Gloucestershire Hospitals
NHS Foundation Trust

SOP 05: End of Trial procedures – Close Down

SOP reference:	SOP 05	
Version:	5.0	
Author:	Chris Ford	
Approved by Commercial Director:	Claire Richardson 22/09/2023	
Implementation date of current version:		30/10/2023
Date of Review:		30/10/2025

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the Research & Development Webpage for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive version of all Gloucestershire Hospitals NHS Foundation Trust SOPs appear online. If you are reading this in printed form, check that the version number and date below is the most recent one as shown on the R&D website:

https://www.gloshospitals.nhs.uk/about-us/research-our-hospitals

The Gloucestershire Hospitals NHS Foundation Trust wishes to acknowledge York Hospitals NHS Foundation Trust and University Hospitals Bristol NHS Foundation Trust who gave permission to use their templates in the development of these SOPs.

VERSION HISTORY LOG

This area will be updated with details of all changes made to the SOP whether due for full review or not.

Version	Details of Change	Date Implemented
1.0	Original SOP	29/12/2014
2.0	Review and update on storage of information in Pharmacy files trials which do not recruit a participant	03/02/2017
3.0	Rebranding to GHNHSFT, updating of contact details and reference documents	31/03/2018
4.0	Updating of website links. Addition of HRA requirement for studies not requiring REC favourable opinion. Reminder where it is a hosted trial that it is checked that all funding for the trial has been claimed. Provision of a Trust close down check list when one is not provided by the Sponsor.	21/04/2021
5.0	Correction of typographical errors Deletion of out-of-date webpages Addition of use of generic R&D email address to receive end of trial reports rather than Senior Research Manager Updated end of trial forms Acknowledgement of electronic ISFs Removal of SOP categories and change of reference codes	30/10/2023

This SOP will be reviewed every two years unless changes to any relevant legislation require otherwise

Related Documents:

SOPs
SOP 02 - Research File Management
SOP 06 - Trial Archiving

Glossary

CI	Chief Investigator
CRO	Clinical Research Organisation
CSR	Clinical Study Report
CTIMP	Clinical Trial of Investigational Medicinal Product
e-ISF	electronic Investigator Site File
EudraCT	European union drug regulating authorities Clinical Trials
GCP	Good Clinical Practice
HRA	Health Research Authority
IMP	Investigational Medicinal Product
IRAS	Integrated Research Application System
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
NIHR	National Institute for Health and Care Research
PI	Principal Investigator
QC	Quality Control
REC	Research Ethics Committee
SAP	Statistical Analysis Plan
SmPC	Summary of Products Characteristics
TMC	Trial Management Committee
TMF	Trial Master File
TPF	Trial Pharmacy File

Contents

1. Introduction, Background and Purpose

The purpose of this SOP is to set out the matters to be considered upon the completion of a trial and the steps to be taken, including the notification of relevant bodies.

In this SOP the phrase 'Close Down' will be used throughout and is synonymous with 'Close Out', Close Out checklist and 'Completion'. Typically, 'Close Out' refers to the official visit of the Sponsor or delegated representative to a participating site to review documentation before formally closing the trial at that site. This can be performed remotely if appropriate.

There are three written documents which are produced at the end of the trial:

1) Declaration of End of Trial (see appendices 1, 2, 3 and 4)

2) End of Trial Report - there is no proforma for this but guidance states that it should include whether the study achieved its objectives, the main findings, and arrangements for publication or dissemination of the research, including any feedback to participants.

   At the end of the trial, commitments made to research participants must be fulfilled. 'Care after research' (See HRA website http://www.hra.nhs.uk) states that responsible transition of participants out of the trial may include:

   - Making arrangements for aftercare;
   - Ensuring safety;
   - Communicating with caregivers;
   - Sharing information with participants: aggregate results and, as appropriate, individual results and incidental findings;
   - Showing appreciation; and

3) Clinical Study Report (CSR) / Publication

   This document accurately reflects the objectives of the trial the summary of what happened and the outcome or results. (See information on the NIHR Clinical trial toolkit)

End of study under HRA Approval.

Where a project has HRA Approval and has been reviewed by a Research Ethics Committee (REC) then the Sponsor need only inform the REC when the study has ended. Where a project has HRA Approval and was not reviewed by an NHS REC, the Sponsor will need to tell HRA when the project has ended. The Sponsor should send this notification by email to hra.approval@nhs.net including the IRAS ID and Sponsor contact information (phone and email).

2. Who should use this SOP

2.1 Trust Sponsored or Co-sponsored Trials

- Sponsor
- Chief Investigators (CIs),
- Research Nurses
- Clinical Research Practitioners
- Research co-ordinators,
- Research Support Officers
- Health professionals
- Administrative research staff
- Research links in support departments
- R&D governance team
- Any contracted Clinical Research Organisations CROs

The Sponsor may delegate the tasks involved in trial completion to the CI or external vendor such as a CRO but must have mechanisms in place to maintain oversight of the delegated activities.

2.2 Trust hosted trials

- Principal Investigators (PIs)
- Research Nurses
- Clinical Research Practitioners
- Research co-ordinators,
- Research Support Officers
- Health professional

- Administrative research staff
- Research links in support departments
- R&D governance team

The PI may delegate the responsibility for trial completion activities to members of the research team duly documented on the delegation log.

3. When this SOP should be used

This SOP will be used at the end of the trial as defined in the trial protocol (the end of the recruitment period does not automatically signify the end of the trial). It will be used for all the following types of research:

- a CTIMP or a non-CTIMP that is sponsored or co-sponsored by the Trust

- a CTIMP or a non-CTIMP hosted by the Trust taking into consideration an SOP for this purpose provided by the trial Sponsor SOP

4. Process for close down of Trust sponsored trials

4.1 Who is responsible for the Declaration of the end of trial?

- It is the responsibility of Sponsor, to notify the main REC, the MHRA, EudraCT and the CI and every participating site of the end of the trial. (Appendix 1 - Trial Completion Declaration MHRA notification forms; NHS HRA website for REC notification; EudraCT documentation). Note that once the declaration of the end of a clinical trial form has been received by the competent authority only the clinical trial summary report will be accepted, and no further amendments can be submitted.

- The Sponsor may delegate this task to the CI.

- Where there has been a clinical trial of an investigational medical device the manufacturer will notify the MHRA.

- Where a project has HRA Approval and was not reviewed by an NHS REC, the Sponsor will need to tell HRA when the project has ended. The Sponsor should send this notification by email to hra.approval@nhs.net including the IRAS ID and Sponsor contact information (phone and email).

4.2 Final analysis of data and locking of database

- Final analysis of data will take place promptly after the appropriate follow-up period, following the details in the trial protocol and or the Statistical Analysis Plan (SAP).

- Analysis of the data will be recorded in an analysis plan with all the outcome measures set out in the protocol fully addressed. The analysis will be discussed by the trial management group (if applicable) to assist with interpretation and discuss finding

- The trial database will then be locked at this stage and no further modification or manipulation will be permitted.

4.3 Time lines for end of trial reporting

4.3.1 At the conclusion of the trial under HRA Approval

Where a project has HRA Approval and has been reviewed by a REC the CI/ Sponsor need only inform the REC when the trial has ended. Where a project has HRA Approval and was not reviewed by an NHS REC, you will need to tell HRA when the project has ended. You should send this notification by email to approvals@hra.nhs.uk including your IRAS ID and your contact information (phone and email).The Sponsor/ CI must notify the competent authorities that the clinical trial has ended within 90 days of the conclusion of the trial as defined in the protocol.

- Declaration of end of a clinical trial of investigational medicinal products to MHRA: A ‘Declaration of the end of a Clinical Trial’ form

should be sent to the MHRA by the sponsor within 90 days of the trial conclusion. Note that the MHRA can be informed separately by email of the end of the trial in the UK when other non-UK sites remain active in order to terminate the annual service charge, however this is a separate process from the formal notification of the end of trial (refer to MHRA website for details https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency).

- Declaration of end of a clinical investigation of medical device to MHRA: Manufacturers are required to notify the MHRA when a clinical investigation comes to an end

- Notification of end of study to Confidentiality Advisory Group: If you have an application with the Confidentiality Advisory Group, when your study is completed, you should notify the Confidentiality Advice Team as soon as possible in writing. Once received the Confidentiality Advice Team will review the information provided, update the approval register and write to confirm receipt of the application closure notice.

The application will remain on the approval register on the HRA website for at least 12 months following notification of application closure.

All this information can be sent by email.

4.3.2 Early termination of the trial

If the trial is terminated early the competent authorities must be notified immediately and at the latest within 15 days after the trial is halted by the CI/Sponsor representative. This applies to early termination due to safety measures, financial or business difficulties or very slow recruitment. This does not apply to a trial which has reached full recruitment early. A notice of substantial amendment can be submitted alongside a declaration of early termination where it is necessary to seek ethical review of related actions such as informing trial participants of the early closure and arranging continuing care and follow up outside the trial setting.

4.3.3 Abandoned Trials

If a trial is abandoned prior to recruitment starting, the Sponsor / CI will notify the competent authorities by letter outlining the reasons for abandoning the trial.

4.3.4 End of Trial Report to R&D

The CI must submit an end of trial report to the Research & Development departmental email address ghn-tr.glos.rdsu@nhs.net within 10 months of the date of the end of trial. This report is saved with paper or electronic R&D files and uploaded onto EDGE.

4.3.5 End of Trial Report to Competent Authorities

The CI, acting on behalf of the Sponsor is responsible for submitting the end of trial report to the HRA, REC and MHRA to arrive within 12 months of the date of the end of the trial.

4.3.6 Clinical Study Report (CSR) / Publications

The production and quality control (QC) of the CSR/ Publication will be defined and approved by the Sponsor and overseen by the Trial Management Committee (TMC), if applicable.

The CSR and/or Publication will reflect the conduct of the trial and provides a summary of the results including a list of all the significant non-compliances (see SOP 22 - Non-Compliance and Serious Breaches) that occurred during the trial and how these have contributed to the analysis of the trial data.

A statement of compliance with GCP will be included in the CSR/ Publication.

4.4 Close Down and Essential Documentation

- In the case of a multi-centre trial the Sponsor/ CI and the central team will arrange a Close-Down monitoring visit for each site which may be on-site or remote. Support departments (e.g. pharmacy) should also be notified in order that they can prepare for Close-Down.

- All essential documentation for a particular site must be confirmed to be in the appropriate files which provide clear audit trails of the trial conduct at the site. All issues raised in previous monitoring reports must be resolved and fully documented in reports and site file notes.

- Before close down all site data will be collected, entered and validated. All data queries will be resolved where feasible.

- All unused trial supplies will be returned or destroyed according to the trial protocol and trial agreement.

- Final drug accountability will be fully documented at site (TPF) and in the TMF. Drugs will be returned or destroyed at site according to the trial protocol and site agreement and certificates of destruction filed in the site file.

- Where regulatory authority approval is in place participants samples or data will be contributed to existing bio-bank or data-sharing repositories.

- All financial matters will be resolved and site payments are complete as agreed and documented in the site agreement.

- The Trial Master File (TMF) must be organised ensuring all necessary documents are present whether in paper or electronic form (see SOP 02 - Research Documentation and File Management).

- The CI site will not be closed until all participating sites have been closed down.

- Instigate archiving procedures (see SOP 06 - Trial Archiving)

5. Trust Hosted Trials

5.1 PI responsibilities

- The PI or delegated senior member of the research team must confirm that all trial related activities have stopped.

- The PI or delegated senior member of the research team must ensure a full in-house reconciliation of all documentation has been performed.

- A complete Quality Assurance review of the study must be performed, and any corrective action, including the addition of file notes must be performed and documented prior to transfer for archiving.

- For some trials, the trial office / sponsor may send a representative to the site to complete a final close down visit or organise a remote visit to confirm that all procedures have been completed correctly prior to archiving of study documentation.

5.2 Whole Site Responsibilities

All departments that have collected or generated documents during the conduct of the trial must transfer upon request these documents to the responsible senior member of the research team for the final reconciliation of the ISF.

5.2.1. Pharmacy

The pharmacist responsible for the trial will review and document the final accounting of IMP(s) received at the site, dispensed to subjects, returned to sponsor or the method and date of destruction of unused IMP(s) at site as detailed in the trial protocol and site agreement.

When all essential documents have been filed in the Trial Pharmacy File (TPF) it is to be returned to the delegated senior member of the research team for archiving alongside the ISF. In some circumstances, the TPF may be archived by the Pharmacy Department, depending on the protocol. In such cases, the ISF will include a site file note stating the location of the TPF.

In the case that a trial has not recruited a participant during the time it has been open to recruitment the research pharmacist should check exactly what documentation is required in the Pharmacy File. If the Sponsor is in agreement, then site file notes listing the Summary of Product Characteristics (SmPC) and where they can be found electronically can be used and the paper copies destroyed to minimise storage requirements.

5.2.2 Clinical Samples

The wishes of the participants as documented on their consent forms will dictate whether clinical samples will be stored in accordance with the trial protocol, site agreement and the Human Tissue Act or disposed of.

5.3 Close down and essential documentation

It must be noted that not all 'essential documentation' may be in paper form (see Appendix 8). Electronic registers or electronic site files must also be 'archived' according to Trust IT Policies and Guidelines (see appendix 4). The checklist provided by the Sponsor should be used to confirm all documentation has been collated back into the ISF/ eISF. When one is not provided then the teams must use the Trust Checklist must be used (see appendix 5)

5.4 Claiming Income

During close down the PI or research team much check with the R&D governance team that all invoices have been raised and paid. Do not complete close down sign off until this has been done

7. References

MHRA end of trial

End a trial:
https://www.gov.uk/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues#end-of-trial

Suspend or terminate a trial:
https://www.gov.uk/clinical-trials-for-medicines-manage-your-authorisation-report-safety-issues#suspend-or-terminate-a-trial

End of trial for medical devices
https://www.gov.uk/notify-mhra-about-a-clinical-investigation-for-a-medical-device

NIHR clinical trials tool kit
http://www.ct-toolkit.ac.uk/routemap/clinical-trial-summary-report

https://www.ct-toolkit.ac.uk/routemap/end-of-trial-declaration/

NHS HRA website REC end of trial reporting
https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/ending-your-project/

EudraCT website for 'declaration' proforma
EudraCT Public Protocol Documentation page (europa.eu)

HRA Notification of end of study to Confidentiality Advisory Group
http://www.hra.nhs.uk/research-community/end-of-study-and-beyond/notifying-the-end-of-study/

Care of participants after the trial has stopped
http://www.hra.nhs.uk/documents/2013/08/care-after-research.pdf

European Directive (2010/C 82/01)
Communication from the Commission — Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial (CT-1)
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2010:082:0001:0019:en:PDF

APPENDIX 1 - DECLARATION OF THE END OF TRIAL FORM for CTIMP and IMP/Device trials that were not submitted through combined review otherwise you should complete and submit the end of trial form in IRAS

Ending your project - Health Research Authority (hra.nhs.uk)

Declaration of the End of Trial Form (cf. Section 4.2.1 of the *Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal*

***product for human use, the notification of substantial amendments and the declaration of the end of the trial[1]*)**

NOTIFICATION OF THE END OF A CLINICAL TRIAL OF A MEDICINE FOR HUMAN USE TO THE COMPETENT AUTHORITY AND THE ETHICS COMMITTEE

For official use

Date of receipt :	Competent authority registration number : Ethics committee registration number:

To be filled in by the applicant

A MEMBER STATE IN WHICH THE DECLARATION IS BEING MADE :

B TRIAL IDENTIFICATION

B.1 EudraCT number :	**(..)**
B.2 Sponsor's protocol code number:	**(..)**
B.3 Full title of the trial :	

C APPLICANT IDENTIFICATION (please tick the appropriate box)

C.1	**DECLARATION FOR THE COMPETENT AUTHORITY**	☐
C.1.1	Sponsor	☐
C.1.2	Legal representative of the sponsor	☐
C.1.3	Person or organisation authorised by the sponsor to make the application.	☐
C.1.4	**Complete below**:	
C.1.4.1	Organisation :	
C.1.4.2	Name of person to contact :	
C.1.4.3	Address :	
C.1.4.4	Telephone number :	
C.1.4.5	Fax number :	
C.1.4.6	E-mail	

C.2	**DECLARATION FOR THE ETHICS COMMITTEE**	☐
C.2.1	Sponsor	☐
C.2.2	Legal representative of the sponsor	☐
C.2.3	Person or organisation authorised by the sponsor to make the application.	☐
C.2.4	Investigator in charge of the application if applicable[2]:	
	• Co-ordinating investigator (for multicentre trial):	☐
	• Principal investigator (for single centre trial):	☐
C.2.5	**Complete below** :	
C.2.5.1	Organisation:	
C.2.5.2	Name :	
C.2.5.3	Address :	
C.2.5.4	Telephone number :	
C.2.5.5	Fax number :	
C.2.5.6	E-mail :	

D END OF TRIAL

D.1	**Date of the end of the complete trial in all countries concerned by the trial**?
D.1.1	(YYYY/MM/DD):

[1] OJ, C82, 30.3.2010, p. 1; hereinafter referred to as 'detailed guidance CT-1'.

[2] According to national legislation.

D.2	**Is it an early termination?**[3]	yes ☐ no ☐
D.2.1	If yes, give date (YYYY/MM/DD):	
D.2.2	Briefly describe in an annex (free text):	
D.2.2.1	The justification for early termination of the trial;	
D.2.2.2	Number of patients still receiving treatment at time of early termination in the MS concerned by the declaration and their proposed management;	
D.2.2.3	The consequences of early termination for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product.	

E SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

E.1 I hereby confirm that/confirm on behalf of the sponsor that (delete which is not applicable):

- The above information given on this declaration is correct; and
- That the clinical trial summary report will be submitted within the applicable deadlines in accordance with the applicable guidance by the Commission.[4]

E.2	**APPLICANT TO THE COMPETENT AUTHORITY** (as stated in C.1)	☐
E.2.1	Date :	
E.2.2	Signature :	
E.2.3	Print name:	

E.3	**APPLICANT TO THE ETHICS COMMITTEE** (as stated in C.2) **:**	☐
E.3.1	Date :	
E.3.2	Signature :	
E.3.3	Print name:	

APPENDIX 2 - HEALTH RESEARCH AUTHORITY END OF STUDY PROCEDURES FOR NONCTIMP STUDIES

http://www.hra.nhs.uk/research-community/end-of-study-and-beyond/notifying-the-end-of-study/

DECLARATION OF THE END OF A STUDY

(For all studies except clinical trials of investigational medicinal products)

To be completed in typescript by the Chief Investigator and submitted to the Research Ethics Committee (REC) that gave a favourable opinion of the research within 90 days of the conclusion of the study or within 15 days of early termination. For questions with Yes/No options please indicate answer in bold type.

1. Details of Chief Investigator

Name:	
Address:	

[3] Cf. Section 4.2. of the detailed guidance CT-1.

[4] Section 4.3. of the detailed guidance CT-1.

Telephone:	
Email:	

2. Details of study

Full title of study:	
IRAS ID:	
Name of REC:	
REC reference number:	
Date of favourable ethical opinion:	
Research Sponsor:	

3. Study duration

Date study commenced:	
Date study ended:	
Did this study terminate prematurely?	*Yes / No* *If yes, please complete sections 4, 5, 6, & 7.* *If no, please go direct to section 8.*

4. Recruitment

Number of participants recruited	
Proposed number of participants to be recruited at the start of the study	
If different, please state the reason or this	

5. Circumstances of early termination

What is the justification for this early termination?	

6. Potential implications for research participants

Are there any potential implications for research participants as a result of terminating/halting the study prematurely? Please describe the steps taken to address them.	

7. Final report on the research

Have you submitted a Final Report?	*Yes / No* If no, please submit a Final Report within 12 months of the end of the study (or for paediatric CTIMPs within 6 months). More information is available on the HRA website

8. Declaration

Signature or Electronic Authorisation of Chief Investigator/Sponsor representative: Please print below or insert electronic signature	
Print name:	
Date of submission:	

APPENDIX 3 - AFTER COMPLETION OR TERMINATION OF THE TRIAL - LOCALITY OF DOCUMENTATION

Title of Document	Purpose	Located in Files of	
		Investigator/ Institution	Sponsor
INVESTIGATIONAL PRODUCT(S) ACCOUNTABILITY AT SITE	To document that the investigational	X	X

	product(s) have been used according to the protocol. To documents the final accounting of investigational product(s) received at the site, dispensed to subjects, returned by the subjects, and returned to sponsor		
DOCUMENTATION OF INVESTIGATIONAL PRODUCT DESTRUCTION	To document destruction of unused investigational products by sponsor or at site	X (if destroyed at site)	X
COMPLETED SUBJECT IDENTIFICATION CODE LIST	To permit identification of all subjects enrolled in the trial in case follow-up is required. List should be kept in a confidential manner and for agreed upon time	X	

Title of Document	Purpose	Located in files of	
		Investigator/ institution	Sponsor
TREATMENT ALLOCATION AND DECODING DOCUMENTATION	Returned to sponsor to document any decoding that may have occurred		X
FINAL REPORT BY INVESTIGATOR TO IRB/IEC WHERE REQUIRED, AND WHERE APPLICABLE, TO THE REGULATORY AUTHORITY(IES)	To document completion of the trial	X	
CLINICAL STUDY REPORT	To document results and interpretation of trial	X (if applicable)	X
FINAL TRIAL CLOSE-OUT MONITORING REPORT	To document that all activities required for trial close-out are completed, and copies of essential documents are held in the appropriate files		X

APPENDIX 4

Countywide IT Policies

Information Governance policy
http://glnt313/sites/ghnhsft_policy_library/NonClinPolices/B0413.pdf

Clinical and non clinical information systems
http://glnt313/sites/ghnhsft_policy_library/NonClinPolices/B0259.pdf

IT Security
http://glnt313/sites/ghnhsft_policy_library/NonClinPolices/B0591.pdf

Portable IT equipment and removal media
http://glnt313/sites/ghnhsft_policy_library/Procedures/B0692.pdf

Information Governance Forensic Readiness
http://glnt313/sites/ghnhsft_policy_library/Procedures/B0693.pdf

APPENDIX 5 - TRUST INVESTIGATOR SITE FILE CLOSE DOWN FORM (where one is not provided by Sponsor)

Please complete this form for close-out and keep the original in the front of your site file

Name of trial: _____

Document required to be in electronic or paper-based ISF	Yes	No	Comments
Study Protocol			
Protocol – current and superseded versions of protocol			
Investigator Brochure/Summary of Product Characteristics – current and superseded versions of IB/SmPC			
Study Management Documents			
Site Staff **–** Study Delegation Log/Site Responsibility Log			
Site Staff **–** CVs of Principal investigator and Co/Sub-Investigators and Research Staff (if applicable) **-** GCP certificates			
Site Staff –Signed investigator statement (if applicable)			
Site Staff – training information/slides, training log			
Documents given to Patients - Master Patient Information - current and superseded information sheets and consent forms			
Other Documents related to trial – current and superseded GP letter, diary cards, QoL questionnaires and relevant supplementary information			
Patient Records – subject screening and enrolment log and identification log (if applicable)			
Correspondence (except Ethics or Trust R&D)			
Sponsor Correspondence – general and site specific communications with sponsor (letters, emails, meeting notes, notes of telephone calls, newsletters			
Sponsor Correspondence			

- Contact details for Trial Unit and other relevant parties			
Randomisation/Data Collection			
Randomisation Documents – signed informed consent forms, registration and randomisation confirmations and supporting documentation			
Sample case report forms – current and superseded versions of CRFs and guidelines			
Completed Case Report Forms and data queries -or file note detailing location if separate			
Patient Records – source documents (file note to be created documenting where source information can be found**)**			
Pathology Documentation			
Pathology Documentation -lab ranges, accreditation certificates and any relevant documents			
Pathology Documents –logs**/**record of retained body fluids/tissue samples and any correspondence			
Pharmacy Documentation			
**Pharmacy Documents – ** current and superseded blank prescriptions, correspondence related to pharmacy, relevant guidelines, drug information (if applicable or file note if separate pharmacy ISF)			
Safety Information			
Safety **-**Sample SAE form and reporting procedures			
Safety **-**SAE log and completed SAE forms			
Safety **–** All correspondence, SAE notifications and safety information			
Regulatory and Governance Documentation			
Ethics **–** all appropriate Ethics Committee(s) approvals, correspondence, submission documentation (including SSA) and approvals and reports			

Regulatory Authority Approval – Trust R&D approval, correspondence & submission documentation, Data Protection documentation			
Regulatory -Regulatory Authority Authorisations/Approvals, Clinical Trial Agreement			
Financial Documentation			
Finance **-**Details of subvention funding (if applicable) - Financial Disclosure Statements -Insurance Statement/Indemnity			
Monitoring & Audit			
Site Initiation - study initiation report/slides			
Monitoring -monitoring log, reports and correspondence			
Audit -reports and correspondence			
Study Report **-** clinical study report (if applicable)			
Additional Documentation			
Supplementary Information			

I confirm that the above documents are stored in the Local Investigator Site File

Name of Centre		Date:
Signature		
Print Name & Job Title		