Gloucestershire Hospitals
NHS Foundation Trust

Trial Delivery 01: Research Documentation and File Management

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.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:

http://www.gloshospitals.nhs.uk/en/About-Us/Research--Development/

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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	Review and update along with reorganisation into the Gloucestershire R&D Consortium suite of SOPs previously SOP 09	01/11/2014
2.0	Update on HRA and electronic data	01/02/2017
3.0	Rebranding to GHNHSFT and updating of contact details	31/03/2018

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

Contents

1. Introduction, Background and Purpose

Maintenance of the correct and appropriate documentation in a manner suitable for managing the conduct of the trial and enabling evaluation by audit and inspection is essential for GCP compliance.

It must be possible to reconstruct the conduct of the trial at all stages from:

- set up (prior to patient recruitment),
- during patient recruitment and direct involvement
- for some time after its completion

from the documentation which is filed and retained within:

- the Trial Master File (TMF)
- Investigator Site File (ISF)
- Trial Pharmacy File (TPF)
- Research and Development Study File (R&DSF)

from the perspective of :

- Sponsor/ CI
- PI and local research team
- Trust Research and Development Department (local research governance).

Trust policies and procedures must be adhered to in conjunction with this SOP and any that the Sponsor has written specifically for their trial. Any variations between SOPs from various sources should be discussed and decided upon before any trial activity starts at site.

2. Who should use this SOP?

All staff working on a trial should be familiar with the lay out and requirements of the file that is relevant to their role:

- Chief Investigators (CIs) and trial co-ordinators of clinical trials sponsored or co-sponsored by the Trust;
- Principal Investigators (PIs) and research staff at sites where multi-site studies sponsored or co-sponsored by the Trust are being run;
- R&D office personnel, who manage the sponsorship of trials on behalf the Trust and support Trust hosted trials;
- PIs and research staff for externally-sponsored trials "hosted" by the Trust.

3. When this SOP should be used

This SOP must be referred to as soon as a trial is being considered for adding to the Trust trial portfolio. This will ensure that the necessary procedures to secure the quality of every aspect of the trial shall be complied with.

In accordance with Good Clinical Practice (GCP) the Sponsor should ensure appropriately qualified individuals are responsible for the overall conduct of the clinical trial, handling the data, verifying the data, conducting the statistical analyses, and preparing the trial reports.

The Sponsor should normally delegate data management within a clinical trial to the CI. Where the CI further delegates data management to another member of the research team this should be clearly outlined on the Clinical Trial Delegation Log.

For hosted trials, the PI or Local Collaborator (LC) is responsible for delegating roles and responsibilities at the participating site documented on the delegation log.

4. Trial Master File, Investigator Site File and Trial Pharmacy File

4.1.1 Indexing TMF

The MHRA advise typically organising Sponsor files as follows:

Global level files	Documents in this file are relevant to the conduct of the trial at any site ie Investigator Brochure.
Country level files	Documents in this file are country – specific and are relevant to the conduct of the trial at any site in that country
Site level files	Documents in this file are specific to the conduct of the trial at a particular investigator site ie, protocol signed by PI and delegation log

Potential document sources for the Sponsor TMF include:

- Trial pharmacovigilance documentation (SAE cases and reconciliation)
- Regulatory documentation
- Trial contracts
- Clinical operations documentation
- Data management documentation
- R&D office documentation
- Vendor selection/ oversight documents
- Data management documentation
- Trial specific training records
- Trial specific computer system validation documentation
- Statistics documentation
- Trial specific IMP documentation (QP certification, certificates of analysis, shipping records)

4.1.2 Indexing ISF

The Site File Index provided by the Sponsor/TU should be used. If because of local requirements additional sections are needed to make essential documentation storage more practical, the Sponsor/TU will be informed and the Site File Index annotated with the additional information.

If a Sponsor does not provide a Site File/ Site File Index then the Trust proforma template will be used (based on NIHR templates – Appendix 2)

4.1.3 Indexing R&D Study Files

The Trust indexes for both paper files and electronic files should be used for all types of research (see Appendix 9)

4.2 Essential Documents

Essential documents are those records created from following trial procedures as well as those listed in guidance relating to the conduct of the trial and should be retained to demonstrate compliance with ICH GCP (see Appendix1).

Below are listed the minimum essential documents listed in E8 of GCP Guidelines:

- Investigator's Brochure
- Signed protocol and amendments, if any, and sample case report form (CRF)
- Information given to trial subject
    - Informed consent form (including all applicable translations)
    - Any other written information
    - Advertisement for subject recruitment (if used)
- Financial aspects of the trial
- Insurance statement (where required)
- Signed agreement between involved parties e.g.:
    - investigator/institution and sponsor
    - investigator/institution and CRO
    - sponsor and CRO
    - investigator/institution and authority(ies) (where required)
- Dated, documented approval/ favourable opinion of Trust R&D department (Institutional Review Board) and Independent Ethics Committee (REC) of the following:
    - protocol and any amendments
    - CRF (if applicable)
    - Participant Information Sheet/ Informed Consent Form(s)
    - any other written information to be provided to the subject(s)
    - advertisement for subject recruitment(if used)
    - subject compensation (if any)

- any other documents given approval/ favourable opinion

- Trust R&D department (Institutional Review Board) and Independent Ethics Committee (REC) composition
- Regulatory authority (MHRA) Authorisation/ approvals
- HRA
- Notification of protocol (where required)
- Curriculum Vitae and/ or other relevant documents evidencing qualifications of investigator(s) and sub-investigator(s)(signed and dated, updated annually)
- Normal values/ range(s) for medical / laboratory/ technical procedure(s) and/ or test(s) included in the protocol, (signed and dated by Laboratory Manager)
- Medical / laboratory/ technical/ procedures/ tests
  - certification or
  - accreditation or
  - established quality control and/or external quality assessment or
  - other validation (where required)
- Sample of label(s) attached to investigator product container(s)
- Instructions for handling of investigational product(s) and trial – related materials (if not included in protocol or Investigator's Brochure)
- Shipping records for investigational product(s) and trial related material(s)
- Certificate(s) of analysis of investigational product(s) shipped
- Decoding procedures for blinded trials
- Master randomisation list
- Pre-trial monitoring report
- Trial initiation monitoring report

The list on the previous page is not exhaustive and has some key omissions, below are some or all of which will be required to demonstrate GCP compliance :

- IMP handling
  - Qualified Person (QP) certification,
  - green-light document to release and ship IMP(s)
- electronic database documentation
- trial specific training given by PI to research staff
- centralised records relevant to a number of trials
  - written procedures
  - staff training records
  - maintenance and calibration records of equipment used in a trial

Therefore an assessment of all activities carried out within a trial will be undertaken to determine whether they need to be documented to enable reconstruction of the trial conduct from the paperwork alone. Consideration will also be given to centrally stored electronic data for example Trust Mandatory Training/ other staff training records. These must be stored in accordance with Trust IT policies and guidelines and site file notes place in the TMF, SIF and TPF to indicate how these may be accessed by appropriately authorised Trust staff.

5. Source data, CRF and e-CRF

5.1 Source data

Trial participants' notes, hospital / clinical records in any format (paper or electronic) are source documentation for source data. Any format used must permit the reconstruction of the clinical care given to the participant and describe participant-specific events that have occurred during the conduct of the trial. Where copies are provided, they must be certified by the provider.

Key events to be recorded in trial participants' notes include:

- Eligibility decision and any required supporting information not available elsewhere within the notes (signed and dated by PI or Co-investigator)
- Provision of subject information sheet/ invitation to consider the trial
- Receiving informed consent
- Randomisation or trial entry
- Trial visits or follow up phone calls required by the protocol
- Treatment and dosing decisions, including changes to concomitant medication
- Reconfirmation of consent
- Any trial–related decisions relating to the clinical care of the subject
- Adverse events, their seriousness, causality and severity
- Withdrawal, termination or end-of trial involvement including any protocol defined follow up.

Where trial specific work sheets are provided by the Sponsor or devised by the research team to capture trial specific information completed sheets should be retained within the hospital notes and blank versions filed in the site file.

The definition of source data must be agreed with the Sponsor during trial set up and documented so that future Sponsor monitoring for Source Data Verification purposes can be facilitated with the minimum of additional work for the research team.

The recording of data will be:

- Completed contemporaneously
- Signed and dated by the person making the entry. This may be wet ink signature or an appropriately controlled electronic signature
- If retrospective entries or annotations are made then these should be obvious and will be signed and dated with the date the entries where added – electronic entries must have a clear audit trail
- All entries must include the details of the staff involved in the consultation and are countersigned where decisions have been made by staff other than the person making the entry. For example, a nurse is making the entry about dosing when the clinician decides to amend

the dose – this then will need to be countersigned by the treating clinician.

- Where data is stored centrally on a trust computer system, the clinician must still be able to demonstrate that they have assessed these reports during the course of the trial.

5.2 Case Report Forms (CRFs) and electronic - Case Report Forms (e-CRF)

CRFs should be completed according to the specifications of each study by a delegated member of the research team, who has received training on the data collection requirements of the specific trial / study. CRFs should be completed in a timely fashion and, where possible within one month of the event taking place, unless another time frame is specified in the protocol (see Appendix 8 for Trust guidelines on completion CRFs).

6. File management

TMF, ISF, TPF and R&DSF should all be maintained contemporaneously. All documents must be filed in date order from most recent date to oldest date.

Copies of all correspondence between the site staff, Sponsors and trial participants must be retained. This includes printing off emails, faxes (including receipts), with highlighting of pertinent information or adding numbering to the documents so that it is easier to reconstruct the flow of information.

The research team must check whether a trial participant has more than one set of notes within the Trust, for example general hospital notes and departmental specific notes (maternity, haematology, oncology, ophthalmology). Notification that the patient is a participant in a trial must be included in all notes so that all health care teams are alerted to the patient's involvement in a trial.

7. Format

The format of the documentation and its storage will be agreed with the Sponsor at trial set up.

8. Version Control

Systems should be in place for version control of documents. A chronology of amendments will be kept on file that records all the amendments submitted and the documents that they relate to. Old versions of documents should be

retained on file alongside the new versions with the old versions, clearly marked as superseded.

9. Storage

Documents contained in the TMF, ISF and R&DSF may be original regulatory approvals and confidential information. The files should therefore be stored in a secure place with restricted access. A locked drawer, cupboard or dedicated room is recommended, depending on the size of the project.

Before, during and after the conduct of the research, it is useful to bear in mind the archiving of the documentation. Documentation may need to be retrieved at a future stage and so a catalogue or index of documents should be maintained to ensure this process is not burdensome. (Further details are given in the R&D SOP TD 04 End of Trial Procedures and Close Down and R&D SOP TD05 Trial Archiving.)

a. Where a study is not submitted electronically, digital versions of the documents should be requested from the sponsor and an Electronic Folder set up as above.
b. If the documents are not available electronically at all the paper copies provided will be scanned and stored in the usual manner.
c. The cover and spine of the physical R&D file should contain the same information as recorded on the R&D Number Allocation List

10. Other SOPs and documents

Appendix 1: GCP Guidelines E8

	Title of Document	Purpose	Located in Files of	
			Investigator/ Institution	Sponsor
8.2.1	INVESTIGATOR'S BROCHURE	To document that relevant and current scientific information about the investigational product has been provided to the investigator	X	X
8.2.2	SIGNED PROTOCOL AND AMENDMENTS, IF ANY, AND SAMPLE CASE REPORT FORM (CRF)	To document investigator and sponsor agreement to the protocol/amendment(s) and CRF	X	X
8.2.3	INFORMATION GIVEN TO TRIAL SUBJECT - INFORMED CONSENT FORM (including all applicable translations)	To document the informed consent	X	X
	- ANY OTHER WRITTEN INFORMATION	To document that subjects will be given appropriate written information (content and wording) to support their ability to give fully informed consent	X	X
	- ADVERTISEMENT FOR SUBJECT RECRUITMENT (if used)	To document that recruitment measures are appropriate and not coercive	X	
8.2.4	FINANCIAL ASPECTS OF THE TRIAL	To document the financial agreement between the investigator/institution and the sponsor for the trial	X	X
8.2.5	INSURANCE STATEMENT (where required)	To document that compensation to subject(s) for trial-related injury will be available	X	X

8.2.6	SIGNED AGREEMENT BETWEEN INVOLVED PARTIES, e.g.: - investigator/institution and sponsor - investigator/institution and CRO - sponsor and CRO - investigator/institution and authority(ies) (where required)	To document agreements	 X X X	 X X (where required) X
8.2.7	DATED, DOCUMENTED APPROVAL/FAVOURABLE OPINION OF INSTITUTIONAL REVIEW BOARD (IRB) /INDEPENDENT ETHICS COMMITTEE (IEC) OF THE FOLLOWING: - protocol and any amendments - CRF (if applicable) - informed consent form(s) - any other written information to be provided to the subject(s) - advertisement for subject recruitment (if used) - subject compensation (if any) - any other documents given approval/ favourable opinion	To document that the trial has been subject to IRB/IEC review and given approval/favourable opinion. To identify the version number and date of the document(s)	 X	 X

8.2.8	INSTITUTIONAL REVIEW BOARD/INDEPENDENT ETHICS COMMITTEE COMPOSITION	To document that the IRB/IEC is constituted in agreement with GCP	X	X
8.2.9	REGULATORY AUTHORITY(IES) AUTHORISATION/APPROVAL/ NOTIFICATION OF PROTOCOL (where required)	To document appropriate authorisation/approval/notification by the regulatory authority(ies) has been obtained prior to initiation of the trial in compliance with the applicable regulatory requirement(s)	X (where required)	X (where required)
8.2.10	CURRICULUM VITAE AND/OR OTHER RELEVANT DOCUMENTS EVIDENCING QUALIFICATIONS OF INVESTIGATOR(S) AND SUB-INVESTIGATOR(S)	To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects	X	X
8.2.11	NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/ LABORATORY/TECHNICAL PROCEDURE(S) AND/OR TEST(S) INCLUDED IN THE PROTOCOL	To document normal values and/or ranges of the tests	X	X
8.2.12	MEDICAL/LABORATORY/TECHNICAL PROCEDURES/TESTS - certification or - accreditation or - established quality control and/or external quality assessment or - other validation (where required)	To document competence of facility to perform required test(s) , and support reliability of results	X (where required)	X
8.2.13	SAMPLE OF LABEL(S) ATTACHED TO INVESTIGATIONAL PRODUCT CONTAINER(S)	To document compliance with applicable labelling regulations and appropriateness of instructions provided to the subjects		X

8.2.14	INSTRUCTIONS FOR HANDLING OF INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS (if not included in protocol or Investigator's Brochure)	To document instructions needed to ensure proper storage, packaging, dispensing and disposition of investigational products and trial-related materials	X	X
8.2.15	SHIPPING RECORDS FOR INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS	To document shipment dates, batch numbers and method of shipment of investigational product(s) and trial-related materials. Allows tracking of product batch, review of shipping conditions, and accountability	X	X
8.2.16	CERTIFICATE(S) OF ANALYSIS OF INVESTIGATIONAL PRODUCT(S) SHIPPED	To document identity, purity, and strength of investigational product(s) to be used in the trial		X
8.2.17	DECODING PROCEDURES FOR BLINDED TRIALS	To document how, in case of an emergency, identity of blinded investigational product can be revealed without breaking the blind for the remaining subjects' treatment	X	X (third party if applicable)
8.2.18	MASTER RANDOMISATION LIST	To document method for randomisation of trial population		X (third party if applicable)
8.2.19	PRE-TRIAL MONITORING REPORT	To document that the site is suitable for the trial (may be combined with 8.2.20)		X
8.2.20	TRIAL INITIATION MONITORING REPORT	To document that trial procedures were reviewed with the investigator and the investigator's trial staff (may be combined with 8.2.19)	X	X

Appendix 2 Suggested Site File Contents

Investigator Site File Contents

SECTION	TITLE	CONTENT/COMMENTS	SIGN & DATE WHEN COMPLETE
1	Protocol / amendments	Current protocol Protocol amendments Historical protocols	
2	Sample CRF/ QLQ Diary Cards	If too bulky to put in file place file note in this section stating where it can be found	
3	Regulatory approval documentation		
4	Site signature /responsibility log		
5	Curriculum Vitae	CVs for all research personnel listed in the signature/responsibility log	
6	Patient Identification form Patient recruitment /screening form		
7	Sample of current and all historical Patient Information / Informed Consent form and GP Letter Completed patient Information and Informed Consent Forms		
8	Correspondence	File in chronological order all correspondence to/from the coordinating research body. File email communication Include a separate section here for newsletters	
9	Minutes from Initiation meeting Monitoring logs Notes of telephone calls	If the study is not monitored state this in a file note in this section Document telephone call in relation to agreements or significant discussions regarding trial administration, trial conduct, adverse events or protocol violations	
10	Blank serious adverse event forms and guidelines for their completion		
11	Notification of serious adverse events and/or safety reports	By Investigator to co-ordinating research body By co-ordinating research body to Investigator By co-ordinating research body to regulatory authorities (if this will not be supplied place a file note stating this)	

12	Randomisation details	Instructions (if applicable)	
13	Instructions for handling trial medication and trial related materials Shipping records	This responsibility is normally that of the clinical trial pharmacist if this is the case place a file note in this section stating this	
14	Clinical Laboratory	Laboratory normal reference ranges (including revisions) Laboratory certificate(s)	
15	Contracts	Investigator Commitment Statement/Study Acknowledgement Indemnity Confidentiality Clinical Trial Agreement including financial details. Completed and signed FDA 1572 form (if applicable) Financial disclosure letter (if applicable)	
16	Investigator's Brochure Safety alert letters/Updates		
17	Completed Data Queries		
18	Study Training Materials		
19	Miscellaneous (specify).....		

AFTER THE COMPLETION OF THE TRIAL THE FOLLOWING MUST BE ALSO FILED IN THE SITE FILE

20	Investigational product(s) accountability at site	This will be with the clinical trials pharmacist	
21	Documentation of Investigational product destruction	If destroyed at site this will be with the clinical trials pharmacist	
22	Final report	From Investigator to REC	
23	Clinical study report	To document results and interpretation of trial	

Appendix 3 Site file note

File Note

Study:	Principal Investigator:
Date:	Time:

Print Name.....

Signature ..... Date. .....

Role .....

Appendix 4 Trial Specific Training Log

[Study Title] Training Log

Topic	Date	Training given by	Training given to

Appendix 5 Study Specific Tracking Log

DOCUMENT	VERSION	DATE TAKEN FOR USE	LOCATION	SIGNATURE	DATE RETURNED	SIGNATURE

Appendix 6 Trial Specific Treatment Allocation Log

Treatment Allocation Log

Study:	Patient ID:

Date	Treatment	Dose	Comments

Appendix 7: Appointment Checklist

Patient Details

STUDY: _____

STUDY ID: _____

Appointment Date						
Time						
Visit No						
Medical/Dr						
Annual Review						
Notes						
Bloods						
Meds						
PFT						
ECG						
Echo / CIMT						
Exam - Eye / E.Photos						
Transport						
Interpreter						
GP letter						
In Diaries						
Comments						

Appendix 8: CRF completion guidelines

Paper CRF'S

- Always check you are using the **correct version** number of the CRF.
- Always use a **black ink** ballpoint pen.
- Writing should be in **block capitals** wherever possible and only written in the designated box or lined area.
- If the CRFs are printed on carbonless duplication paper, always make sure that a suitable separator is inserted under the form being completed. In addition, it is important to ensure that the bottom copy is legible before sending the top copy to the Trials Office. If necessary, a copy of the top copy should be made and retained. If the CRFs are only written on standard paper then ensure photo copies are kept. However photocopies of Quality of Life questionnaires should not be made.
- Ensure all entries are **accurate, legible** and **verifiable** with the source data in the medical record and that data is entered in accordance with CRF completion guidelines for that particular trial.
- Where source data forms (SDF's) are used to collect the information required for a CRF it is important not to rely on this data solely but also to check all other forms of information such as notes, correspondence, clinic sheets, OPMAS annotations, laboratory results, PAS (for information regarding inpatient and outpatient visits), or other relevant hospital system such as APEX or Oasis, pharmacy and radiotherapy prescriptions. Where protocol visits are widely spaced, for example three monthly, all the information for the time between visits should be reviewed. Any discrepancies between the source data form and other information should be discussed with the person responsible for completing the SDF.
- Any discrepancies with source data should be checked with a member of the medical team and an explanation of the significance should be noted in the CRF and/or patient's medical records. For laboratory values outside the laboratory's reference range or some other range agreed with the study Sponsor, or if a value shows significant variation from one assessment to the next, this should be commented on and the significance noted in the CRF and/or patients medical records.
- **Never over-write an entry**. Corrections should be made as instructed by the TU, below are listed some examples:

    - Corrections should be made on the data query forms sent out by the Trials Unit (TU) and not on the retained copy of the CRF unless stipulated by the TU. If the retained copy is amended/updated this must be recopied and

sent to the TU to ensure that they have the most up to date version. Ensure any amendments to the CRF's are signed and dated.

- In some cases CRF's are amended by the TU (some trials have an SOP in place to make self-evident correction) these amended CRFs are sent from the TU and should be attached to the relevant CRF.

- If it becomes apparent that data has been omitted or entered incorrectly in a manner which will not trigger the Trial Unit to issue a data query then the Trial Unit should be advised of the correct data in the format which they specify e.g. by email. Original CRFs should not be amended unless instructed to do so.

- Cross out the incorrect entry with a single line so that it is still readable. Never use correction fluid or obliterate entries made on the CRF. Enter the correct data and initial and date the correction.

- The procedure to be followed for the resolution of data queries should be agreed with the study sponsor / TU and these should be completed by site staff in a timely fashion.

- The CRF must be **signed** where indicated, by the Principal Investigator or designee (as appropriate) to assert that he/she believes they are complete and correct.

- CRFs should be kept in a **secure location** during the course of the study. When CRFs have been completed they should be filed in a secure location with a file note in the site file to say where they are stored. When the study is closed to both recruitment and data collection CRFs should be archived, or stored according to the protocol.

Electronic CRFs

- **Training** should be completed as designated by TU before entering any electronic data.

- The SOP provided by the TU for inputting data/answering discrepancies / amending data should be adhered to.

- Discrepancies should be answered in a timely fashion in accordance with trial SOP.

- All data must be **saved prior to logging out**, as unsaved data will be lost.

- Electronic CRF data should be verified by a nominated person/trained member of staff to certify that the completed data is correct and in accordance with the patients source data, as stipulated in trial SOP.

In General

- Ensure data entry is as complete as possible without omissions for both paper and electronic CRFs. **It is impossible for personnel doing the data entry to interpret blank spaces. If data is unavailable write, for example, *'unknown', 'missing', 'test not done',*** etc as defined by CRF Completion Guidelines (if applicable). Avoid using the ambiguous phrase, *'not available'*.

- Unless requested by the protocol, CRF or TU, laboratory values should be entered without conversion from printed reports even if in multi-centre study units of measurement differ from centre to centre, this applies to both paper and electronic CRFs. The units used should be specified where they differ from those shown on the CRF. If hard copies of laboratory values are required protocol, measures should be followed in terms of removing personal identifiable information such as the patient's full name.

- The patient's identity should remain as confidential as possible at all times, providing only data requested by the TU. A record must be kept by the Investigator of patients in the study consisting of the patient's full name and study number; this is the Subject Identification Log.

Appendix 9 R&D Governance Study File Guidelines

1. **Allocation of unique identifiers**
   Immediately upon receipt of a new application, the study details will be added to the R&D allocation list for the appropriate Trust(s) as stored on the RDSU Shared Network Drive

   The R&D Reference is generated sequentially. For example YY_XXX_Trust, where YY denotes the year of submission and XXX is a sequential number starting from 001. The Trust acronyms are:

   Gloucestershire Hospitals NHS Foundation Trust - GHT,
   Research running across several or all the Gloucestershire NHS Trusts will be suffixed with MTS (Multi-Trust Study)

2. **Naming Electronic folders**
   Each folder will use the following format:
   R&D Reference_BRIEF TITLE/ACRONYM
   For example 15/001/GHT_TEST

3. **Organising electronic folders on the shared IT drive GLNT199 (RDSU)**
   The electronic folder for trials in feasibility/ set up and delivery stages will be filed as follows:
   - PROJECTS
   - folder for the year of submission
   - TRUST acronym

4. **Sub folders within each electronic folder**
   R&D – all governance documentation including:
   - Trust Approval Letter
   - Support Department approvals/agreements
   - Local SSI Application form
   - R&D Application form
   - CVs/Good Clinical Practice certificates
   - Sponsor Letters
   - Indemnity Certificates
   - Investigator Brochures
   - Clinical Trial Agreements
   - Original Ethics Favourable Opinions/Amendment prior to R&D Approval
   - MHRA Clinical Trial Authorisations/Amendments prior to R&D Approval

   Current Study Documents – One set of the current, approved protocol and patient documentation. Superseded documents will be moved to the SUPERSCEDED folder within this folder

   Finance – all details of study funding will be stored here

For commercially sponsored trials the NIHR Costing Template **MUST** be included in this folder.

For academic trials details of any income or expenditure will be stored here.

Amendments – To be organised within subfolders named by the REC amendment reference number and date. It will include the Amendment Approval Notification (letter or email)

Honorary Contracts/Letters of Access – Copies of relevant Research Passport and associated documentation along with copies of Honorary Contracts and Letters of Access will be stored here.

Correspondence – any pertinent correspondence relating to the study.

Serious Adverse Events/ Adverse Events – Details of SAEs and any AEs that require reporting to the R&D Office.

Governance Breaches – Details of any governance breaches.

5. Where a study is not submitted electronically, electronic versions of the documents should be requested from the sponsor and an Electronic Folder set up as above.

6. If the documents are not available electronically then the paper copies provided will be scanned and stored as for all research submissions.

Appendix 10: Links to trust specific policies

a. Records management
http://glnt313/sites/ghnhsft_policy_library/NonClinPolices/B0259.pdf
b. Clinical and non clinical information systems management policy
http://glnt313/sites/ghnhsft_policy_library/NonClinPolices/B0676.pdf
c. Health records
http://intranet.glos.nhs.uk/en/Your-Division/Diagnostic-Specialties-Division/Health-Records/
d. Fax policy:
http://glnt313/sites/ghnhsft_policy_library/Procedures/B0594.pdf
e. Maternity Health records
http://glnt313/sites/ghnhsft_policy_library/WPP/B0556.aspx
f. Information Governance Policy
http://glnt313/sites/ghnhsft_policy_library/NonClinPolices/B0413.pdf
g. Data Quality
http://glnt313/sites/ghnhsft_policy_library/NonClinPolices/B0406.pdf
h. Consent Policy
http://glnt313/sites/ghnhsft_policy_library/ClinPolices/A0297.pdf
i. IT Security
http://glnt313/sites/ghnhsft_policy_library/NonClinPolices/B0591.pdf
j. E-Communications and Internet Use policy (including mobile phones and social networking)
http://glnt313/sites/ghnhsft_policy_library/NonClinPolices/B0590.pdf
k. Clinical Audit- undertaking and learning lesons
http://glnt313/sites/ghnhsft_policy_library/NonClinPolices/B0679.pdf