Joint Research Office of Doncaster & Bassetlaw Hospitals NHS Foundation Trust, Rotherham Doncaster & South Humber NHS Foundation Trust and NHS Doncaster CCG	**Page 1 of 4**
Research Management & Governance	SOP No. RM&G0001, Version 1
SOP Management	**Supersedes:** Not applicable
	Attachments: None
	Effective date: 29 July 2013

Signatures:

Role	Name	Function	Date (DD-MM-YYYY)	Signature
Author	Emma Hannaford	Research Management & Governance Manager	27-07-2013	
Reviewer	Amy Beckitt	Clinical Research Development Manager	27-07-2013	

1 Definitions

Please refer to the current version of the SOP RM&G0002 for a glossary of all terms and acronyms.

2 Purpose

The purpose of this SOP is to cover the procedures surrounding the writing, reviewing, maintentance and retirement of SOPs within the joint Research and Development office for Doncaster & Bassetlaw Hospitals NHS Foundation Trust, Rotherham, Doncaster & South Humber NHS Foundation Trust and NHS Doncaster CCG.

3 Scope

This SOP covers all personnel within the Research Management & Governance team who are involved in the writing, reviewing and maintenance of internal SOPs. In addition, this covers any individual who uses the internal SOPs.

4 Procedure

4.1 Creating a new study

SOPs are necessary to cover all procedures within the Research & Development department that require standardisation. This also means that when someone who normally carries out a particular activity is absent, another individual can carry out the activity using the SOP as guidance.

All SOPs for the Research & Development department will be individually identified with the prefix ‘RM&G’ followed by a sequential four digit number. For example, this SOP is RM&G0001 and the following one will be RM&G0002. Whenever an existing SOP is updated, this identifying number will remain the same, however the version number will be updated.

4.2 Writing SOPs

SOPs should be written in a format that is clear and easy to understand. Care should be taken to ensure the SOP is not ambiguous and that the details presented in the SOP are appropriate to the level of background understanding the intended audience has.

Where possible, SOPs should be written in step-by-step format, either as bullet points or in prose, documenting all the necessary steps from beginning to end in order for the activity to be completed.

The author of an SOP can be anyone with sufficient knowledge to document the procedure, but will most likely be either the Director of Research & Development, the Research Management & Governance Manager or the Clinical Research Development Manager.

4.3 Reviewing SOPs

Once an SOP has been written, it needs to be reviewed by someone other than the author. The reviewer will read through the SOP and advise the author of any changes required. The review should involve confirming the SOP documents the procedures correctly, and also ensuring that the assumed knowledge of the reader is appropriate.

Once the review has been completed and both the author and the reviewer have agreed the final version, the SOP will be signed by both parties and will become 'active'. This means that all procedures covered within the SOP must be carried out in accordance with the SOP content.

The reviewer of SOP will be one of the following:

- The Director of Research & Development
- The Research Management & Governance Manager
- The Clinical Research Development Manager

4.4 Maintentance of SOPs

As SOPs should document the current practice, they should be updated whenever the practice changes. For this reason, whenever an SOP-documented procedure alters, the SOP covering that procedure must be updated as soon as possible.

Review dates will not be stated on the SOPs, however routine reviews will typically take place every three years.

4.5 Retirement of SOPs

When an SOP-documented procedure is ceased, the SOP covering that practice will be retired. The original signed copy of the SOP will be retained and archived indefinitely within the Research & Development office.

5 Health and Safety

There are no health and safety risks associated with this SOP.