Essential Documents: Setting Up a Trial Master File & Sponsor Oversight File

NJRO-GEN-SOP-010

Contents

1. Background/Introduction

A Trial Master File (TMF) is a standard filing system for the effective storage and location of essential documents related to clinical research. Essential documents are defined as: "those documents which individually and collectively permit evaluation of the conduct of the trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, Sponsor, and monitor with the standards of GCP and with all applicable regulatory requirements". The regulatory and approvals documents within the TMF should be maintained alongside Case Report Forms (CRFs) and source documentation.

Not all documents will be of relevance to every project – the content of the TMF will therefore differ according to the nature of the study. For example, most of the essential documents must legally be maintained for Clinical Trials of Investigational Medicinal Products (CTIMPs) whereas, for solely observational studies, certain documents will not be applicable. Therefore, the SOP should be interpreted in the context of the individual project.

2. Purpose

This SOP describes the procedure for setting up a TMF and details the essential documentation that should be maintained within the TMF. Additionally the document explains the requirements to maintain a Sponsor Oversight File (SOF). The SOP is mainly aimed at CTIMPs that fall under the remit of the Medicines for Human Use (Clinical Trials) Regulations. However, it also relevant for any project conducted within the NHS, which has to meet the requirements of the UK Policy Framework for Health and Social Care Research, and other clinical investigations that may have an impact on the safety and well-being of human participants.

3. Scope of Document

This SOP is applicable to all personnel carrying out clinical research, or related activities, within The Newcastle upon Tyne Hospitals NHS Foundation Trust (NuTH FT).

4. Definitions

TMF	Trial Master File
CRFs	Case Report Forms
SOF	Sponsor Oversight File
ISF	Investigator Site File
CI	Chief Investigator
CTIMPs	Clinical Trials of Investigational Medicinal Products

5. Roles & Responsibilities

The Sponsor, or their delegate, is responsible for reviewing the TMF to ensure that all required documents are present.

6. Procedures

6.1. Establishing a TMF

It is essential that a TMF is established as soon as possible after an outline protocol/proposal is available and/or first contact is made with a research sponsor. The Chief Investigator (CI) and the study sponsor must agree the contents of the TMF and a dedicated member of staff should be assigned responsibility for maintaining and updating the essential documents within the TMF from this time until the project is formally closed. This should be the CI or their delegate. Appendix 1 lists the essential documents that should be maintained within a TMF in accordance with ICH GCP. As noted above, the specific documents filed will differ according to the nature of a study. The list is not exhaustive, and it is strongly recommended that any approvals, agreements and communications not listed here should also be retained. The TMF should be held at the lead investigation site or with the appropriately delegated organisation, with copies of relevant documents kept at participating sites in Investigator Site Files (ISF). For any document stored outside of the TMF (for example IMP accountability may be kept in a separate Pharmacy file and stored within the Pharmacy Department), this should be documented in a file note and stored within the appropriate section of the TMF.

As some of the documents within a TMF will be originals and possibly contain confidential data, it is important that the TMF is retained within a secure place, with restricted access. It is recognised as best practice to store documents within a locked cupboard within a locked room. Documents should be maintained in a legible condition, with prompt retrieval possible. It is important to note that in 2014 the MHRA updated their critical GCP inspection findings to include incidences “where the TMF is not readily available or accessible, or the TMF is incomplete to such an extent that it cannot form the basis of inspection and therefore impedes or obstructs inspectors carrying out their duties in verifying compliance with the regulations”.

6.2. Maintaining a TMF

The CI, or their delegate, is responsible for updating the TMF in a timely manner as the trial progresses. The delegation of this responsibility must be recorded on a formal delegation log filed within the TMF. All documentation that requires signatures, need to be fully signed when filed in the TMF, this includes, but not limited to, Protocols, Monitoring Plans and contracts. As documents may need to be amended during a

project, it is important that amendment chronologies are kept, indicating the changes and the dates they are implemented. A copy of the old document must be retained in the TMF alongside the new amended version(s) and the old copy should have the word "SUPERSEDED" written on to the front page and be signed and dated by the person responsible. Superseded documents can be filed elsewhere if correctly cross referenced with the TMF to highlight their location. The filing of new documents into the TMF must be done in a timely manner.

6.3. Archiving a TMF

Once the trial has finished, the Sponsor, or their delegate, is responsible for reviewing the TMF to ensure that all the required documents are present. It may be necessary for the results of a clinical research project/trial to be examined and checked after it has finished so the TMF should be archived in an easily accessible way and readily available on request. For CTIMPs archiving should occur after the trial has undergone a final closeout visit and the closeout report has been issued. The documents should be stored in a secure location with limited access to authorised personnel only. Environmental controls must be in place to protect the documents e.g. from fire, water damage or destruction by pests. The trial related documents should be centrally archived to prevent accidental damage, amendment, loss or destruction and any change in the ownership or location of documentation should be recorded to allow the tracking of the stored records.

For TMFs of those studies sponsored by NuTH FT, research teams must follow NJRO – GEN-SOP-012 Archiving Clinical Research Documents

6.4 Establishing and Maintaining the SOF

The Sponsor is responsible for establishing the SOF. Any document that is deemed appropriate (for example: Regulatory Approvals, Continuous Risk Assessments, Serious Breach reviews and Monitoring report reviews) to demonstrate Sponsor oversight shall be included. Documents may be stored in paper format although electronic storage is recommended. Files shall be displayed as per NJRO-REG-GUIDE-001 Sponsor oversight file structure naming convention. Where NuTH FT is Sponsor but the study is deemed low to medium risk a SOF must also be created and maintained by the relevant personnel. Various departments within NuTH FT Research & Development will have access to the SOF and are delegated the task to maintain their individual sections, for example: Funding development and Quality Assurance. Responsibility remains with the Regulatory Compliance Team for high risk studies and the Research Governance Team for hosted/NuTH low to medium risk studies. Documents held within the SOF shall be uploaded/filed in a timely manner and where possible be contemporaneous.

7. References

7.1. ICH Topic E 6 (R2) Guideline for Good Clinical Practice
7.2. Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendments.
7.3. UK Policy Framework for Health and Social Care Research
7.4. MHRA: Good Clinical Practice for Clinical Trials - https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials
7.5. Newcastle Joint Research Office: SOPs and WIs – https://newcastlejro.com/research/resources/documents/

Note any literature quoted in the procedure or that has direct relevance to the procedure.

8. Appendices

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8.1. Example of Essential Documents to be maintained in a TMF *(these are examples and do not represent a definitive list)*

Title of Document	ICH GCP Guideline Reference	Further Details
1. Protocol & Consent		
Final, signed research protocol and amended protocols, with version numbers and dates	8.2.2 & 8.3.2	To document the Chief Investigator and sponsor agreement to the protocol/amendment(s).
Investigator Brochure and updates	8.2.1 & 8.3.1	To document that relevant and current scientific information about the investigational product has been provided to Investigators.
Example of Informed Consent Form and any amendments, with version numbers and dates	8.2.3 & 8.3.2	To provide evidence of how informed consent will be documented.
Examples of any other written information give to project/trial participants and any updates (e.g., Participant Information Sheets (PIS) with version numbers and dates	8.2.3 & 8.3.2	To document that research participants will be given sufficient written information (content and wording) to allow them to give fully informed consent. It should also include any documents that require completion by the participant themselves
Copy of any advertisements for participant recruitment and any amendments	8.2.3 & 8.3.2	To document that the recruitment measures are appropriate and not coercive.
Copy of any letter/information for a patient's GP or Consultant	8.2.3 & 8.3.2	
2. HRA and REC		
Final HRA application and any amendments		
Favourable opinion letter from REC	8.2.7 & 8.3.3	To document that the trial has received a favourable ethical opinion and to identify the version number and date(s) of the approved documents.

		Approvals to any amendments need to be stored alongside originals.
Main Research Ethics Committee composition (if not already detailed in notification of a favourable ethical opinion letter) and relevant correspondence	8.2.8	To document that the Research Ethics Committee is constituted in agreement with GCP. All NHS Research Ethics Committees that are approving clinical trials encompassed by the Clinical Trials Regulations will have been granted 'authorised' status from the National Research Ethics Service (NRES) and will therefore work in compliance with GCP.
REC reports	8.3.19	For example, annual reports, safety reports, final study report.
3. Research & Development		
Trust R&D project registration form and approval letter	8.2.9 & 8.3.4	To document that the trial has received Trust R&D approval where the research is being conducted and access to patients in their care as applicable.
Copy of financial information relating to the study (funding application/ award letter/costings) if not detailed in a Clinical Trial Agreement.	8.2.4	To document that financial arrangements for the study are in place
Insurance Statement (copy of any certificate/letter/agreement), plus any updates	8.2.5	To document provisions to the participant(s) for any study-related harm they might experience. This includes cover for negligent and non-negligent harm. Evidence of insurance cover for the lifetime of the study provided by certification each year.
Copy of the sponsor agreement and allocation of responsibilities	8.2.6	To document that a research sponsor has been identified to ensure appropriate arrangements are in place for the initiation, management and financing of the project.
Copy of any signed agreement(s) between involved parties.	8.2.6	To document agreements and responsibilities for the preparation, conduct and closure of the trial.
4. Regulatory		
Regulatory application forms (if applicable)		e.g. MHRA, NIGB, ARSAC, GTAC

Regulatory approvals (if applicable)	8.2.9 & 8.3.4	To document that appropriate authorisation has been issued prior to the project commencing
5. Research Team – Staff & Training		
Signed and dated CVs evidencing the qualifications of the Chief Investigator/research team	8.2.10 & 8.3.5	To document the qualifications and eligibility of the CI/PI(s) and any key members of the research team to conduct the study, or to provide medical supervision of subjects. An up-to-date copy of GCP certificate and where applicable HTA certificates are retained.
Delegation of responsibilities log/signature log	8.3.24	To document the roles and responsibilities of the research team. Also used to document the signature and initials of ALL members of the research team. The delegation of tasks must be signed off by the main investigator (CI or PI) at the site as it is their responsibly to ensure the staff are appropriately trained and qualified for their role in the study. Please note, for studies involving drug prescribing, it is essential that staff that are able to prescribe are clearly identified on the delegation log. Trust Pharmacy cannot process a prescription for a CTIMP or ATIMP study unless this is signed by an individual on the delegation log. There must always be at least two people identified that can prescribe for the study.
Staff training records	8.2.10 & 8.3.5	To document any study-specific training or general competency training undertaken by each member of the research team. Proof of professional registration status for medical staff and professional registration status for NMAHP.
6. Participant Information		
Master randomisation list (if applicable)	8.2.18	To document the actual randomisation of the trial participants to different treatment arms.

Participant screening log	8.3.20	To document identification of subjects who entered pre-trial screening (where required). Appropriate space should be included to show who has conducted the screening/enrolment
Subject ID code list	8.3.21	A confidential list of the trial number allocated to the participants enrolled into the study
7. Data Collection		
Sample case report form and completion guidance	8.2.2	
Sample log for retained body fluids/tissue samples (if any)	8.3.25	To document the location of any retained samples.
Normal laboratory reference ranges for any tests used or medical/technical procedures detailed in the protocol	8.2.11 & 8.3.6	To document the normal values and/or reference ranges of the test results.
Lab/technical procedures/tests certification of accreditation	8.2.12 & 8.3.7	To document competence of the facility to perform required test(s) and support reliability of the results (e.g. CPA accreditation for Trust laboratories)
Copies of calibration records for technical equipment.	8.2.12 & 8.3.7	To document that the equipment in use is accurate. Can be requested during inspections by the competent authority.
Signed, dated and completed Case Report Forms (CRF) (original)	8.3.14	To document that the investigator or authorised member of the investigator's staff confirms the observations recorded
Documentation of CRF corrections (original)	8.3.15	To document all changes/additions or corrections made to CRF after initial data were recorded
8. Serious Adverse Events		
Sample SAE form and copy of reporting procedures		To document the information required when submitting a SAE and the procedure for reporting a SAE including contact details
Completed SAE forms (if not included in the CRF)	8.3.18	Where SAEs have been reported to the sponsor then there must be a follow-up and resolution report to confirm the outcome of the SAE.

Copies of correspondence from Chief Investigator to Sponsor/Regulatory Authority/Authorities reporting SAEs	8.3.16 & 8.3.17	To document that all SAEs have been reported to the appropriate authority
Copy of minutes from Data Monitoring Committee/research team meetings		Monitoring safety is an important part of any study. For CTIMP studies where NuTH FT acts as Research Sponsor, it is a requirement that a Data Monitoring Committee (DMC) is established. For these studies, safety monitoring and review of SAE is a delegated responsibility to the main investigator and discussions should be minuted and recorded for reference. These minutes should be kept in the study file as a record of decisions made.
Notification by Sponsor to Investigators of Safety Information	8.3.18	
Safety Reports	8.3.19	Interim or annual reports provided to REC
9. Pharmacy/Product Related		**All Pharmacy documents may be stored in a separate Pharmacy file.**
Instructions for handling of IMP and trial-related material (if not included in the protocol)	8.2.14	Required for all CTIMPs and ATIMPS to document instructions needed to ensure proper storage, packaging, dispensing and disposal of IMP.
Sample label for IMP	8.2.13	Required for all CTIMPs and ATIMPS to document compliance with labelling regulations (EU Good Manufacturing Practice (GMP) Directive) and appropriate instructions provided to the subject.
Shipping records for IMP	8.2.15 & 8.3.8	Required for all CTIMPs and ATIMPS to document shipment dates, batch numbers and methods of shipment of IMP(s) and trial-related materials and for tracking of product batch, review of the shipping conditions and accountability.
Certificate of analysis of IMP	8.2.16 & 8.3.9	Required for all CTIMPs and ATIMPS to document the identity, purity and strength of any IMP(s) to be used in the trial.
IMP accountability at site	8.3.23 & 8.4.1	and ATIMPS.
IMP destruction record	8.4.2	Required for all CTIMPs and ATIMPS to document the destruction of any unused IMP.

10. Monitoring & Audit		
Record of all monitoring reports	8.2.19, 8.2.20 & 8.3.10	May include the pre-trial report, compiled after the site suitability visit, and a trial initiation report which documents the trial procedures that were reviewed with the investigator and the research team.
Final close-out monitoring report	8.4.5	To document that all study-related activities have been completed and that copies of essential documents are held in appropriate files.
Audit certificate (if applicable)	8.4.4	To document that audit was performed.
Clinical trial report	8.4.7 & 8.4.8	Required to document the results and interpretation of the trial.
11. General Correspondence		
Relevant written correspondence	8.3.11	May include letters, copies of emails, meeting notes & minutes

8.2. Example of Essential Documents to be maintained in a SOF *(these are examples and do not represent a definitive list)*

Title of Document	Further Details
1. Protocol & Consent	
Final, signed research protocol and amended protocols, with version numbers and dates	To document the Chief Investigator and sponsor agreement to the protocol/amendment(s).
Investigator Brochure and updates	To document that relevant and current scientific information about the investigational product has been provided to Investigators.
Example of Informed Consent Form and any amendments, with version numbers and dates	To provide evidence of how informed consent will be documented.
Examples of any other written information given to project/trial participants and any updates (e.g., Participant Information Sheets (PIS) with version numbers and dates	To document that research participants will be given sufficient written information (content and wording) to allow them to give fully informed consent. It should also include any documents that require completion by the participant themselves
Copy of any advertisements for participant recruitment and any amendments	To document that the recruitment measures are appropriate and not coercive.
Copy of any letter/information for a patient's GP or Consultant	
2. HRA	
Final HRA and REC application and any amendments	Signed by Sponsor and Chief Investigator
Favourable opinion letter from REC	To document that the trial has received a favourable ethical opinion and to identify the version number and date(s) of the approved documents. Approvals to any amendments need to be stored alongside originals.
REC reports	For example, annual reports, safety reports, final study report.
3. Finance & Governance	

Copy of financial information relating to the study (funding application/ award letter/costings) if not detailed in a Clinical Trial Agreement.	To document that financial arrangements for the study are in place
Insurance Statement (copy of any certificate/letter/agreement), plus any updates	To document provisions to the participant(s) for any study-related harm they might experience. This includes cover for negligent and non-negligent harm.
Copy of the sponsor agreement/delegation agreement and allocation of responsibilities	To document that a research sponsor has been identified to ensure appropriate arrangements are in place for the initiation, management and financing of the project.
Copy of any signed agreement(s) between involved parties.	To document agreements and responsibilities for the preparation, conduct and closure of the trial.
Additional sites amendment paper work	Any correspondence and forms that relate to decision making processes for amendments and the addition of sites.
Minutes	All relevant minutes from TMGs/DMCs/TSCs and other important catch-up meetings.
4. Regulatory	
Risk Assessments and Continuous Risk Assessments	
Regulatory application forms (if applicable)	e.g. MHRA, NIGB, ARSAC, GTAC
Regulatory approvals (if applicable)	To document that appropriate authorisation has been issued prior to the project commencing

7. Vendors	
Vendor Assessment Forms	Including any documentation sent to Sponsor from Vendor.
Sponsor review forms for Vendor Assessments	Including any audits reports of vendors.
Technical Agreements	Correspondence and final signed versions.
8. Serious Adverse Events	

Sample SAE form and copy of reporting procedures	To document the information required when submitting a SAE and the procedure for reporting a SAE including contact details
Completed SAE forms	Where SAEs have been reported to the sponsor then there must be a follow-up and resolution report to confirm the outcome of the SAE. A file note can be used to cross-reference the location of SAE reports if too numerous to file in the SOF.
Copies of correspondence from Chief Investigator to Sponsor/Regulatory Authority/Authorities reporting SAEs	To document that all SAEs have been reported to the appropriate authority
Copy of minutes from Data Monitoring Committee/research team meetings	Monitoring safety is an important part of any study. For CTIMP studies where NuTH FT acts as Research Sponsor, it is a requirement that a Data Monitoring Committee (DMC) is established. For these studies, safety monitoring and review of SAE is a delegated responsibility to the main investigator and discussions should be minuted and recorded for reference. These minutes should be kept in the study file as a record of decisions made.
Notification by Sponsor to Investigators of Safety Information	
Safety Reports	Interim or annual reports provided to REC
Deviation reports/spreadsheets	A copy of the deviation reports and/or spreadsheets listing deviations
Sponsor review of Deviations	Forms and correspondence of Sponsor review
Serious Breaches	All correspondence and applicable forms for a serious breach.
9. Pharmacy/Product Related	**All Pharmacy documents may be stored in a separate Pharmacy file.**
Relevant Documentation	Pharmacy documentation will remain within the pharmacy team but form part of the SOF
10. Monitoring & Audit	
Record of all monitoring reports	May include the pre-trial report, compiled after the site suitability visit, and a trial initiation report which documents the trial procedures that were reviewed with the investigator and the research team.
Final close-out monitoring report	To document that all study-related activities have been completed and that copies of essential documents are held in appropriate files.

Sponsor Review Documentation	Forms and correspondence of Sponsor review
Audit certificate (if applicable)	To document that audit was performed. And reports where applicable.
Clinical trial report	Required to document the results and interpretation of the trial.
11. General Correspondence	
Relevant written correspondence	May include letters, copies of emails, meeting notes & minutes

8.3. Example TMF Checklist for CTIMPs

Title of Research Project:	
Protocol number (if applicable):	NHS Trust R&D Ref:
EudraCT Ref:	Chief Investigator:
Sponsor:	Funder:
Start date:	Proposed end date:

1. Protocol	
Current research protocol, signed and dated by the Investigator	☐
Superseded version(s) of the protocol	☐
Current participant information sheet & informed consent form, any amendments	☐
Superseded participant information sheet(s) & informed consent form(s)	☐
Examples of any other written information provided to subjects and any updates	☐
Copy of advertisement for participant recruitment and any amendments	☐
Copy of any letter/information for a patient's GP or Consultant	☐
2. Ethics	
Final ethics application and any amendments	☐
Ethics favourable opinion letter(s)	☐
Composition of the main ethics committee that approved the study	☐
Ethics correspondence	☐
Ethics reports	☐
3. Research & Development	
Trust R&D application form and approval letter	☐
Copy of financial information relating to the study if not included in Clinical Trial Agreement (CTAg) - (funding application/award letter/costings)	☐
Insurance statement (copy of a certificate/letter/agreement) and updates	☐
Copy of sponsor agreement and allocation of responsibilities if not included in CTAg	☐
Copy of signed, CTAg or any signed agreement(s) between involved parties	☐
4. Regulatory	
Regulatory application form (and any amendments)	☐
Regulatory approval (and any amendments)	☐
Copy of end of trial notification sent to the MHRA	☐
Copy of any other regulatory applications & approvals (e.g. NIGB, ARSAC)	☐

5. Research Team	
Signed & dated CVs detailing qualifications of CI/research team & GCP training certificates	☐
Delegation of duty log	☐
Signature log	☐
Signed and dated CV and GCP certificate(s) for PI at each research site	☐
6. Participant Information	
Subject screening log (non-identifiable)	☐
Master randomisation list (if appropriate)	☐
Subject ID code list (non-identifiable)	☐
7. Data Collection	
Sample Case Report Form and Completion Guidance	☐
Sample Record for retained body fluids/tissue samples (if any)	☐
Normal laboratory reference ranges (and updates)	☐
Accreditation of all labs used (and updates)	☐
Copies of calibration records for technical equipment	☐
8. Safety	
Unblinding procedure for blinded trials	☐
Copies of broken blinds (at the end of the trial)	☐
Sample AE/SAE/SUSAR forms and copy of reporting procedures	☐
Completed AE/SAE/SUSAR forms (if not included in CRF)	☐
Minutes from DMC or research study meetings	☐
Copies of correspondence from CI to Sponsor/Regulatory Authority(ies) regarding SAE/SUSARs	☐
Notification of safety information to PIs at research sites	☐
Safety reports	☐
Deviation reports/logs	☐
9. Pharmacy/Product-Related	
Investigator Brochure and/or Summary of Product Characteristics plus updates	☐
Certificate of analysis of shipped IMP	☐
Sample labels	☐
Instructions for handling IMP (if not already detailed in IB/SPC)	☐
Green light documentation	☐
Drug delivery/return records	☐
IMP accountability at site	☐
IMP destruction records	☐
10. Monitoring and Audit	
Site initiation report(s) and attendance list	☐
Monitoring plan	☐

Copies of all monitoring reports (including study set-up)	☐
Final close-out monitoring report	☐
Audit certificate	☐
Minutes of Trial Oversight Committee meetings	☐
Clinical trial report	☐
11. Correspondence (except Trust & Ethics)	
General correspondence	☐

8.4. Example TMF Checklist for non-CTIMPs

Title of Research Project:	
Protocol number (if applicable):	NHS Trust R&D Ref:
Chief Investigator:	
Sponsor:	Funder:
Start date:	Proposed end date:

1. Protocol	
Current research protocol, signed and dated by the Investigator	☐
Superseded version(s) of the protocol (can be filed elsewhere if correctly cross-referenced)	☐
Current participant information sheet & informed consent form and any amendments	☐
Superseded participant information sheet(s) & informed consent form(s) (can be filed elsewhere if correctly cross-referenced)screening	☐
Examples of any other written information provided to subjects and any updates	☐
Copy of advertisement for participant recruitment and any amendments	☐
Copy of any letter/information for a patient's GP or Consultant	☐
2. Ethics	
Final ethics application and any amendments	☐
Ethics favourable opinion letter(s)	☐
Composition of the main ethics committee that approved the study	☐
Ethics correspondence	☐
Ethics reports	☐
3. Research & Development	
Trust R&D application form and approval letter	☐
Copy of financial information relating to the study if not included in CTA (funding application/award letter/costings)	☐
Insurance statement (copy of a certificate/letter/agreement) and updates	☐
Copy of sponsor agreement and allocation of responsibilities if not included in CTA	☐
Copy of signed, Clinical Trial Agreement (CTA) or any signed agreement(s) between involved parties	☐
4. Regulatory	
Regulatory application form (and any amendments)	☐
Regulatory approval (and any amendments)	☐

5. Research Team	
Signed & dated CVs detailing qualification of CI/research team and GCP training	☐
Delegation of duty log	☐
6. Participant Information	
Subject screening and enrolment log (appropriate space should be included to show who has conducted the screening/enrolment)	☐
Master randomisation list (if appropriate)	☐
Subject ID code list	☐
7. Data Collection	
Sample Case Report Form and Completion Guidance	☐
Sample Record for retained body fluids/tissue samples (if any)	☐
Normal laboratory reference ranges (and updates)	☐
Accreditation of all labs used (and updates)	☐
Copies of calibration records for technical equipment	☐
8. Safety	
Unblinding procedure for blinded trials	☐
Copies of broken blinds (at the end of the trial)	☐
Sample AE/SAE forms and copy of reporting procedures	☐
Completed AE/SAE forms (if not included in CRF)	☐
Copies of correspondence from CI to Sponsor and/or ethics regarding SAE	☐
9. Monitoring and Audit	
Site initiation visit reports and attendance lists	☐
Copies of all monitoring reports (including study set-up)	☐
Final close-out monitoring report	☐
Audit certificate	☐
Clinical trial report	☐
10. Correspondence (except Trust & Ethics)	
General correspondence	☐