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JOINT RESEARCH SUPPORT OFFICE

STANDARD OPERATING PROCEDURES

UHL Research Support Office
SOP S-1015 UHL V10 April 2020

Standard Operating Procedure for Management of Essential Documents and Trial Filing for Research sponsored by University Hospitals of Leicester NHS Trust (UHL)

PCG Reference No: C18/2014

OFFICE BASE

Research & Innovation
Leicester General Hospital
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1. Introduction

This Standard Operating Procedure (SOP) describes the creation of an audit trail through the retention of essential documents in the Trial Master File (TMF) or Investigator Site file (ISF) for all research sponsored by University Hospitals of Leicester NHS Trust.

The Essential Documents relating to a research study are those documents which individually and collectively enable both the conduct of the research study and the quality of the data produced to be evaluated. These documents serve to demonstrate compliance with the appropriate standards e.g. Good Clinical Practice (GCP) and with all regulatory requirements.

All clinical information must be recorded, handled and stored in such a way that it can be accurately reported, interpreted and verified, while the confidentiality of the trial subjects remains protected.

2. Scope

This SOP applies to all staff, and any external individual who approach the UHL to request that the organisation act as Sponsor for research.

3. Trial Master File (TMF)

A TMF must be prepared prior to study initiation and must be actively maintained and updated until the study is formally closed. When it becomes available, the final report must be filed in the TMF.

The TMF contains all the essential documents relating to a research study before it commences, during study conduct and after completion of the study. It is the responsibility of the Chief Investigator to establish a TMF for each research study they initiate. The TMF must be structured in a way that allows the reconstruction of the study from the documentation. (Further information on site file organisation is available on the NIHR website). The documentation contained within the TMF should be sufficient to adequately reconstruct the study activities undertaken, along with key decisions made concerning the study. Consideration should be given to the TMF being a stand-alone set of documentation that does not require additional explanation as competent authority inspections often take place some years after study completion when personnel involved may no longer be available.

The documentation listed in Eudralex Volume 10/ ISO 14155:2011 should not be used as a definitive checklist for TMF content, but rather a subset of potential documentation that could be regarded as essential for reconstruction of the study conduct, as not all documents essential to reconstruct the study are included in the above e.g. the green light document. In addition, it is recommended that an assessment of all activities is undertaken to determine whether they need to be documented to enable reconstruction of the study conduct from the paperwork alone, e.g. training provided by the investigator to site staff.

Where a risk-adapted approach is being followed however, some documents listed in the guidance may not be in the TMF-for example-IMP temperature storage records. If this is the case the rationale for this must be documented in the study risk assessment.

4. Investigator Site File (ISF)

The ISF consists of essential documents relating to the specific investigator site, before the study commences, during study conduct and after completion of the study. It is the responsibility of the Principal Investigator to establish an ISF for each research study they participate in.

A multi-centre study must have a TMF, and also a file for each individual site taking part in the study. It is acceptable to have individual sections rather than files for each site contained within the TMF.

For a single centre study it is acceptable for all documents to be held in one single file which acts as both the TMF and ISF.

A tabulated guide to TMF/ISF documents is contained in Appendix 1 (TMF/ISF Index for CTIMP studies), Appendix 1a (TMF/ISF index for Non CE Marked Medical Device Studies) and Appendix 2 (TMF/ISF Index for Non CTIMP studies), Appendix 2a (TMF/ISF index for CE Marked/Proof of Concept Studies). The Index may be adapted to reflect specific study requirements.

It is expected that all TMF and ISF are 'inspection ready' at all times. Non-compliance and/or where areas of concern have been identified will be escalated in accordance with the Non compliance SOP S-1016 UHL.

There is a legal requirement that researchers retain the TMF/ISF and all other study related documentation. Appendix 4 details minimum requirements for each type of study.

NB: The UHL Sponsor aspects of the TMF / ISF are held electronically in the EDGE system. Access to EDGE to see the files will be granted on request.

5. Procedure

5.1 Responsible Personnel

The CI or PI will be responsible for establishing and maintaining the TMF / ISF and may delegate these activities to a research team member. This must be recorded on the Delegation of Authorities Log. The files must be actively maintained until the study is formally closed

5.2 Storage of TMF / ISF

All essential documents must be appropriately stored at all times. The TMF/ISF must be stored in a secure location, preferably in a lockable cabinet, but within a secure locked area with minimal staff access, other than research staff. The Investigator must be able to demonstrate that all reasonable measures have been taken to ensure its security and to protect confidentiality and data integrity. It may not be possible for all documentation to be stored in one file. Where separate file/s, including electronic versions of documents are required / maintained, a file note must be made in the TMF/ISF which documents the location and title of the additional file/s. Where a separate pharmacy file is created for the purposes of study management, this remains part of the TMF/ISF but can remain in Pharmacy. Where there are multiple files, the spine of the files must be labelled clearly e.g. Study ID, PI, File X of Y.

5.3 Version Control

All documents must be version controlled, signed and dated where appropriate. All previous versions of documents must be retained, but marked as superseded by striking through the front cover with a single line in BLACK pen and marking as superseded by the later version. It is recommended that a Version Control Tracker be utilised (Appendix 3). A file note (signed and dated by the CI/PI) must be placed in the file giving details of any missing or unavailable documents.

5.4 Vendors/Third Party Contractors

Copies of fully executed contracts and any formal technical agreements/plans detailing delegated functions between the Vendor and Sponsor must be maintained within the TMF/ISF. Copies of all documentation generated by either party relating to the agreements and delegated functions must also be present.

5.5 Archiving

Archiving of the TMF/ISF and all associated essential documents must be undertaken as per SOP S-1024 UHL Process for Study Close Down for Research Sponsored by UHL and SOP S-1029 UHL Archiving of Essential Documents for Research Sponsored by UHL.

6. Non Compliance

Failure to demonstrate compliance to this SOP will result in implementation of the SOP S-1016 UHL Non Compliance SOP at a minimum of a CRITICAL Finding.

7. Responsibilities

	Responsibility	Undertaken by	Activity
1.	Chief Investigator/Principal Investigator	Chief Investigator/Principal Investigator	Establishing the TMF/ISF at the beginning of the study
2.	Chief Investigator/Principal Investigator	Chief Investigator/Principal Investigator	Maintaining the TMF/ISF during the life of the study
3.	Chief Investigator/Principal Investigator	Chief Investigator/Principal Investigator	Ensure the safe storage of the TMF/ISF at all times.
4.	Chief Investigator/Principal Investigator	Chief Investigator/Principal Investigator	Ensure the TMF/ISF is archived as per the approved protocol and the SOP S-1024 UHL Study Close-down and SOP S-1029 UHL Archiving

This table is used to track the development and approval of the document and any changes made on revised / reviewed versions

DEVELOPMENT AND APPROVAL RECORD FOR THIS DOCUMENT		
Author / Lead Officer:	Carolyn Maloney	**Job Title:** Head of Research Operations
Reviewed by:	UHL R&I Management Meeting	
Approved by:	Professor Nigel Brunskill	**Date Approved:** 1/10/20

REVIEW RECORD			
Date	**Issue Number**	**Reviewed By**	**Description Of Changes (If Any)**
April 2015	2	Carolyn Maloney	Change of Logo and corporate identity
June 2015	3	Carolyn Maloney	Updated clauses and Appendices
August 2016	5	CM, LW, JJ	Consistency checks.
November 2016	6	CM	Upgrade to CRITICAL finding for non-compliance.
February 2017	7	Carolyn Maloney	Update Logo
Jan 2018	8	CM	Update to Logo, added file numbering, added Guidelines for document retention
April 2019	9	JJ	Updated to include CE Marked/Non CE Marked Medical Device TMF/ISF indexes
April 2020	10	LW,JJ,AM	

DISTRIBUTION RECORD:			
Date	**Name**	**Dept**	**Received**

Trial Master File / Investigator Site File Index
Clinical Trials of Investigational Medicinal Products

This Trial Master File/ Investigator Site file index template has been produced with regards to the documentation required by UHL, as Sponsor, for the completion of both single and multi-centre CTIMP studies. This index can be modified to suit individual study requirements.

The documentation detailed in plain text is for individual Site, Investigator Site Files. The additional documentation detailed in italic is with regards to the requirement for the Trial Master File only, held and maintained by the Chief Investigator.

SECTION	TITLE	DOCUMENTS
1.	Contact List	Including details of relevant study site staff, responsible HRA/REC, R&I contacts, pharmacy, laboratory and other relevant departments involved in the study *At Trial Master File level:* *Copies of contact lists from all collaborating centres*
2.	Protocol	Current protocol signed and dated by PI Signed and dated protocol signature page(s) for all protocol versions. Superseded protocol(s) Completed protocol read log/s for all relevant study personnel Protocol deviationlog master template Completed protocol deviation log File note template *At Trial Master File level:* Signed protocol signature page for current and all superceded protocols for all collaborating sites Copy of signed and dated protocol deviation logs for collaborating sites. Completed protocol read log/s for all relevant study personnel

3.	Health Research Authority / Ethics Committee	Signed and dated IRAS application Statement of activities / Organisational Information Document/ schedule of events HRA initial assessment letter (where applicable) REC letter of acknowledgement REC letter of provisional /full favourable opinion HRA approval letter Substantial Amendments: Substantial amendment application form (via IRAS) to HRA/REC HRA /REC confirmation of submission email HRA categorisation email HRA approval letter / REC favourable opinion letter Non Substantial Amendments: Minor amendments application form (via IRAS) to HRA/REC HRA /REC confirmation of submission email HRA approval /REC favourable opinion GCP compliance / REC constitution /composition / list of members (Evidence that list of data monitoring committee members (where applicable) has been sent to REC) (forms part of REC favourable opinion) HRA / Ethics correspondence <u>*At Trial Master File level:*</u> *Completed feasibility form* *Copy of completed / statements of activities/ organisational information document/schedule of events and relevant HRA approvals / REC favourable opinion.* *Evidence of receipt of amendment from all collaborating centres* *Correspondence where appropriate with Sponsor / HRA & REC*

4.	Competent Authority	Clinical Trial Authorisation (CTA) application CTA acceptance letter Submission / acknowledgement / approval of amendment/s letter/s MHRA Correspondence <u>*At Trial Master File level:*</u> *CTA and acknowledgement letters for all relevant amendments for all collaborating centres* *Correspondence with MHRA with regards to collaborating centres*
5.	R&I	R & I application/capability assessment R & I approval / authorisation Submission / notification and R&I acknowledgement/approval / authorisation of all Substantial and Non-Substantial Amendments R & I correspondence <u>*At Trial Master File level:*</u> *Collaborating sites R&I/R&D submission and approval/ authorisation documentation.* *Notification / receipt of all subsequent amendments/approvals / authorisation* *Local R&I / R&D correspondence*
6.	Investigator Site Personnel	Template of Delegation of Authority Log Template signature log (eDOA only) Completed Delegation of Authority Log(s) Completed signature log (e DOA only) Original signed and dated current CVs for all study personnel named on the delegation log/eDOA, covering the period of the study Evidence of GCP training/consent training e.g. certificate / email, covering the total period of the study

		Evidence of study specific training *<u>At Trial Master File level:</u>* *Collaborating centre: copy of current completed delegation of duties / authorised signatures forms. Signed and dated CVs for PI and all staff named on delegation log.* *Trial training documentation:-* *- GCP training evidence for all staff named on delegation log* *- Consent training evidence where required.* *- Pharmacovigilance Training where appropriate* *- Protocol-related training / Investigator meeting documentation*
7.	Standard Operating Procedures	Details of where and how to access current Sponsor SOPs Complete Standard Operating Procedures Read Log for all study staff members. All relevant Sponsor standard operating procedures must be read by all research team members. *<u>At Trial Master File level:</u>* *Completed SOP read log for all staff named on collaborating centres delegation logs.*
8.	Study Documentation	Template of all current approved participant information sheets and informed consent forms printed on UHL headed paper (make sure the version and date number is entered) Superseded documentation e.g. participant information sheets and informed consent forms Template of GP letter Template of any other study related material e.g. invitation letters/posters/questionnaires) Sample Case Report Form *<u>At Trial Master File level:</u>* *Evidence that collaborating sites are utilising the current approved version of all study documentation.*

9.	Subject Documentation	Template screening log (where applicable) Completed screening log/s containing non identifiable participant data only (where applicable) Template subject enrolment/identification log Completed subject enrolment/identification log (not to be removed from site). <u>*At Trial Master File level:*</u> *Details of subject enrolment numbers utilised for individual collaborating sites. No patient identifiable data.*
10.	Randomisation	Documentation of randomisation process Details of randomisation process and all relevant guidance documentation if utilised. Master randomisation list (in sealed envelope) anddetails of electronic randomisation process/details of where master randomisation list is held and relevant contact details. Evidence (where applicable) of randomisation i.e. envelopes / email / IVRS Location of code breaker. <u>*At Trial Master File level:*</u> *Details of randomisation process and relevant contact details for all collaborating centres.*
11.	Data Management	Statistical Analysis Plan-*TMF only* Details of electronic/paper case report form storage/security Data Management Plan- *TMF only* Superceded data management plan/statistical analysis plan where applicable Electronic Data Capture (EDC)/ eCase Report Form (eCRF) training records

12.	Source Data	Source Data Schedule Data query/response documentation <u>*At Trial Master File level:*</u> *Site/s source data schedule/s* *Site data query/response document*
13.	Informed Consent	Original copies of all completed consent forms including all re consent forms where applicable, with associated patient information sheets Copy of 100% consent form audit record where applicable <u>*At Trial Master File level:*</u> *Copies of 100% consent form audit records where applicable for all collaborating centres*
14.	Pharmacovigilance/Safety Reporting	SAE reporting guidelines/pharmacovigilance/governance contact details. Please refer to the SOP relating to safety reportingCurrent SAE form template and SAE form completion guidance document. Completed Serious Adverse Event/ Serious Adverse Reaction report forms and Sponsor /R&I/R&D acknowledgement documentation. SUSAR reporting guidelines Completed SUSAR reports and acknowledgements from Sponsor/MHRA/R&I/R&D SAE/SAR/SUSAR tracking log Annual Development Safety Update Report/Short format DSUR (where applicable) and acknowledgement correspondence (MHRA & REC) Evidence of Data Monitoring Committee meetings - agenda/minutes <u>*At Trial Master File level:*</u> *Copies of all collaborating centre SAE/SUSARs reports and acknowledgements/adjudication* *Evidence of provision/receipt of DSUR/Short format DSUR for all collaborating centres* *Correspondence*

15.	Reference Safety Information	Investigator Brochure / Summary of Products Characteristics with evidence of annual review and update by CI/PI(signed and dated) Investigational Medicinal Product Dossier (where applicable) Superseded IB/IMPD/SMPC documents Safety alert updates <u>*At Trial Master File level:*</u> *Evidence of receipt of IB/SMPC/ IMPDsafety alert updated for all collaborating centres* *Correspondence*
16.	Monitoring	Agenda and minutes from initiation/ pre-trial meeting Study specific monitoring plan Initiation visit/site/pharmacy report Monitoring Log Template Completed monitoring log Interim monitoring documentation e.g.site/pharmacy monitoring visit reports and CI/PI responses Final trial close out/site/pharmacy monitoring reports External audit reports and responses Associated correspondence <u>*At Trial Master File level:*</u> *Copies of all site/pharmacy monitoring reports and associated responses for all centres. External audits and responses.*

17.	Clinical Laboratory	Central laboratories certificates of accreditation, where applicable Central laboratories normal reference ranges (including revisions) where applicable Local laboratories certificates of accreditation, where applicable Local laboratories normal reference ranges (including revisions) where applicable Lab manual/sample processing instructions, where applicable Details of sample storage facilities/ processes/relevant personnel contact details Sample shipment receipt/ tracking logs, where applicable Temperature logs for sample storage Sample storage instructions/Inventory of samples/specimens, where applicable Inventory/destruction log of all samples/specimens Details of sample storage arrangements (where applicable) for all samples held for future research <u>*At Trial Master File level:*</u> *Certificates of accreditation and normal reference ranges for local labs of all participating sites* *Inventory of samples/specimens storage and temperature logs as applicable* *Contact details of all relevant personnel responsible for sample management*
18.	Pharmacy	Evidence of GCP training e.g. certificate/email covering the period of the study Original signed and dated current CVs for all pharmacy personnel named on the Delegation Log, covering the period of the study Sponsor Green Light approval documents

		Investigational Medicinal Product packaging (label specification, copies of labels) Instructions for handling and storage of trial medication and trial related materials (randomisation, re-supply, return / destruction. Code breaking (unblinding) documentation(IVRS if applicable) Master template prescription form Completed prescription forms Template of Accountability forms / Inventory Forms / Dispensing logs / Temperature logs for all sites. Drug Destruction documentation. (completed documents will be filed in the pharmacy file) The following is applicable when Pharmacy is involved with Investigational Medicinal Product Manufacturing: - GMP certificate - Certificate of Analysis - Authorisation of release by Qualified Person The above documents will be filed in the pharmacy file) <u>*At Trial Master File level:*</u> *For all collaborating centres:* *Sponsor green light documentation* *Confirmation of drug receipt/ Drug Accountability/IMP destruction.* *Pharmacy correspondence*
19.	Financial / Legal	Contracts / contract addendums with all investigators and sub-contractors Chief Investigator Agreement, where applicable Confirmation of sponsorship Evidence of peer review, where applicable Funding Letter(s)/ financial agreement Insurance and indemnity statement for all investigators

		Clinical trial agreement with all investigators Financial correspondence Records of subject expenses <u>*At Trial Master File level:*</u> *Copies of all contacts and agreements/ amendments with collaborating centres and external vendors*
20.	Study Related Supplies	Shipment/delivery Collection/return Supplies re-order form templates Completed supply request forms Evidence of maintenance/calibration certification of all applicable equipment <u>*At Trial Master File level:*</u> *Copies of all relevant supply documentation and evidence of equipment maintenance/calibration for all collaborating centres*
21.	Annual /End of study declaration/Final report	Annual reports to HRA / REC and Sponsor Notice to HRA / REC, MHRA and R&I / R&D of trial completion (end of study declaration)-*TMF only* Final study report and acknowledgement from HRA/REC/ MHRA/Sponsor Confirmation that the final report/study publication has been uploaded to EudraCT and any public databases as detailed in the ethical application. <u>*At Trial Master File level:*</u> *Confirmation that all reports have been received and acknowledged by collaborating centres*
22.	Publications	Copies of all study analysis publications

23.	Correspondence	Correspondence with CI / Sponsor and internal site correspondence, including newsletters and other study specific correspondence. Meeting agendas and minutes General correspondence *At Trial Master File level:* *Relevant trial related correspondence with all collaborating centres*
24.	Miscellaneous (detail documents where applicable)	

Trial Master File / Investigator Site File Index for Non-CE Marked Medical Device Studies

This Trial Master File/ Investigator Site file index template has been produced with regards to the documentation required by UHL, as Sponsor, for the completion of both single and multi-centre Non CE-Marked Medical Device Studies. This Index can be modified to suit individual study requirements.

The documentation detailed in plain text is for individual Site, Investigator Site Files. The additional documentation detailed in italic is with regards to the requirement for the Trial Master file only, held and maintained by the Chief Investigator.

SECTION	TITLE	DOCUMENTS
1.	Contact List	Including details of relevant study site staff, responsible HRA/REC, R&I contacts, Device Manufacturer/Supplier, pharmacy (where applicable), laboratory and other relevant departments involved in the study *<u>At Trial Master File level:</u>* *Copies of contact lists from all collaborating centres*
2.	Clinical Investigation Plan (CIP)/Protocol	Current CIP/ protocol signed and dated by PI Signed and dated CIP/protocol signature page(s) for all CIP/protocol versions. Superseded CIP/ protocol(s) Completed CIP/protocol read log/s for all relevant study personnel CIP/Protocol Deviation Log Master Template Completed CIP/Protocol deviation log File note template *<u>At Trial Master File level:</u>* *Signed CIP/ protocol signature page for current and all superceded CIP/protocols for all collaborating site* *Copy of signed and dated CIP/protocol deviation logs for collaborating centres.* *Completed CIP/protocol read log/s for all relevant study personnel*

3.	Health Research Authority / Ethics Committee	Signed and dated IRAS Application Statement of Activities(where applicable) Organisational Information Document / Schedule of Events HRA Initial Assessment Letter (where applicable) REC letter of acknowledgement REC letter of provisional /full favourable Opinion HRA approval letter Substantial Amendments: Substantial amendment application form (via IRAS) to HRA/REC HRA /REC confirmation of submission email HRA categorisation email HRA Approval letter / REC favourable opinion letter Non Substantial Amendments: Minor amendments application form (via IRAS) to HRA/REC HRA /REC confirmation of submission email HRA approval /REC favourable opinion GCP Compliance / REC Constitution /Composition / List of members (forms part of REC favourable opinion) HRA / Ethics Correspondence *<u>At Trial Master File level:</u>* *Completed Feasibility Form* *Copy of completed Statements of Activities/Organisation Information Document/ Schedule of Events and relevant HRA approvals / REC favourable opinion.* *Evidence of receipt of amendment from all collaborating centres* *Correspondence where appropriate with Sponsor / HRA & REC*

4.	Competent Authority	Clinical Trial Authorisation (CTA) application CTA acceptance letter Submission / Acknowledgement / Approval of amendment/s letter/s MHRA Correspondence <u>*At Trial Master File level:*</u> *CTA and acknowledgement letters for all relevant amendments for all collaborating centres* *Correspondence with MHRA with regards to collaborating centres*
5.	R&I	R & I application/capability assessment R & I approval / authorisation Submission / Notification and R&I acknowledgement/approval / authorisation of all Substantial and Non-Substantial Amendments R & I Correspondence <u>*At Trial Master File level:*</u> *Collaborating sites R&I/R&D submission and approval/ authorisation documentation.* *Notification / receipt of all subsequent amendments/approvals / authorisation* *Local R&I / R&D correspondence*
6.	Investigator Site Personnel	Template of Delegation of Authority Log Completed Delegation of Authority Log(s) Original signed and dated current CVs for all study personnel named on the Delegation Log, covering the period of the study Evidence of GCP training/consent training e.g. certificate / email, covering the total period of the study Evidence of study and device specific training

		At Trial Master File level: *Collaborating centre: Copy of current completed delegation of duties / authorised signatures forms. Signed and dated CVs for PI and all staff named on delegation log.* *Trial Training documentation:-* *- GCP Training evidence for all staff named on delegation log* *- Consent training evidence where required.* *- Study and device training where appropriate* *- CIP/Protocol-related training / Investigator Meeting Documentation*
7.	Standard Operating Procedures	Details of where and how to access current Sponsor SOPs Complete Standard Operating Procedures Read Log for all study staff members. All relevant Sponsor Standard Operating Procedures must be read by all research team members. *At Trial Master File level:* *Completed SOP read log for all staff named on collaborating centres delegation logs.*
8.	Study Documentation	Template of all current approved Participant Information Sheets and Informed Consent Forms printed on UHL headed paper (make sure the versions and date number is entered) Superseded documentation e.g. Participant Information Sheets and Informed Consent Forms Template of GP letter Template of any other study related material e.g. invitation letters, posters questionnaires) Sample Case Report Form *At Trial Master File level:* *Evidence that collaborating sites are utilising the current approved version of all study documentation.*

9.	Subject Documentation	Template Screening Log (where applicable) Completed Screening Log/s containing non identifiable participant data only (where applicable) Template Subject Enrolment/Identification log Completed Subject Enrolment/Identification log (not to be removed from site). <u>*At Trial Master File level:*</u> *Details of Subject enrolment numbers utilised for individual collaborating sites. No patient identifiable data.*
10.	Randomisation	Documentation of randomisation/ Decoding process Details of randomisation/ decoding process and all relevant guidance documentation if utilised. Master Randomisation List (in sealed envelope)/ details of electronic randomisation process/details of where master randomisation list is held and relevant contact details. Evidence (where applicable) of randomisation i.e. envelopes / email / IVRS <u>*At Trial Master File level:*</u> *Details of Randomisation process and relevant contact details for all collaborating centres.*
11.	Informed Consent	Copies of all completed consent forms including all re consent forms where applicable with associated patient information sheets Copy of 100% consent form audit record <u>*At Trial Master File level:*</u> *Copies of 100% consent audits for collaborating centres*

12.	Data Management	Statistical analysis plan -*TMF only* Details of electronic/paper case report form storage/security Data Management Plan- *TMF only* Superceded Data Management Plan Electronic Data Capture (EDC)/ eCase Report Form (eCRF) training records
13.	Source Data	Source Data Schedule Data query/response documentation <u>*At Trial Master File level:*</u> *Site/s source data schedule/s* *Site data query/response document*
14.	Medical Device/ Study Related Supplies	Details of Labelling/Master copy of label (where applicable) Investigator Brochure(IB)(signed and dated) and/or Manufacturer Instructions/Manual Superceded versions of IB/Manufacturer Instructions/Manuals Shipment/Receipt records Device Accountability Log Template Completed Device Accountability Logs Component Supplies order form templates Completed supply request forms Temperature logs (where applicable) Evidence of maintenance/calibration certification of all applicable equipment <u>*At Trial Master File level:*</u> *Copies of all relevant supply documentation and evidence of equipment maintenance/calibration for all collaborating centres*

15.	Safety Reporting	Serious Adverse Event (SAE)/ Serious Adverse Device Effect (SADE) reporting Guideline/Event Categorisation Flow Chart Current SAE/SADE/USADE form template (Form C) Completed SAE/SADE/USADE forms and Sponsor acknowledgement documentation Unexpected Serious Adverse Device Effect (USADE) reporting Guidelines Evidence of notification of USADE to MHRA and REC Adverse Event/Device Effect Record Template Competed Adverse Event/Device Effect Record(s) Medical Device Deficiency Report Form Template Completed Medical Device Deficiency Report Forms Evidence of notification of Device Deficiency (where applicable) to MHRA. Device safety alert updates (Please refer to the Sponsor SOP for safety reporting for medical devices UHL S-1040) <u>*At Trial Master File level:*</u> *Copies of all collaborating centre SAE/SADE/USADE reports and acknowledgements/adjudication (where applicable)* *Serious adverse event/serious adverse device effect line listing for all collaborating centre(where applicable)* *Copies of medical device deficiency report forms for all collaborating centres* *Correspondence*

16.	Monitoring	Agenda and minutes from Initiation/ Pre-trial Meeting Study Specific Monitoring Plan Initiation visit/site/pharmacy report Template monitoring log template Completed monitoring log Interim Monitoring Documentation e.g.Site/Pharmacy monitoring visit report and CI/PI responses Final trial close out/site/pharmacy monitoring reports External Audit reports and responses Associated correspondence <u>*At Trial Master File level:*</u> *Copies of all site/pharmacy monitoring reports and associated responses for all centres. External audits and responses.*
17.	Clinical Laboratory	Central Laboratories Certificates of accreditation, where applicable Central Laboratories Normal Reference Ranges (including revisions) where applicable Local Laboratories Certificates of accreditation, where applicable Local Laboratories Normal Reference Ranges (including revisions) where applicable Lab Manual/sample processing instructions, where applicable Details of sample storage facilities/ processes/relevant personnel contact details Sample Shipment Receipt/ Tracking, where applicable

		Temperature logs for sample storage Sample storage instructions/Inventory of samples/specimens, where applicable Inventory/destruction log of all samples/specimens Details of sample storage arrangements (where applicable) for all samples held for future research <u>*At Trial Master File level:*</u> *Certificates of accreditation and normal Reference Ranges for local labs of all participating sites* *Inventory of samples/specimens storage and temperature logs as applicable* *Contact details of all relevant personnel responsible for sample management*
18.	Financial / Legal	Contracts / Contract addendums with all investigators and Sub-contractors Confirmation of Sponsorship Evidence of Peer Review (where applicable) Funding Letter(s)/ Financial Agreement Insurance and Indemnity Statement for all investigators Clinical Trial Agreement with all investigators Financial Correspondence Records of subject expenses <u>*At Trial Master File level:*</u> *Copies of all contacts and agreements/ amendments with collaborating centres and external vendors*

19.	Annual Report /End of study declaration/Clinical Investigation Report	Annual Reports to HRA / REC and Sponsor Notice to HRA / REC, MHRA and R&I / R&D of trial completion (end of study declaration)-*TMF only* Final Clinical Investigation Report report and acknowledgement from HRA/REC/ MHRA/Sponsor Confirmation that the Final report/study publication has been uploaded to EudraCT and any public databases as detailed in the ethical application. *At Trial Master File level:* *Confirmation that all reports have ben received and acknowledged by collaborating centres*
20.	Publications	Copies of all study analysis publications
21.	Correspondence	Correspondence with CI / Sponsor and internal site correspondence, including Newsletters and other study specific correspondence. Meeting agendas and minutes General correspondence *At Trial Master File level:* *Relevant trial related correspondence with all collaborating centres*
22.	Miscellaneous (detail documents where applicable)	

Trial Master File / Investigator Site File Index
For studies NOT involving Investigational Medicinal Products

This Trial Master File/ Investigator Site file index template has been produced with regards to the documentation required by UHL, as Sponsor, for the completion of both single and multi-centre Non-CTIMP studies. This index can be modified to suit individual study requirements.

The documentation detailed in plain text is for individual Site, Investigator Site Files. The additional documentation detailed in italic is with regards to the requirement for the Trial Master file only, held and maintained by the Chief Investigator.

SECTION	TITLE	DOCUMENTS
1.	Contact List	Including details of relevant study site staff, responsible HRA/REC, R&I contacts, laboratory and other relevant staff involved in the study *At Trial Master File level:* *Copies of contact lists from all collaborating centres*
2.	Protocol	Current Protocol signed and dated by PI Signed and dated protocol signature page(s) for all protocol versions. Superseded Protocol(s) Completed protocol read log/s for all relevant study personnel Protocol Deviation Log Master Template Completed protocol deviation log File note template *At Trial Master File level:* *Signed protocol signature page for current and all superceded protocols for all collaborating site* *Copy of signed and dated protocol deviation logs for collaborating sites.* *Completed protocol read log for all relevant study personnel*

3.	Health Research Authority / Ethics Committee	Signed and dated IRAS Application Statement of Activities / Organisational Information Document Schedule of Events HRA initial assessment letter (where applicable) REC letter of acknowledgement REC letter of provisional /full favourable opinion HRA approval letter Substantial Amendments: Substantial amendment application form (via IRAS) to HRA/REC
		HRA /REC confirmation of submission email HRA categorisation email HRA approval / REC favourable opinion Non Substantial Amendments: Minor amendments application form (via IRAS) to HRA/REC HRA /REC confirmation of submission email HRA approval /REC favourable opinion GCP Compliance / REC Constitution /Composition / List of members (forms part of REC favourable opinion) HRA / Ethics correspondence <u>*At Trial Master File level:*</u> *Completed Feasibility Form* *Copy of completed Statements of Activities/ Organisational Information Document Schedule of Events and relevant HRA approvals / REC favourable opinion* *Evidence of receipt of amendment from all collaborating centres* *Correspondence where appropriate with Sponsor / HRA & REC*

4.	R&I	R&I application/capability assessment R&I approval / Authorisation Submission / Notification and R&I acknowledgement/approval/authorisation of all Substantial and Non-Substantial Amendments R & I correspondence *<u>At Trial Master File level:</u>* *Collaborating sites R&I/R&D submission and approval/ authorisation documentation.* *Notification / receipt of all subsequent amendments/approvals / authorisation* *Local R&I / R&D correspondence*
5.	Investigator Site Personnel	Template of Delegation of Authority Log Template signature log (eDOA only) Completed Delegation of Authority Log Completed signature log Original signed and dated current CVs for all study personnel named on the Delegation Log/eDOA, covering the period of the study Evidence of GCP training/consent training e.g. certificate/email, covering the total period of the study Evidence of study specific training *<u>At Trial Master File level:</u>* *Collaborating centres: Copy of current completed delegation of duties / authorised signatures forms. Signed and dated CVs for PI and all staff named on the delegation log.* *Trial Training documentation:-* *- GCP Training evidence for all staff named on delegation log* *- Consent training evidence (where required)* *- Protocol-related training / Investigator Meeting documentation*

6.	Standard Operating Procedures	Details of where and how to access current Sponsor SOPs Complete Standard Operating Procedures Read Log for all study staff members. All relevant Sponsor standard operating procedures must be read by all research team members. *<u>At Trial Master File level:</u>* *Completed SOP read log for all staff named on collaborating centres delegation logs.*
7.	Study Documentation	Template of all current approved participant information sheets and informed consent forms- approved versions printed on UHL headed paper (make sure the version and date number is entered) Superseded documentation e.g. participant information sheets and informed consent forms Template of GP letter Template of any other study related material e.g. invitation letters/ posters/questionnaires Sample Case Report Form *<u>At Trial Master File level:</u>* *Evidence that collaborating sites are utilising the current approved version of all study documentation*
8.	Subject Documentation	Template screening log (where applicable) Completed screening log /s containing non identifiable participant data only (where applicable) Template subject enrolment/Identification log Subject enrolment/Identification log (not to be removed from site) *<u>At Trial Master File level:</u>* *Details of subject enrolment numbers utilised for individual collaborating sites. No patient identifiable data.*

9.	Randomisation	Documentation of randomisation process Details of randomisation process and all relevant guidance documentation if utilised. Master randomisation list (in sealed envelope) and details of electronic randomisation process/details of where master randomisation list is held and relevant contact details. Evidence (where applicable) of randomisation i.e. envelopes / email / IVRS <u>*At Trial Master File level:*</u> *Details of randomisation process and relevant contact details for all collaborating centres*
10.	Informed Consent	Original copies of all completed consent forms including all re consent forms where applicable, with associated patient information sheets Copy of 100% consent form audit record where applicable. <u>*At Trial Master File level:*</u> Copy of 100% consent form audit record where applicable for all collaborating centres.
11.	Data Management	Statistical analysis plan-*TMF only* Data management plan – *TMF only* Superseded data management plan/statistical analysis plan where appicable Details of electronic/paper case report form storage/security Electronic Data Capture (EDC)/ eCase Report Form (eCRF) training records

12.	Source Data Verification	Source data schedule Data query/response documentation <u>*At Trial Master File level:*</u> Site data query response document Site/s source data schedule/s
13.	Safety Reporting	SAE reporting guidelines/pharmacovigilance/governance contact details.Please refer to the SOP relating to safety reporting Current SAE form template and SAE form completion guidance document Completed Serious Adverse Events forms and Sponsor acknowledgement documentation SAE Tracking Log <u>*At Trial Master File level:*</u> *Copies of all collaborating centre SAE reports and acknowledgements/adjudication* *Correspondence*
14.	Monitoring	Agenda and minutes from initiation/ pre study meeting Study specific monitoring plan (where applicable) Initiation visit report Template monitoring log Completed monitoring log Interim monitoring documentation e.g. monitoring visit reports and CI/PI responses Final trial close out report External audit reports and responses Associated correspondence

		At Trial Master File level: *Copies of all monitoring reports and associated site responses for all centres. External audits and responses.*
15.	Clinical Laboratory	Central laboratories certificates of accreditation, where applicable Central laboratories normal reference ranges (including revisions) where applicable Local laboratories certificates of accreditation, where applicable Local laboratories normal reference ranges (including revisions) where applicable Lab manual/sample processing instructions, where applicable Details of sample storage facilities/ processes/relevant personnel contact details Sample shipment receipt/ tracking logs, where applicable Temperature logs for sample storage Sample storage instructions/ Inventory of samples/specimens, where applicable Inventory/destruction log of all samples/specimens Details of sample storage arrangements (where applicable) for all samples held for future research *At TMF site level file:* *Certificates of accreditation and normal reference ranges for local labs of all participating sites* *Inventory of samples/specimens storage and temperature logs as applicable* *Contact details of all relevant personnel responsible for sample management*

16.	Financial / Legal	Contracts / contract addendums with all investigators and sub-contractors Chief Investigator agreement, where applicable Confirmation of sponsorship Evidence of peer review, where applicable Funding letter(s)/ financial agreement Insurance and indemnity statement for all investigators Clinical trial agreement with all investigators Financial correspondence Records of subject expenses <u>*At TMF Site Level File:*</u> *Copies of all contacts and agreements/ amendments with collaborating centres and external vendors*
17.	Study Related Supplies	Shipment/delivery Collection/return Supplies Re-order form templates Completed supply request forms Evidence of maintenance/calibration certification of all applicable equipment <u>*At Trial Master File level:*</u> *Copies of all relevant supply documentation and evidence of equipment maintenance/calibration for all collaborating centres*
18.	Annual /End of study declaration/Final report	Annual reports to HRA/REC and Sponsor Notice to HRA/REC and R&D/R&I of trial completion (end of study declaration)-*TMF only* Final study report and acknowledgement from HRA/REC/ Sponsor

		Confirmation that the final report/study publication has been uploaded to all relevant public databases as detailed in the ethical application. *<u>At Trial Master File level:</u>* *Evidence of supply and acknowledgement of documentation to all collaborating centres*
19.	Publications	Copies of all study analysis publications
20.	Correspondence	Correspondence with CI / Sponsor and internal site correspondence, including newsletters and other study specific correspondence. Meeting agendas and minutes General correspondence *<u>At TMF Site Level File:</u>* *Relevant trial related correspondence with all collaborating centres*
21.	Miscellaneous (detail documents where applicable)	

Trial Master File / Investigator Site File Index
For studies of CE Marked and Proof of Concept Studies

This Trial Master File/ Investigator Site file index template has been produced with regards to the documentation required by UHL, as Sponsor, for the completion of both single and multi-centre CE marked and Proof of Concept studies. This index can be modified to suit individual study requirements.

The documentation detailed in plain text is for individual Site, Investigator Site Files. The additional documentation detailed in italic is with regards to the requirement for the Trial Master file only, held and maintained by the Chief Investigator.

SECTION	TITLE	DOCUMENTS
1.	Contact List	Including details of relevant study site staff, responsible HRA/REC, R&I contacts, laboratory and other relevant staff involved in the study *<u>At Trial Master File level:</u>* *Copies of contact lists from all collaborating centres*
2.	Clinical Investigation Plan (CIP)/Protocol	Current CIP/protocol signed and dated by PI Signed and dated CIP/protocol signature page(s) for all CIP/protocol versions. Superseded CIP/protocol(s) Completed CIP/protocol read log/s for all relevant study personnel CIP/protocol deviation log master template Completed CIP/protocol deviation log File note template *<u>At Trial Master File level:</u>* *Signed CIP/protocol signature page for current and all superceded CIP/protocols for all collaborating site* *Copy of signed and dated CIP/protocol deviation logs for collaborating centres.* *Completed CIP/protocol read log for all relevant study personnel*

3.	Health Research Authority / Ethics Committee	Signed and dated IRAS application Statement of activities/ organisational information document/ / schedule of events HRA initial assessment letter (where applicable) REC letter of acknowledgement REC letter of provisional /full favourable opinion HRA approval letter Substantial Amendments: Substantial amendment application form (via IRAS) to HRA/REC HRA /REC confirmation of submission email HRA categorisation email HRA approval / REC favourable opinion Non Substantial Amendments: Minor amendments application form (via IRAS) to HRA/REC HRA /REC confirmation of submission email HRA approval /REC favourable opinion GCP compliance / REC constitution /composition / list of members (forms part of REC favourable opinion) HRA / Ethics correspondence *<u>At Trial Master File level:</u>* *Completed feasibility form* *Copy of completed statements of activities/ schedule of events and relevant HRA approvals / REC favourable opinion* *Evidence of receipt of amendment from all collaborating centres* *Correspondence where appropriate with Sponsor / HRA & REC*

4.	R&I	R&I application/capability assessment R&I approval / authorisation Submission / notification and R&I acknowledgement/approval/authorisation of all Substantial and Non-Substantial Amendments R & I Correspondence *<u>At Trial Master File level:</u>* *Collaborating sites R&I/R&D submission and approval/ authorisation documentation.* *Notification / receipt of all subsequent amendments/approvals / authorisation* *Local R&I / R&D correspondence*
5.	Investigator Site Personnel	Template of Delegation of Authority Log Template signature log (eDOA only) Completed Delegation of Authority Log Completed signature log (eDOA only) Original signed and dated current CVs for all study personnel named on the delegation log/eDOA, covering the period of the study Evidence of GCP training/consent training e.g. certificate/email, covering the total period of the study Evidence of study and device specific training *<u>At Trial Master File level:</u>* *Collaborating centres: copy of current completed delegation of duties / authorised signatures forms. Signed and dated CVs for PI and all staff named on the delegation log.* *Trial training documentation:-* *- GCP training evidence for all staff named on delegation log* *- Consent training evidence (where required)* *- Study and Device specific training(as applicable)* *- CIP/Protocol-related training / Investigator meeting documentation*

6.	Study Documentation	Template of all current approved participant information sheets and informed consent forms- approved versions printed on UHL headed paper (make sure the versions and date number is entered) Superseded documentation e.g. participant information sheets and informed consent forms Template of GP letter Template of any other study related material e.g. invitation letters/posters/questionnaires Sample Case Report Form <u>At Trial Master File level:</u> *Evidence that collaborating sites are utilising the current approved version of all study documentation*
7.	Subject Documentation	Template screening log (where applicable) Completed screening log /s containing non identifiable participant data only (where applicable) Template subject enrolment/Identification log Subject enrolment/Identification log (not to be removed from site) <u>At Trial Master File level:</u> *Details of subject enrolment numbers utilised for individual collaborating sites. No patient identifiable data.*

8.	Standard Operating Procedures	Details of where and how to access current Sponsor SOPs Complete Standard Operating Procedures read log for all study staff members. All relevant Sponsor standard operating procedures must be read by all research team members. *<u>At Trial Master File level:</u>* *Completed SOP read log for all staff named on collaborating centres delegation logs.*
9.	Randomisation	Documentation of randomisation process Details of randomisation process and all relevant guidance documentation if utilised. Master randomisation list (in sealed envelope)/ details of electronic randomisation process/details of where master randomisation list is held and relevant contact details. Evidence (where applicable) of randomisation i.e. envelopes / email / IVRS *<u>At Trial Master File level:</u>* *Details of randomisation process and relevant contact details for all collaborating centres*
10.	Informed Consent	Original copies of all completed consent forms including re consent forms where applicable Copy of consent form audit record where applicable. *<u>At Trial Master File level:</u>* *Copy of consent form audit record where applicable for all collaborating centres.*

11.	Data Management	Statistical analysis plan-*TMF only* Details of electronic/paper case report form storage/security Electronic Data Capture (EDC)/ eCase Report Form (eCRF) training records
12.	Source Data	Source Data Schedule Data query/response documentation <u>*At Trial Master File level:*</u> *Site/s source data schedule/s* *Site data query/response document*
13.	Medical Device/ Study Related Supplies	Details of labelling/master copy of label(where applicable) Manufacturer instructions/manual Superceded versions of manufacturer instructions/manuals Shipment/receipt records Device accountability log master Completed device accountability logs Component supplies order form templates Completed supply request forms Temperature logs (where applicable) Evidence of maintenance/calibration certification of all applicable equipment <u>*At Trial Master File level:*</u> *Copies of all relevant supply documentation and evidence of equipment maintenance/calibration for all collaborating centres*

14.	Safety Reporting	Serious Adverse Event (SAE)/ Serious Adverse Device Effect (SADE) reporting guideline/event categorisation flow chart Current SAE/SADE form template(Form C) Completed SAE/SADE forms and Sponsor/ REC(where applicable) acknowledgement documentation Adverse Event/Device Effect record template Competed Adverse Event/Device Effect record(s) Medical Device Deficiency report form template Completed Medical Device Deficiency report forms Device safety alert updates (Please refer to the Sponsor SOP for safety reporting for medical devices UHL S-1041) <u>*At Trial Master File level:*</u> *Copies of all collaborating centre SAE/SADE reports and acknowledgements/adjudication (where applicable)* *Serious adverse event/serious adverse device effect line listing for all collaborating centre(where applicable)* *Copies of medical device deficiency report forms for all collaborating centres* *Correspondence*
15.	Monitoring	Agenda and minutes from initiation/ pre study meeting Study specific monitoring plan (where applicable) Initiation visit report Template monitoring log Completed monitoring log Interim monitoring documentation e.g. monitoring

		visit report and CI/PI responses Final trial close out report External audit reports and responses Associated correspondence <u>*At Trial Master File level:*</u> *Copies of all monitoring reports and associated site responses for all centres. External audits and responses.*
16.	Clinical Laboratory (where applicable)	Central laboratories certificates of accreditation, where applicable Central laboratories normal reference ranges (including revisions) where applicable Local laboratories certificates of accreditation, where applicable Local laboratories normal reference ranges (including revisions) where applicable Lab manual/sample processing instructions, where applicable Details of sample storage facilities/ processes/relevant personnel contact details Sample shipment receipt/ tracking Temperature logs for sample storage Sample storage instructions/ inventory of samples/specimens, where applicable Inventory/destruction log of all samples/specimens Details of sample storage arrangements (where applicable) for all samples held for future research <u>*At TMF site level file:*</u> *Certificates of accreditation and normal reference ranges for local labs of all participating sites* *Inventory of samples/specimens storage and temperature logs as applicable*

		Contact details of all relevant personnel responsible for sample management
17.	Financial / Legal	Contracts / contract addendums with all investigators and sub-contractors Confirmation of sponsorship Evidence of peer review (where applicable) Funding letter(s)/ financial agreement Insurance and indemnity statement for all investigators Clinical trial agreement with all investigators
		Financial Correspondence Records of subject expenses <u>*At TMF Site Level File:*</u> *Copies of all contacts and agreements/ amendments with collaborating centres and external vendors*
18.	Annual /End of study declaration/Final report	Annual reports to HRA/REC and Sponsor Notice to HRA/REC and R&D/R&I of trial completion (end of study declaration)-*TMF only* Final study report and acknowledgement from HRA/REC/ Sponsor Confirmation that the final report/study publication has been uploaded to all relevant public databases as detailed in the ethical application. <u>*At Trial Master File level:*</u> *Evidence of supply and acknowledgement of documentation to all collaborating centres*
19.	Publications	Copies of all study analysis publications

20.	Correspondence	Correspondence with CI / Sponsor and internal site correspondence, including newsletters and other study specific correspondence. Meeting agendas and minutes General correspondence *<u>At TMF Site Level File:</u>* *Relevant trial related correspondence with all collaborating centres*
21.	Miscellaneous (detail documents where applicable)	

LEICESTER'S RESEARCH

NHS
University Hospitals of Leicester
NHS Trust

VERSION CONTROL DOCUMENT – keep at front of Trial Site File

THE MOST UP-TO-DATE VERSION OF EACH DOCUMENT MUST BE PLACED UPPERMOST IN THE FILE – Retain all earlier versions for audit purposes and mark: 'Superseded by Version (No) on (date)' to avoid accidental use of wrong version.

PROTOCOL

VERSION No.	DATE	DATE APPROVED BY ETHICS	DATE APPROVED BY MHRA	DATE C&C issued BY R&I	DATE IMPLEMENTED	COMMENTS e.g. date new version sent to co-investigator or to participating sites, acknowledgement of receipt, etc

PARTICIPANT INFORMATION SHEET

VERSION No.	DATE	DATE APPROVED BY ETHICS	DATE APPROVED BY MHRA	DATE APPROVED BY R&I	DATE IMPLEMENTED	COMMENTS e.g. date new version sent to co-investigator or to participating sites, acknowledgement of receipt, etc

INFORMED CONSENT FORM

VERSION No.	DATE	DATE APPROVED BY ETHICS	DATE APPROVED BY MHRA	DATE APPROVED BY R&D	DATE IMPLEMENTED	COMMENTS e.g. date new version sent to co-investigator or to participating sites, acknowledgement of receipt, etc

OTHER .....

VERSION No.	DATE	DATE APPROVED BY ETHICS	DATE APPROVED BY MHRA	DATE APPROVED BY R&D	DATE IMPLEMENTED	COMMENTS e.g. date new version sent to co-investigator or to participating sites, acknowledgement of receipt, etc

OTHER .....

VERSION No.	DATE	DATE APPROVED BY ETHICS	DATE APPROVED BY MHRA	DATE APPROVED BY R&D	DATE IMPLEMENTED	COMMENTS e.g. date new version sent to co-investigator or to participating sites, acknowledgement of receipt, etc

LEICESTER'S RESEARCH

NHS
University Hospitals of Leicester
NHS Trust

Archiving Time Table

The table below is designed to provide guidance on the minimum Sponsor/ regulatory requirements for archiving of study data for studies sponsored by University Hospitals of Leicester NHS Trust. Archiving requirements for individual studies will be reviewed and confirmed at as part of the Sponsor review.

Type of study	Retention Time Period
Clinical Trial of an Investigational medicinal product **Clinical investigation or other study of a medical device** **Combined trial of an investigational medicinal product and an investigational medicinal device.**	**Trials which are not to be used in regulatory submissions** At least five years after completion of the trial. These documents should be retained for a longer period if required by the applicable regulatory requirement(s), the sponsor or the funder of the trial **Trials to be included in regulatory submissions** The sponsor-specific essential documents should be retained for at least 25 years after completion or discontinuation of the trial or for at least two years after the last approval of a marketing application in the EU.
Clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice	Five years
Basic science study involving procedures with human subjects **Study administering questionnaires/interviews for quantitave analysis or using mixed quantitative/qualitative methodology**	Two years
Studies involving qualitative methods only **Studies limited to working with Human tissue samples(or other human biological samples)** **Studies working with data (specific project only)** **Research Tissue Banks** **Research Databases**	One year.