QUEEN'S UNIVERSITY BELFAST

GUIDELINES FOR RESEARCH FILES

1. Introduction

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.

A RF should be established when an outline study protocol/proposal has been developed and/or first contact is made with the research sponsor.

It should be noted that not all documents will be of relevance to every project and therefore the content of the RF will vary from project to project.

2. Responsibilities

The Chief Investigator (CI)/Principal Investigator (PI) has overall responsibility for the content of the maintenance 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.

The University's Research Support Office will be responsible for maintaining the appropriate financial information and the Contracts Team will maintain the contractual information associated with the study.

3. Setting up a RF: Content and Structure

The table in Appendix 1 details the recommended format and content of the RF. As a 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 secure filing cabinets can be used. The chosen format should be clearly labelled with the:

- CI/PI 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.

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. RF 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.

5. RF Archiving

The SOP Archiving Research Study Documents (QUB-ADRE-027) details the University's archiving requirements for study documentation.

6. RF Audit

The RF may be subject to audit by the University Research Governance Team or when appropriate by external funders or legislative bodies (eg Human Tissue Authority).

7. References

Archiving Research Study Documents (QUB-ADRE-027)
http://www.qub.ac.uk/directorates/ResearchEnterprise/ResearchGovernanceandEthics/StandardOperatingProcedures/OtherResearch/)

8. Appendices

Appendix 1 – RF Content and Structure

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 subjects and any updates	To document that research subjects will be given sufficient written information (content and wording) to enable them to give fully informed	

	consent (eg Participant Information Sheets).	
Copy of advertisement for subject 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 SREC application form, NHS REC form (IRAS), SSI form for non NHS sites (IRAS), NIB 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		
Trust and R&D application form and approval letter	To document that the study has received local R&D office approval where the research is being conducted and access to patients in their care as applicable (eg NHS/HSC R&D form (IRAS), SSI form for NHS sites (IRAS), any Trust specific application forms – RAFs etc).	
Copy of Trust Permissions	To document that the trust has confirmed that the study has approval to begin.	
Copy of financial information relating to the study (funding application/award letter/costings)	To document that financial arrangements for the study are in place.	
Insurance Statement (copy of certificate/letter/agreement)	To document provisions to the subject(s) for any study-related harm they might experience. This includes cover for negligent and non-negligent harm.	
Copy of sponsor agreement and allocation of responsibilities	To document that a research sponsor has been identified 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).	

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).	
4. 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).	
5. Correspondence (except Trust and Ethics)		
Relevant written correspondence	For example relevant letters, meeting notes and minutes, records of telephone conversations, emails.	
6. Research Team		
CVs for Chief Investigator/research team (or other relevant documents)	To document the qualifications and eligibility of the CI/PI(s) 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).	
Honorary Contracts for non-NHS Trust staff		
7. 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.	
Subject ID code list	To document that the CI/PI keeps a confidential list of all subjects allocated to study numbers on enrolling in the study.	
Master randomisation list (if applicable)	To document the actual randomisation of the study subjects to different treatment arms.	
Subject screening log (if applicable)	Required to identify all subjects who entered pre-study screening even if they were not entered into the study. Document reasons for non-entry as appropriate.	
Subject enrolment log (if applicable)	To document the chronological enrolment of subjects into the study.	
8. 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.	
9. 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).	
10. 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.	
11. Audit		
Record(s) of all audit reports	For example copies of Research Governance audit reports.	