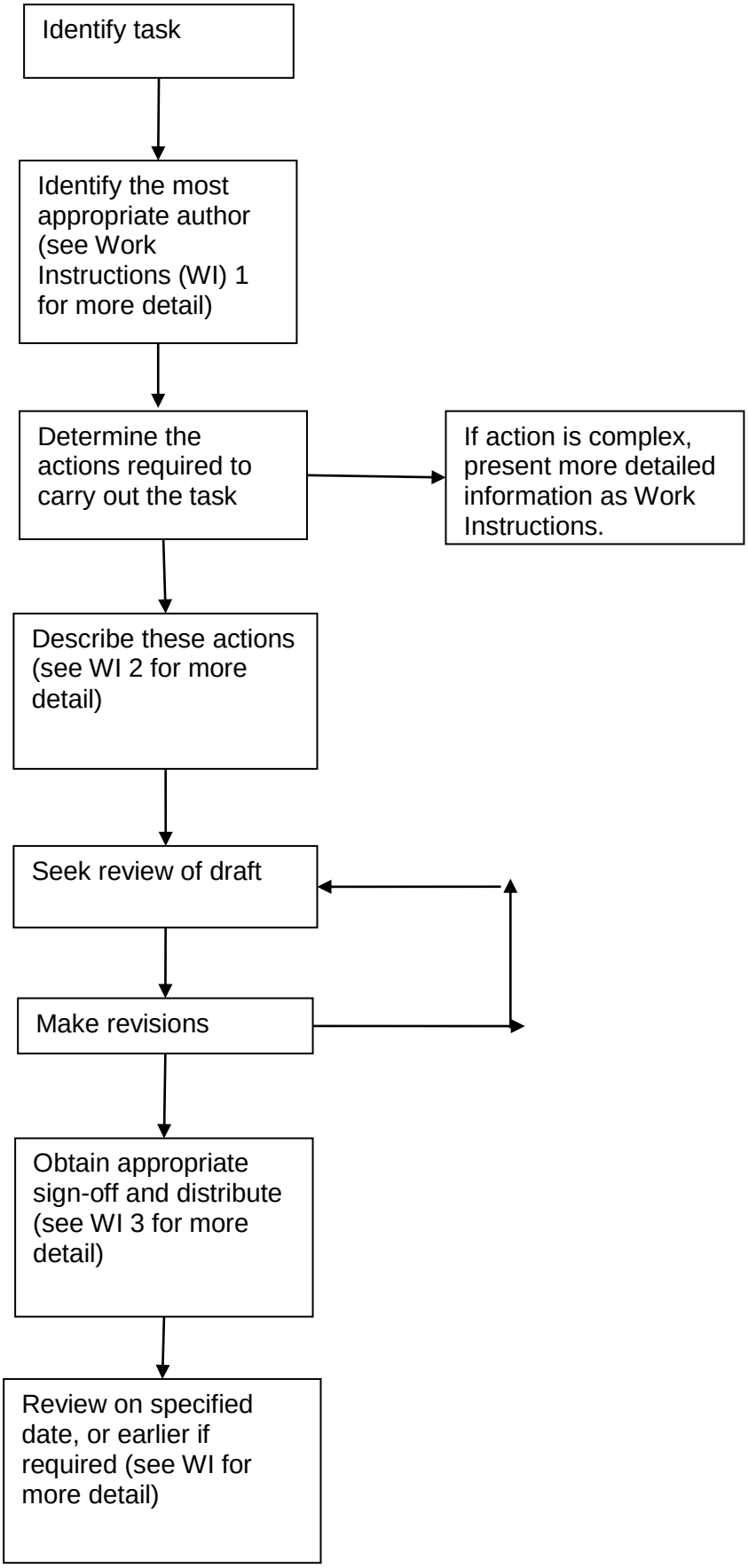
1. Purpose

This Standard Operating Procedure describes the process for writing, approval, distribution, implementation, review and storage of Standard Operating Procedures, used for the governance of research within Queen's University Belfast.

2. Scope

This SOP applies to all members of University staff; both academic and support staff as defined by Statute 1 and including honorary staff and students who are conducting research within or on behalf of the University.

3. Procedure


Identify task
Identify the most appropriate author (see Work Instructions (WI) 1 for more detail)
Determine the actions required to carry out the task
If action is complex, present more detailed information as Work Instructions.
Describe these actions (see WI 2 for more detail)
Seek review of draft
Make revisions
Obtain appropriate sign-off and distribute (see WI 3 for more detail)
Review on specified date, or earlier if required (see WI for more detail)

4. References

International Conference on Harmonisation (ICH) Harmonisation Tripartite Guideline: Guideline for Good Clinical Practice EB (R1): http://www.ich.org/products/guidelines.html (last accessed September 2021).

5. Appendices

Work Instructions 1 – Authorship
Work Instructions 2 – Layout and Referencing
Work Instructions 3 – Signoff and Distribution
Work Instructions 4 – Review and Archiving

Appendix 1: Standard Operating Procedure – Template.

Work Instructions 1 – Authorship

1. SOPs should be in place for all research governance arrangements within the University and for all studies where the University is acting as a Sponsor. Where a study is co-sponsored, the study specific sponsorship framework will identify which institution is responsible for particular components of the study. The SOPs of the responsible Institution will apply.
2. It is recommended that each SOP is written by the most appropriately qualified person to do so. For study specific SOPs this can be delegated by the CI. However, the CI remains responsible for ensuring that SOPs are written, implemented and maintained; ensuring that this involves all relevant members of the study team including other research sites as appropriate.
3. Study specific SOPs will be written in accordance with the Sponsor's requirements, on the instruction of the CI for the study. It is recommended that the numbering system for study specific SOPs is the Research Governance/Management number of the lead sponsoring organisation.
4. Abbreviations should be written in full on first use, followed by the abbreviation in brackets.
5. Draft research governance SOPs should be circulated to relevant personnel for comment to ensure that the SOP conforms to UK regulatory and statutory standards and University Regulations. All comments and discussions received during consultation should be documented and retained.

Work Instructions 2 – Layout, and Referencing

1. Each SOP will be identified with an SOP number and numbered sequentially from 1. Associated forms relevant to the SOP will be located in consecutively numbered appendices. Each appendix should be individually paginated.
2. The format of each SOP should be identical and follow the template laid out in this document and in Appendix 1. The SOP should have:

a. A title page, formatted according to this example recording the SOP reference number, version number, last revision date, review date, the author's name and position, who reviewed the SOP and who approved it. All of which must be dated. "This is a controlled document. When using this document please ensure that the version is the most up to date by checking Queen's Research Governance, Ethics and Integrity website " should appear on the title page.

3. The SOP reference number and version number should appear as a footer on each page.
4. The page number, in the format of 'Page 1 of 2' on each page, preferably in the bottom right corner of each page.
5. Prepared as a word document with text no smaller than Arial 11, on a standard A4 page.
6. Following the title page each document must contain a revision log. This should include the previous SOP version number, modification reason, details of modification, date of modification, signature and date of author (if possible) and the new SOP version number.
7. The SOP should be set out in numbered sections. Sections should include, but are not limited to:

- Purpose — describing what the SOP is intended to do;
- Scope — describing who it applies to;
- Responsibilities — identifying specific people (where necessary);
- Procedure — outlining instructions and indicating Working Instructions as appropriate;
- References — detailing sources used to prepare the SOP and any legal framework and/or guidance documents;
- Appendices — Appendices should be numbered consecutively, i.e. QUB-RGEI-001 Appendix 1, QUB-RGEI-001 Appendix 2,
  The location of any appendix referenced in an SOP, should be quoted in full.

8. Each template SOP will be assigned a unique, sequential number.

Work Instruction 3 – Sign off and Distribution

Authorising SOPs

1. Before SOPs, prepared by the Research Governance Department, can be implemented, review and authorisation is required by the relevant University Committee, following the appropriate consultation / review.
2. For study specific SOPs these are authorised by the CI, or the person with delegated responsibility.

Distribution of SOPs

1. All University wide SOPs will be added to the Research Governance, Ethics and Integrity website, once authorised. It is the responsibility of all members of the University to check the website regularly to ascertain if these SOPs have been added or amended. Researchers will be informed of the SOPs when they are given management permission to commence the study.

2. Study specific SOPs should be maintained on the study research file.

Version Control

1. University wide SOPs will be "draft" until they have been authorised by the appropriate individual. The table on the front cover documents the SOPs version history and this is to be amended with each change to the SOP. Once finalised, the document will be called "final" version, with version number e.g. 1.0. Updates to the SOP will result in an increase in version number.

2. Final 'master' copies will be accessible through the Research Governance, Ethics and Integrity website. Any printed versions will be classed as uncontrolled documents and readers will be referred to Queen's Research Governance, Ethics and Integrity website for up-to-date versions.

Work Instruction 4 – Review and Archiving

SOP review

1. Once a final SOP has been issued, it must not be informally altered. Any amendments required must be formally approved and a new version of the SOP issued.
2. All SOPs will have a review date. SOPs also need to be reviewed on an *ad hoc* basis as a result of amendments to legislation, process or organisational change.
3. Each SOP should bear a list of its revision dates. If no changes have been made at the review, the entry should indicate "reviewed, not changed" followed by the date of review.
4. Obsolete SOPs will be withdrawn from circulation.

Storage and Archiving

1. The master hard copy of signed SOPs will be stored under Controlled Access in the Research Governance Office. Master electronic files are maintained in the Research Governance Department folder of the shared Research and Enterprise drive.
2. When an SOP has been superseded, it shall be removed from the master file, marked "SUPERSEDED" and retained in an archive file. Similarly the electronic version shall be moved into an archive folder. Superseded SOPs will be retained in accordance with the Records Management policy.

Template - Standard Operating Procedure

Title:			
SOP Reference Number:	Example: QUB-RGEI-001	Version Number:	Draft/Final v
Revision Date		Review Date	

Name and Position	Signature	Date
Author:		
Reviewed and Approved by:		

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1. Purpose
2. Scope
3. Responsibilities (where appropriate)
4. Procedure
5. References
6. Appendices