Queen's University Belfast

Research and Enterprise

Standard Operating Procedure
Research Governance

Title:	**Archiving Research Study Documents**		
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	Name and Position	**Signature**	**Date**
Author:	Dr Stephen Liggett Research Governance Manager	----------	----------
Reviewed by:	Mrs Louise Dunlop, Head of Research Governance	----------	_____
Approved by:	Professor James McElnay, Chair Research Governance Steering Group	----------	_____

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Revision Log

Previous Version number	Date of Review/Modification	Reason for Review/Modification	New Version Number
v1.0	6 October 2014	Periodic Review	v2.0
v 2.0	23 January 2017	Periodic Review	v 3.0

1. Purpose

This procedure is to ensure that when the University has acted as Sponsor, study files generated during non-CTIMP research studies are archived in a standardised manner. It is important to recognise that the archival process should comply with relevant legislation and University Policies.

2. Introduction

A structured archival process is necessary for study files generated for a research study. There are also legislative and regulatory responsibilities regarding the archival of study files should the need arise to review a study within a reasonable or contractually defined time limit. Funders often dictate in a research agreement the retention time of study data and materials. The information contained within the files may be of a sensitive nature and it is of reputational importance to the University to ensure that this information is managed in a professional manner.

In the event of a plagiarism allegation, it is essential that study files have been retained in accordance with the principles of this SOP. The ability to produce the 'original' research and related essential documentation is often the best defence against this assertion.

3. Scope

This SOP applies to the study files generated for non-CTIMP research studies were the University has acted as sponsor. These files are sometimes termed the Trial Master File and should be organised in accordance with the relevant University SOP (QUB-ADRE-008). The archival of study files must be in an organised way that will permit the audit of such files.

4. Responsibilities

The Chief Investigator (CI) will be the designated archivist for the study and is responsible for the following activities:

- The archiving of all related paper and electronic documents once the study has ended;
- Control of access to the archived material;
- Ensure that the place of storage is fit for purpose;
- Ensure compliance with legislation and contractual obligations;
- On request, provide the archived study files to a relevant University/external auditor.

Documentation and materials held by a contractor must also be considered when archiving a study. All tasks can be delegated, but the CI retains full accountability for the archival of the study in accordance with the principles of this SOP.

5. Procedure

A study file should be archived when the End of Study Declaration and Study Summary has been submitted to ORECNI. The archival process will consist of the following steps:

1. The study shall be physically marked as closed and highlighted as requiring archival;
2. The University currently requires data to be held for 5 years, however some of the main funding bodies require a longer period of data retention as detailed in Table1:

Funder	Typical research data retention requirements
QUB	Minimum 5 years
MRC	Minimum 10 years for basic research
EPSRC	Minimum 10 years
CRUK	Minimum 5 years
NERC	Not stated

Table 1: Data retention requirements of major funders (Oct 2012)

3. It is also likely that the funder will have included contractual obligations regarding the publication and sharing of research data. The archival of the file must permit the CI to comply with any such stipulations;
4. It is expected that the TMF should be archived in its entirety, but a checklist (QUB-ADRE-027 Appendix 1) should be used as a guide to the general elements that should be confirmed as present;
5. In general, the following aspects should be considered when archiving a study:
    - Funding Award letters/Peer reviews
    - Protocol
    - Amendments
    - Approvals
    - Audit certificates
    - Participant information forms
    - Consent forms
    - IRAS application
    - Advertisements
    - Financial
    - Study agreements
    - Trust approval/correspondence
    - Important correspondence
    - Any adverse events or complaints
    - Completed consent forms
    - CV's of study staff
    - Any reports relating to lab testing
    - Supporting quality documentation
    - Raw data
    - Source forms
    - Safety information
    - Risk assessments
    - Annual reports
    - End of Study declarations
    - Final report/summary reports
    - Publications
    - Supporting lab/fieldwork documentation
6. All electronic files will also be moved into an electronic archive. The archive folder will be password protected and access should be restricted;
7. Once the tasks detailed on the checklist are complete the CI should sign and place at the front of the file;
8. A copy of the checklist should be retained by the CI;
9. Some funders may have defined standards for this process in excess of is the requirements detailed in this procedure. These must be complied with

6. References

None

7. Appendices

Appendix 1- Archival Checklist (QUB-ADRE-027-Appendix1)

Appendix 1
QUB-ADRE-027

Archival Checklist

Full Title of Study to be Archived:

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_____

Ethics Approval Reference: _____

Date Study Can be Destroyed: _____

Archival of Study File (Hard Copy)

Action	Completed	Signed
The file has been marked as closed	□	
An end of study declaration and study summary have been submitted to ORECNI	□	
The following documentation is present within the file:		
• **Protocol**	□	
• **Sponsorship letter**	□	
• **Ethics/regulatory approval**	□	
• **IRAS form**	□	
• **Investigator CV's**	□	
• **Peer reviews**	□	
• **Lab/field notebooks collected**	□	
• **Adverse events/complaint forms**	□	
• **Amendments**	□	
• **End of study declaration/study summary**	□	
• **Funding requirements met**	□	
• **Trust approval/correspondence documentation**	□	
All electronic files associated with this study have been moved to a restricted access folder	□	

Comments:

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Chief Investigator: **Date:**