Standard Operating Procedure

Title:	Setting Up, Maintaining and Archiving Research Files		
SOP Reference Number:	QUB-RGEI-008	Version Number:	FINAL 1.0
Revision Date	15 September 2021	Review Date	15 September 2024

	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

1. Purpose

A Research File (RF) is a standardised filing system which allows for the effective storage of documentation relating to a specific research project. A RF ensures that all essential documentation for the project is easily located and readily available for inspection/audit. This Standard Operating Procedure (SOP) describes the essential documentation which is required to be held and maintained within a RF. It also outlines the requirements for the storage and archiving of RFs.

2. Scope

It applies to all members of University staff; both academic and support staff as defined by Statute 1, including honorary staff and students.

3. Responsibilities

The Chief Investigator (CI) has overall responsibility for the content, maintenance and archiving of the RF. The day to day maintenance of a RF can be delegated to another member of the research team but the CI still retains overall responsibility.

4. Procedure

4.1 Structure and Content

The table in Appendix 1 details the recommended format and content of the RF. As a general rule, any study related approvals and communication not listed should also be retained.

A lever arch file(s) is the best format for the storage of essential documentation, though electronic folders can also be used. The chosen format should be clearly labelled with the:

- CI name
- Title of the research project
- Research project reference number(s) (eg REC Ref)

It should be noted that a RF may consist of more than one volume. Should this be the case label the files accordingly e.g. File 1 of 3, File 2 of 3 and File 3 of 3 etc.

The documents should be filed in the appropriate sections as detailed in Appendix 1, then in chronological order within each section. A copy of the content checklist should be included in the folder.

As the project progresses documents may require amendment. Amendments should be kept in chronological order indicating the changes made and the dates they are implemented. Old documents/versions should also be retained and marked superseded.

The content checklist is not exhaustive and the documents retained in the RF may vary. Where certain sections, outlined in Appendix 1, are not applicable to the research, it is good practice to detail a note in the file/section explaining why this section is not required. When documents listed are not held within the RF then is the storage location should be documented in the RF.

Documents (or copies) filed in the RF should contain all required signatures.

4.2 Storage

As the RF may contain essential original documents and/or confidential data it is important that it is retained in a secure location and in secure conditions. Where RFs are held in electronic format, these should be password protected and access should be restricted.

4.3 Archiving

A RF should be archived when the End of Study Declaration and Study Summary has been submitted to the NHS/HSC Research Ethics Committee (REC). 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 10 years
NERC	Minimum 10 years

Table 1: Data retention requirements of major funders (July 2021)

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 RF should be archived in its entirety, but a checklist (Appendix 2) 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
    - Supporting lab/fieldwork documentation
    - 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
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.

5. Appendices

Appendix 1 Research File Content Checklist
Appendix 2 Archival Checklist

Appendix 1

QUEEN'S UNIVERSITY BELFAST
Research File Content Checklist*

*Note this is a checklist for guidance only. Documents required will vary according to the type of research.

Research Title:	
Chief Investigator:	
Members of Research Team	
Staff:	**Students:**
Reference Numbers (as applicable)	
QUB Ref:	**Ethics Ref:**
NHS/HSC Trust Ref:	**Other Ref:**

Title of Document	Further Details	Tick if Included
1. Protocol and Consent		
Final research protocol and amended protocols with version numbers	To document the study protocol to be followed and any amendment(s).	
Confirmation of peer review	To provide evidence that the scientific quality of the project has been independently assessed (eg QUB peer review form, funders peer review).	
Example of Informed Consent Form and any amendments	To provide evidence of how informed consent will be logged.	
Examples of any other written information provided to	To document that research participants will be given sufficient written	

participants and any updates	information (content and wording) to enable them to give fully informed consent (eg Participant Information Sheets).	
Copy of advertisement for participant recruitment and any amendments	To document that recruitment measures are appropriate and not coercive (eg poster, email for circulation).	
Copy of any letter/information for a patients GP or consultant		
2. Ethics		
Final Ethics Application and any amendments	For example Faculty/School REC application form, IRAS form (IRAS), Tissue Bank application form.	
Ethics favourable opinion letter(s)	To document that the study has received Ethics Committee approval and to identify the version number and date(s) of the approved documents. Approvals to any amendments need to be stored alongside originals.	
Ethics Reports	For example, annual progress reports, safety reports, end of study declaration and final report.	
Any Ethics Correspondence	Include any relevant communications.	
3. Research and Development		
NHS/HSC Trust application (if applicable)	For example IRAS, OID, SoE, any Trust specific application forms – RAF/PIAF.	
Copy of confirmation of capacity and capability/ management permissions	To document that the trust has confirmed that the study has approval to begin.	
4. Sponsorship and Insurance		
Sponsor Letter	To document that a research sponsor has been identified and agreed	
Copy of sponsor agreement and allocation of responsibilities (if applicable)	To ensure appropriate arrangements are in place for the initiation, management and financing of the project (ie co-sponsorship framework for studies involving HSC Trust and QUB).	
Insurance Statement (copy of certificate/letter/agreement)	To document provisions to the participant(s) for any study-related harm they might experience. This includes cover for negligent and non-negligent harm.	
5. Finance and Contracts		
Copy of financial information relating to the study	For example funding application/award letter/costings. To document that	

	financial arrangements for the study are in place.	
Copy of any signed agreement(s)/contracts between involved parties	To document agreements and responsibilities for the preparation, conduct and closure of the study (eg Service Level Agreements).	
6. Regulatory (if applicable)		
Copy of any correspondence with Regulatory Authority	To document where applicable that due consideration was afforded to legislation (eg confirmation that MHRA approval was not required).	
7. Correspondence (except Trust and Ethics)		
Relevant written correspondence	For example relevant letters, meeting notes and minutes, records of telephone conversations, emails.	
8. Research Team		
CVs for Chief Investigator/ key research team (or other relevant documents)	To document the qualifications and eligibility of the CI and any key members of the research team to conduct the study.	
Delegation of duty log/study management structure	To document roles and responsibilities of staff for the study.	
Training records	To document any study specific training or general competency training each member of the research team has undertaken (eg GCP, HTA training, informed consent training, relevant health and safety training).	
Placement Agreements for non-NHS Trust staff		
9. Participant Information		
Copies of original informed consent forms signed by each project participant	If these are not held within the study folder provide details of the storage location.	
Participant ID code list	To document that the CI keeps a confidential list of all participants allocated to study numbers on enrolling in the study.	
Master randomisation list (if applicable)	To document the actual randomisation of the study participants to different treatment arms.	
Participant screening log (if applicable)	Required to identify all participants who entered pre-study screening even if they were not entered into the study. Document reasons for non-entry as appropriate.	
Participant enrolment log (if applicable)	To document the chronological enrolment of participants into the study.	
10. Data/Sample Collection		
Records of human tissue samples (if any)	To document any human tissue samples stored including the storage	

	location, use and disposal of these samples. If records are stored electronically indicate where these are stored.	
Transport/transfer records for human tissue samples	To document the transfer of human tissue samples, including local records of samples sent and received, Authority to Import forms, Material Transfer Agreements etc.	
Samples of forms used for the study and completion guidance	To document data collection records, questionnaires etc to be used in the study.	
Document of data storage	Indicate the location of hard copies and electronic versions of source data. Indicate back-up procedures for electronic versions of data.	
Standard Operating Procedures	To document study specific SOPs.	
Risk assessments	To document the assessment of risk and implementation of control measures, including risk to personal and if applicable human tissue.	
11. Adverse Events		
Completed Adverse Event report form(s) if applicable	To record any adverse events associated with the study (eg HTA adverse event notification forms).	
12. Intervention/Product Related (if applicable)		
Details of product to be used and the supplier	To document instructions needed to ensure proper storage, packaging, dispensing and disposal.	
Instructions for usage, storage and disposal of any product to be used	To document instructions needed to ensure proper storage, packaging, dispensing and disposal.	
Shipping records for the product	To document shipment dates, batch numbers and methods of shipment and for tracking of product batch, review of the shipping conditions and accountability.	
Certificate(s) of analysis	To document the identity, purity and strength of any products to be used in the study.	
13. Audit		
Record(s) of all audit reports	For example copies of Research Governance audit reports.	

Appendix 2
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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:**

_____ _____