Queen's University Belfast

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-ADRE-001	Date prepared	28 May 2008
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Effective Date:	1 December 2012	Review Date:	August 2018

	Name and Position	Signature	Date
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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
Final v 1.0	10/11/09	Annual Review	Draft v 2.0
Draft v 2.0	10/11/10	Annual Review/ Update following MHRA GCP Inspection	Final v 2.0
Final v 2.0	20/10/11	Amendment to format	Final v 3.0
Final v 3.0	17/08/2012	Periodic Review	Final v 4.0
Final v 4.0	21/10/2014	Periodic Review	Final v 5.0
Final v 5.0	19/09/2016	Periodic Review	Final v 6.0

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. Introduction

Standard Operating Procedures (SOPs) are formal documents that describe the procedures to be followed to complete a task. They are sufficiently detailed to be unambiguous, but not so detailed and inflexible that continuous amendments are required. A well written SOP will ensure consistency in the execution of tasks, and facilitate the successful management of research projects.

3. 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.

4. Responsibilities

4.1 Head of Research Governance

To operate as the 'Quality Manager' and assume overall responsibility for the Research Governance Quality Management System (QMS).

4.2 Research Governance Manager

The preparation, maintenance, distribution logging and retrieval of the University Research Governance SOPs are the responsibility of the Research Governance Manager(s). Additionally, it is expected that the Research Governance Managers will ensure all processes visible to them are conducted in accordance with the QMS.

4.3 Research Governance Assistant

It is the responsibility of the Research Governance Assistant(s) to support the Head of Research Governance and the Research Governance Manager(s) in the maintenance and implementation of the QMS

4.4 Director of Research and Enterprise

Research Governance SOPs must be authorised by the Director of Research and Enterprise, following review by the Research Governance and Integrity Committee.

4.5 Chief Investigator

It will be the responsibility of the Chief Investigator (CI) of a research study to ensure that study specific SOPs are written in accordance with the sponsor's requirements and the needs of the study.

4.6 Author

The SOP author is responsible for allocating the appropriate SOP number, circulating the SOP to the appropriate people for review and incorporating any necessary changes. The author will also be required to ensure that training is provided for the SOP.

5. Procedure

5.1 Layout

5.1.1 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;

5.1.2 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:

5.1.2.1 A title page, formatted according to this example recording the date of preparation, last revision date, version number, effective 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;

5.1.3 The SOP reference number and version number should appear as a footer on each page;

5.1.4 **Do Not Copy** should appear as a header on each page, after the title page;

5.1.5 The page number, in the format of 'Page 1 of 2' on each page, preferably in the bottom right corner of each page;

5.1.6 Prepared as a word document with text no smaller than Arial 11, on a standard A4 page;

5.1.7 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;

5.1.8 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;
- Introduction outlining the reason for the SOP;
- Scope describing who it applies to;
- Responsibilities identifying specific people where necessary;
- Procedure outlining specific instructions;
- 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-ADRE-001 Appendix 1, QUB-ADRE-001 Appendix 2, The location of any appendix referenced in an SOP, should be quoted in full.

5.2 Writing SOPs

5.2.1 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;

5.2.2 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;

5.2.3 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;

5.2.4 Abbreviations should be written in full on first use, followed by the abbreviation in brackets;

5.2.5 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.

5.3 Authorising SOPs

5.3.1 Before SOPs, prepared by the Research Governance Department, can be implemented, authorisation is required by the Director of Research and Enterprise, following the appropriate consultation;

5.3.2 For study specific SOPs these are authorised by the CI, or the person with delegated responsibility.

5.4 SOP review

5.4.1 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;

5.4.2 All SOPs will have an effective date issued and 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;

5.4.3 Each SOP should bear a list of its revision dates on the first page. If no changes have been made at the review, the entry on the first page should indicate "reviewed, not changed" followed by the date of review;

5.4.4 Obsolete SOPs will be withdrawn from circulation.

5.5 SOP referencing

5.5.1 Each template SOP will be assigned a unique, sequential number. The pre-fix assigned to the SOP determines whether it is belonging to a clinical study or research management/administrative activities. The following system should be used:

Clinical SOPs	SOP-CL (and site initials)–001
Administration	SOP-AD (Generating Directorate)-001;

5.5.2 Trial specific SOPs will have the prefix TS before SOP.

Where there is a requirement for a new set of SOPs, they will be given specific letters based on the content and numbered as above.

5.6 Distribution of SOPs

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. Any changes will be flagged on the system as updated. Researchers will be

informed of the SOPs when they are given management permission to commence the study.

Study specific SOPs will be placed on the study master file only.

5.7 Version Control

University wide SOPs will be "draft" until they have been authorised by the appropriate individual e.g. the Director of Research and Enterprise for Administrative SOPs and the CI for study specific SOPs. 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.

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.

5.8 Storage and Archiving

5.8.1 The master hard copy of signed administrative 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. All SOPs are password protected to prevent the unauthorised changes by personnel outside of the Research Governance Department;

5.8.2 The master file of SOPs will contain a complete list of SOPs in use, identifying when they are to be reviewed, who reviewed and if revision was required (as outlined in Appendix 2);

5.8.3 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.

6. 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 2016).

7. Appendices

Appendix 1: Standard Operating Procedure – Template.
Appendix 2: SOP Review Schedule.

Queen's University Belfast

QUB-ADRE-001
Appendix 1

Template - Standard Operating Procedure

Title:			
SOP Reference Number:	Example: QUB-ADRE-001	Date prepared	
Version Number:	Draft/Final v	Revision Date	None
Effective Date:		Review Date:	

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

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SOP LIST AND REVIEW SCHEDULE

SOP Ref. No.	Version	Title	Review Date	Revision Required	Signature (Head of RG)	Date Next Review
				Yes ☐ No ☐		
				Yes ☐ No ☐		
				Yes ☐ No ☐		
				Yes ☐ No ☐		
				Yes ☐ No ☐		
				Yes ☐ No ☐		
				Yes ☐ No ☐		
				Yes ☐ No ☐		