DIRECTORATE OF RESEARCH AND INNOVATION

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Title: Study Documentation and Monitoring, Audit and Inspection	
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	Name	Position
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1. Scope

This SOP is applicable to

- All Great Ormond Street Hospital for Children (GOSH) or UCL Great Ormond Street Institute of Child Health (ICH) research delivery staff working on clinical research. This includes studies where GOSH and UCL are the Sponsor (and where these studies are managed through the Joint R&D Office for GOSH/ICH) or where there is an external Sponsor (hosted studies).

Further to the requirements listed in this SOP, personnel must also comply with:

- Any additional study-specific requirements mandated by the CI, PI, Sponsor or R&I.

2. Purpose

This SOP details the requirements and procedures for study documentation, monitoring, audit and inspection that must be followed during a research study; including:

- Essential Documents (5.1), Trial Master File (5.2) and Source Data (5.3)
- Study Monitoring (5.4), Audit (5.5) and Inspection (5.6)

The study close-out and archiving process is covered in the Archiving SOP 17/GOSH/ICH/SOP/R/004. If essential documents or source data are not managed appropriately, this could affect the safety of the study participants, the credibility of the data and the study results.

3. Definitions/Abbreviations

Audit – A systematic and independent examination of study related activities and documents to determine whether the evaluated activities were conducted, and the data were recorded, analysed and accurately reported according to the protocol, GCP and any applicable legislation, policies, procedures or guidelines.

Certified Copy – A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original.

Clinical Research – As per UK Framework for Health and Social Care Research and HRA/Medical Research Council (MRC) 'Is my study research?' tool.

CRF (Case Report Form) – Form designed to record all of the protocol required information to be reported to the Sponsor on each study participant.

Direct Access – Permission to examine, analyse, verify, and reproduce any records and reports that are important to evaluation of a clinical study. Any party with direct access should take all reasonable precautions within the constraints of the applicable regulatory requirement(s) to maintain the confidentiality of participants' identities and Sponsor's proprietary information.

Essential Documents – Documents that allow the conduct of the study, the integrity of the study data and the compliance of the study with GCP to be evaluated. For definitions of individual essential documents, see section 8.2.

GCP – Good Clinical Practice

Inspection – The act by a regulatory authority(ies) of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the clinical study and that may be located at the study site, at the Sponsor's and/or contract research organization's (CRO's) facilities, or at other establishments deemed appropriate by the regulatory authority(ies).

Monitoring – The act of overseeing the progress of a clinical study, and of ensuring that it is conducted, recorded and reported in accordance with the protocol, written procedures, GCP, and the applicable regulatory and/or ethical requirements.

Source Data – All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical study necessary for the reconstruction and evaluation of the study. Source data are contained in source documents (original records or certified copies) such as medical notes, ECGs, imaging, lab or pharmacy records, participant study files, study diaries or questionnaires.

Trial Master File (TMF) – The TMF is the collection of essential documents for the study. The documentation contained with it should be sufficient to adequately reconstruct the study activities undertaken, along with key decisions made concerning the study. The TMF is normally composed of a Sponsor file, held by the Sponsor organisation, and an Investigator Site File (ISF), held by the investigator. These files together are regarded as comprising the entire TMF for a study. Within this SOP, 'TMF' should be taken to include the ISF unless otherwise stated.

4. Responsibilities

Duties may be delegated but the responsibility always remains with those listed.

4.1 The study Sponsor is responsible for:

- Ensuring the TMF and essential documents are appropriately prepared, maintained and retained. The Sponsor may delegate this to the CI; this is usually applicable to GOSH/ICH sponsored studies.
- Ensuring that the study is adequately monitored.
- Allowing reasonable access to auditors and inspectors and responding in a timely manner to points raised in subsequent reports.

4.2 The auditor/monitor is responsible for:

- Following the designated written procedures and/or any study specific procedures for auditing/monitoring a specific study.
- Reviewing whether the clinical study is being conducted and documented in compliance with the protocol, GCP and any applicable legislation, policies, procedures or guidelines

4.3 The study Principal Investigator (PI) is responsible for:

- Set up, maintenance and appropriate retention of the site section of the TMF (usually called the Investigator Site File (ISF)) with all appropriate documents.
- Allowing reasonable access to monitors, auditors and inspectors and responding in a timely manner to points raised in subsequent reports.
- Ensuring their own and study team compliance with this SOP, the protocol, GCP and any applicable legislation, policies, procedures or guidelines.

4.4 All study staff are responsible for

- Ensuring their practice meets the requirements of this SOP, the protocol, GCP and any applicable legislation, policies, procedures or guidelines.

5. Procedure

5.1 Preparation and Maintenance of Essential Documents

The Sponsor is responsible for the preparation, review, approval, version control, implementation and updating of essential documents.

For studies Sponsored by GOSH and/or ICH, the CI is responsible for drafting the document using the appropriate, current template (see section 6) and ensuring it is appropriately managed (see section 8.1 for flow chart). Essential documents must have documented approval by individuals within the organisation with appropriate authority (see section 8.2 for GOSH/ICH authorisations).

Documents may need to be submitted to research authorities (such as MHRA, HRA and/or Research Ethics Committee), either as part of the initial application or as an amendment, prior to implementation.

The final approved document must be issued to all relevant study staff in a timely manner and filed appropriately in the TMF. A period of time between approval and

implementation may be used to allow for training of relevant personnel if necessary. Training must be documented in the TMF as per SOP/R/002 Training Requirements for Staff Participating in Clinical Research.

Essential documents must be protected from unauthorised access and unauthorised or accidental editing. They must have a version number so that different versions of a particular document can be distinguished from each other. It is recommended that the version number appears on every page and that the document has page numbers.

Essential documents should be reviewed on a periodic basis to check that they still accurately reflect current knowledge and practice. This is a requirement for the Investigator's Brochure (IB) which must be reviewed on an annual basis. Such reviews must be documented even if it was decided no update was necessary.

If the study team prepare documents to facilitate the conduct of the study (e.g. study worksheets) these are also considered essential documents. The Sponsor need to have adequate oversight of the documents – reviewing and approving the documents themselves and/or the methods used to prepare them. The study team must ensure that they inform the Sponsor of any such documents. The process described in section 8.1 should be used to produce these documents.

Care must to be taken to ensure all essential documents are consistent with each other throughout their lifecycle.

5.2 Trial Master File (TMF)

The TMF is the collection of essential documents for the study. It will form the basis of study management and any monitoring, audits or inspections. It is essential that the TMF is suitably maintained and organised throughout the study and retention period to facilitate:

- easy reference and effective study management by the study team
- monitoring, audits or inspection by those unfamiliar with the study

The TMF must be established at the beginning of the study. The Sponsor will usually provide an index for the TMF layout (including the ISF) and the documents contained (see section 6 for GOSH/ICH indexes to be used when GOSH/ICH are Sponsor or if indexes are not provided by the Sponsor).

The PI/site have control of all essential documents and records generated by the site before, during, and after the study.

The PI must ensure that their section of the TMF is actively maintained in an on-going fashion until the study is formally closed and final report is submitted. All the documents must be filed logically and consistently (usually chronologically with the most recent at the top) to enable easy use. Filing essential documents in a timely manner can greatly assist in the successful management of a study and ensure the study is always inspection ready.

The documentation in the TMF must be accurate, legible, contemporaneous (done at the time), original (or certified copy), attributable, complete, consistent, enduring and accessible. The TMF must be securely stored (protected from fire, theft, flood and pests) with access restricted to only authorised personnel.

Where appropriate, documents in the TMF must be signed and dated (signatures are recommended only where it adds value or is a GCP requirement).

The documentation in the TMF must allow for the full historical reconstruction of the study without additional explanation from the people involved. As part of this, any alterations to documents will need to be traceable and all versions of the document used throughout the lifecycle of the study must be kept in the TMF. Past-versions of documents must be clearly marked as superseded (including the name of person superseding, the superseded date and what they were superseded by) to prevent them being inadvertently used. Version trackers may help with document management.

Correspondence (including emails) may also be considered essential documents. Relevant correspondence that are necessary for reconstruction of key activities and/or decisions, or that contain other significant information must be retained. This includes attachments (unless filed elsewhere) and 'sent' as well as 'received'. There is often a section within the TMF to file correspondence but it may be more helpful for reconstruction to keep the correspondence with the information it refers to (e.g. email about a safety report is with the report and not in 'Correspondence').

Some essential documents may only be stored in an electronic format. The media used to store documents needs to be such that they remain complete, legible and suitably accessible (including for monitoring, audit or inspection) throughout the study and required retention period.

If study documents are held separately to the TMF (e.g. information is held on an electronic system, in a different location such as pharmacy, labs or imaging, or in a central location if the information is not study-specific), a file note must be filed in the TMF that clearly states the location. File note templates are available (see section 6).

Duplication of documents within the TMF must be avoided where possible, as this can hinder the effective use of TMF.

When organising the TMF it is essential to segregate those documents that are generated or held by the Sponsor from those generated of held by the PI, as some documentation held by the PI must not be provided to the Sponsor due to:

- Participant confidentiality – No participant information should leave the site unless this is specifically covered by the consent. This is particularly the case for identifiable participant information (e.g. Sponsor must not have signed consent forms or participant identification lists unless covered by consent).

  Even if the document is redacted to remove identifiable data, it should only be shared if absolutely necessary and there is no suitable alternative. There must be a robust quality control check of the redaction (preferably by someone other than the person who did the redaction) to ensure it is complete.

- Data independence – Source data and/or the site's independent copy of the study data must remain under the control of the PI. Providing these to the Sponsor would risk the data integrity of the study (as the Sponsor could make uncontrolled/unauthorised edits to the site's documentation). The study team must not send source data to the Sponsor/CRO for them to complete study data collection (e.g. CRF completion) – data entry must be done by the site.

- Reducing avoidable duplication within the TMF by having documents filed unnecessarily in both the site and Sponsor sections of the TMF.

This clear segregation would be expected in all situations apart from those where the Sponsor and Investigator site are essentially the same.

Where study functions are delegated to a vendor(s); the vendor agreement must include the management of the essential documents generated and/or used by the vendor before, during and after the study.

5.3 Source Data

The Sponsor and study site should maintain a record of the definitions and location(s) of the source data (e.g. in protocol or a source data agreement).

Source data must be accurate, legible, contemporaneous (done at the time), original (or certified copy), attributable, complete, consistent, enduring and accessible to authorised personnel.

Changes to source data must be traceable, attributable, must not obscure the original entry, and must be explained if necessary (e.g., via an audit trail or neatly crossing through the original, writing the correction and explanation if necessary, and signing and dating).

If a study uses study-specific source worksheets to facilitate the recording of study information, these are to be retained within the clinical notes. The study team must ensure they avoid recording the same source data in multiple locations.

Study data reported on to the Sponsor that are derived from source data must be consistent with the source (or the discrepancies must be explained).

Where a vendor(s) will be recording source data; the vendor agreement must include the management of the source data generated by the vendor before, during and after the study.

5.4 Monitoring

Monitoring is one of the key mechanisms whereby the Sponsor can be assured that a research study is in compliance with the applicable requirements. The general approach to monitoring must form part of the protocol although the detail can be in the form of written procedures and/or monitoring plans. The specific approach to monitoring for a study can be determined following a risk assessment, ensuring that the approach is proportionate and directed to critical areas.

5.4.1 Monitoring Strategy

Monitoring may consist of on-site visits, central (or remote) monitoring or a hybrid of the two. The Sponsor is responsible for producing a documented, risk-based, monitoring plan for the study (see section 6 for GOSH/ICH template). Monitoring information is required by the site as part of the assessment of capability, capacity, and costing. The plan may be adaptive and/or may be adjusted during the study (e.g. in response to new risks).

Suggested monitoring activities can be found in the MHRA Grey Guide (chapter 7) and ICH GCP (ICH E6). Monitoring will often include source

data verification (SDV) – checking the accuracy and completeness of the CRF against source documents. The monitoring plan should specify the level of SDV required (i.e. percentage of participants/percentage of data).

Where R&D are responsible for the study monitoring, the monitors must use a monitoring tracker to schedule and record monitoring activity.

Data Monitoring Committees and/or Trial Steering Committees may also be part of the monitoring strategy (guidance can be found on HRA website).

5.4.2 Monitors

Monitors must be suitably trained, qualified and experienced to perform their role.

Monitors from external Sponsors will not require honorary contracts with the Trust or to complete additional Trust training as long as there is an arrangement with the Sponsor for this activity (e.g. clinical trial agreement).

5.4.3 Monitoring and Monitoring Documentation

Monitoring visits should be arranged based on the monitoring plan and be organised sufficiently in advance to allow the study team to prepare and make sure the necessary staff and documents are available (It may not be possible to accommodate visit requests with less than 2 weeks notice).

The PI/study team must allow the monitor reasonable access.

Monitors should complete the visit as per the monitoring plan as well as paying particular attention to the previous monitoring report to ensure that all points raised have been resolved. Monitors may wish to use a checklist based on the monitoring plan (see section 6 for GOSH/ICH template).

Monitors must not make changes to the study documentation.

Monitors may want to collect copies of documents. Monitors may only collect documents that have been agreed in the study contract or that have subsequently been agreed by the R&I QA Manager or the Head of Governance, Clinical Trials and Contracts (see section 8.3). This should be discussed at site selection. If the study team aren't sure why a document is being requested by a monitor, they must ask. For monitors performing visits at GOSH, the monitoring/audit checklist (FRM/R/001) must be used to ensure that there is site oversight and control of the documentation that monitors review and collect.

Any emails sent to monitors must follow the Trust Email Use Policy.

The monitor will provide a written output of the visit detailing what was done, verification that the monitoring plan and escalation procedures were followed, and listing any findings or actions that are required. Ideally this should be sent within 2 weeks of the visit. The study team must review the report to ensure that it accurately represents the visit and ensure that any issues or queries raised in the report are resolved in a timely manner. Any questions or concerns must be raised with the monitor as soon as possible.

If a monitor identifies any serious deviations and/or evidence of fraud or misconduct, the study team must ensure these are reported as per SOP/R/005 Reporting and Escalation for Research.

5.5 Audit

Audits are a way for the Sponsor or site to be assured that the research is in compliance with the applicable requirements. Audits are independent of and separate from routine monitoring or quality control functions. They may be organised by the Sponsor (as part of Sponsor oversight) or by the R&D office (as part of organisational oversight). They may either be systems based (where auditors will select a number of studies to examine the systems used and how they are applied) or study specific. Audits may look at study processes in full or may focus on a particular area (such as consent, or delegation and training). Audits may be of a Sponsor, site or vendor (e.g. CRO or archiving facility).

5.5.1 Audit Strategy

The auditor(s) is responsible for producing a documented audit plan (see section 6 for GOSH/ICH template).

The R&D Office and study Sponsors will conduct routine audits periodically under a risk-based compliance programme. The R&D Office have an audit schedule and record their audit activity – a proportion of studies (minimum 10%) will be routinely audited. R&D use an audit risk assessment tool to assess the level of risk and establish the studies to be audited. Audits may also be triggered if the R&D Office/Sponsor has a concern. In rare circumstances, little or no notice may be given to the study team of these audits.

5.5.2 Auditors

Auditors must be suitably trained, qualified and experienced to perform their role. Auditors should also be independent of the study/systems.

Auditors from external Sponsors will not require honorary contracts with the Trust or to complete additional Trust training as long as there is an arrangement with the Sponsor for this activity (e.g. clinical trial agreement).

5.5.3 Audit and Audit Documentation

Routine audits should be organised sufficiently in advance to allow the study team to prepare and make sure the necessary staff and documents are available. The PI(s) will be notified by the audit team of the intention to audit in writing (for template email see 6 Related Documents). The study teams should be provided with the audit plan (this should be requested from the auditor(s) if not provided).

The PI/study team must allow the auditor reasonable access.

Auditors should complete the audit as per the plan. They may wish to use a checklist based on the audit plan (see section 6 for GOSH/ICH template).

The audit may include interviews with relevant people, a review of the

documentation, such as the TMF, as well as a visit of key facilities (such as pharmacy, labs, clinical areas, archives).

Auditors must not make changes to the study documentation.

For auditors performing audits at GOSH, the monitoring/audit checklist (FRM/R/001) must be used to ensure that there is site oversight of the documentation that auditors review and collect.

At the end of the audit, the study team(s) should be given a verbal summary followed by a written report detailing any findings. Ideally this should be sent within 2 weeks of the audit. Critical findings (where evidence exists that significant and unjustified departure from applicable requirements has occurred) must be escalated to Deputy Director of R&I R&D office (Research.Governance@gosh.nhs.uk) and R&I QA Manager immediately.

The study team(s) must respond to the report in the form of a corrective action and preventative action (CAPA) plan. The CAPAs may be suggested by the auditor (particularly for critical findings). This response must be sent in a timely manner (usually within a maximum of 2-4 weeks depending on the findings). Any questions or concerns should be raised with the auditor as soon as possible. The CAPA plan must be reviewed and followed up by the study team until all actions have been closed.

If an auditor identifies any serious deviations and/or evidence of fraud or misconduct, the study team must ensure these are reported as per SOP/R/005 Reporting and Escalation for Research.

If you are notified of an external audit, you must inform the R&D office (Research.Governance@gosh.nhs.uk) and R&I QA Manager immediately.

To preserve the independence and value of the audit function, the regulatory authority(ies) should not routinely request the audit reports. Regulatory authority(ies) may seek access to an audit report on a case by case basis when evidence of serious GCP non-compliance exists, or in the course of legal proceedings.

5.6 Inspection

Inspections are a way for regulators to be assured that the research is in compliance with the applicable requirements. Inspections are similar to audits but are carried out by regulatory authorities (such as the UK regulator the MHRA or the USA regulator the FDA). They generally only apply to Clinical Trials of Investigational Medicinal Products (CTIMPs). Inspections are either systems based (where inspectors will select a number of clinical trials to examine the systems used and how they are applied) or study specific.

Routine inspections are conducted periodically under a risk-based compliance programme. The organisation will be notified in advance and will be provided with an inspection plan. Inspections may also be triggered if the regulatory authority suspects that the law has been broken. In rare circumstances, little or no notice may be given of these inspections.

The inspection may include interviews with relevant people, a review of the documentation, such as the TMF, as well as a visit of key facilities (such as pharmacy, labs, clinical areas, archives).

At the end of the inspection the organisation will be given a verbal summary followed by a written report detailing any findings. The organisation must respond to the report in the form of a corrective action and preventative action (CAPA) plan. Critical findings (where evidence exists that significant and unjustified departure from applicable legislative requirements has occurred) could result in the requirement for quarterly reporting to the authority, early re-inspection, referral to relevant stakeholders (e.g. GMC, CQC), suspension of clinical trials, a public infringement notice or prosecution.

If an inspector identifies any serious deviations and/or evidence of fraud or misconduct, these must be reported as per SOP/R/005 Reporting and Escalation for Research.

If you are notified of an inspection, you must inform the R&D office (Research.Governance@gosh.nhs.uk) and R&I QA Manager immediately.

5.7 Support and Escalation

If a staff member has questions or queries they can ask for support from a more experienced colleague or their line manager. If the query is related to a specific study, then the study research nurse, PI and/or CRA may also be able to help. If staff (or monitors) have a question regarding the documentation or monitoring process then they can contact the R&I QA Manager or the Head of Governance, Clinical Trials and Contracts.

If a staff member becomes aware of an issue or has any concerns then this must be escalated to the appropriate person(s) in a timely manner (see SOP/R/005 Reporting and Escalation for Research).

5.8 Compliance

Essential documents will be reviewed during the Sponsor assessment of the initial application or subsequent amendments.

TMFs, source data and essential documents will be reviewed during routine monitoring/audit. Monitoring will be reviewed during routine audit.

Systematic or persistent failure to comply with the study procedures and/or this SOP will be seen as non-compliance to GCP and must be bought to the attention of the Head of Governance, Clinical Trials and Contracts who will decide the appropriate action.

6. Related Documents

- GOSH/ICH/TMP/R/005: File note template. File note templates are also available for essential documents that are routinely held outside of the TMF at GOSH, see GOSH/ICH/TMP/R/005x (where ‘x’ is a different letter for each template)
- SOP/R/005: Reporting and Escalation for Research
- SOP/R/002 Training Requirements for Staff Participating in Clinical Research

- SOP/R/003 CSV for Systems used in Research
- Archiving
- FRM/R/001 – Monitoring/Audit Checklist
- TMF index – For GOSH/ICH Sponsored studies
- ISF index – For GOSH/ICH Sponsored studies
- Protocol template – For GOSH/ICH Sponsored studies
- PIS and Informed Consent Form Template – For GOSH/ICH Sponsored studies
- CRF template – For GOSH/ICH Sponsored studies
- Screening log template – For GOSH/ICH Sponsored studies (unless EPIC is used)
- Enrolment log template – For GOSH/ICH Sponsored studies (unless EPIC is used)
- Monitoring plan template – For GOSH/ICH Sponsored studies
- Monitoring report template – For GOSH/ICH Sponsored studies
- Monitoring log template – For GOSH/ICH Sponsored studies
- Audit risk assessment tool – For GOSH/ICH Sponsored and hosted studies
- Audit notification template email – For GOSH/ICH Sponsored and hosted studies
- Audit plan template – For GOSH/ICH Sponsored studies
- Audit report template – For GOSH/ICH Sponsored studies
- CAPA plan template
- Trust Email Use Policy
- Correspondence with MHRA RE essential documents

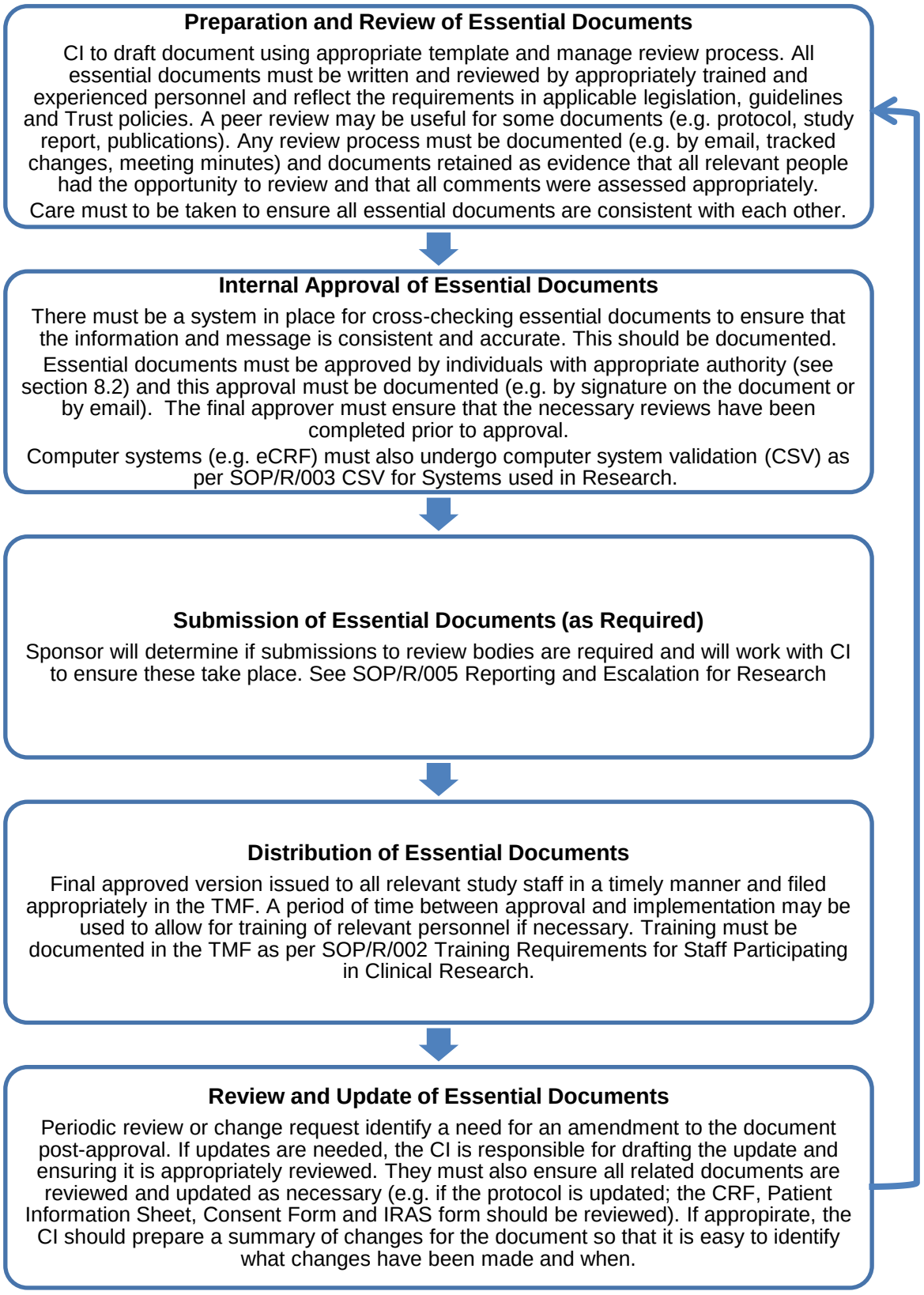
7. References

- UK policy framework for health and social care research
- ICH Harmonised Guideline - Guideline For Good Clinical Practice E6(R2)
- MHRA Good Clinical Practice Guide (Grey Guide) – Chapters 4, 7, 10, 11
- MHRA website
- FDA Guidance on financial disclosures (2013) and FAQs on Form FDA 1572 (2010)

8. Appendices

- Appendix 1 – Preparation and Maintenance of GOSH/ICH Essential Documents
- Appendix 2 – Essential Documents: Definitions and Authorisation for GOSH/ICH Sponsored Studies
- Appendix 3 – Providing Copies of Documents to Monitors

8.1 Appendix 1 – Preparation and Maintenance of GOSH/ICH Essential Documents



8.2 Appendix 2 – Essential Documents: Definitions and Authorisation for GOSH/ICH Sponsored Studies

This list is not-exhaustive.

Essential Documents	Definition/Purpose	Authorisation for GOSH/ICH Sponsored Studies
Protocol	A document that describes the objective(s), design, methodology, statistical considerations, and organization of a study. The protocol usually also gives the background and rationale for the study, but these could be provided in other protocol referenced documents.	Sponsor representative (e.g. R&D Governance Lead/Clinical Trials Manager)
CRF – Case Report Form	A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the Sponsor on each study participant. Must be fit to collect the data required to meet objectives of the study.	Sponsor representative (e.g. R&D Governance Lead/Clinical Trials Manager) An Electronic CRF (eCRF) must have be validated as per SOP/R/003.
Investigator's Brochure (IB)	A compilation of the clinical and nonclinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human participants.	Sponsor representative (e.g. Clinical Trials Manager)
Investigational Medicinal Product Dossier (IMPD)	Summaries of the quality, manufacture, and control of the IMP(s) and data from non-clinical and clinical studies.	Sponsor representative (e.g. Clinical Trials Manager)
Patient Information Sheet (PIS) and Informed Consent Form (ICF)	Clearly describes what the potential participant should expect if they agreed to participate in the study. ICF documents the consent in writing.	Sponsor representative (e.g. R&D Governance Lead/Clinical Trials Manager/Clinical Trials Coordinator)
Clinical Study Report (CSR)	A written description of a study where the clinical and statistical description, presentations, and analyses are fully integrated into a single report.	Sponsor representative (e.g. R&D Governance Lead/Clinical Trials Manager)
Monitoring or Audit Plan	A written plan detailing the monitoring/audit activities and how these are to be done, including the adaptive and escalation aspects	Head of Governance, Clinical Trials and Contracts
Monitoring or Audit Report	Report describing the monitoring/audit visit and listing any findings.	Head of Governance, Clinical Trials and Contracts

8.3 Appendix 3 – Providing Copies of Documents Externally

Document Type	Comment (based on ICH E6 and discussion with MHRA)
Contains participant information (e.g. medical notes, consent form, enrolment log/key)	The study team must only provide routinely if this is covered by the consent (i.e. as per the PIS and/or ICF). If there is consent, the records must be sent directly via a secure pathway such as secure email (e.g. redacted ECGs for central rating should be sent directly to the central rater and not via the monitor). Records containing information that the participant has not specifically consented to provide must only be shared: • in exceptional circumstances and only if absolutely necessary (e.g. as part of a safety or deviation report), **and** • there is no suitable alternative, **and** • the information is suitably redacted to remove identifiable data (there must be a robust quality control check of the redaction, preferably by someone other than the person who did the redaction, to ensure it is complete). **Rationale:** To protect participant confidentiality.
Signature Log	The study team should only provide if the Sponsor uses paper based reporting/back-up systems (such as safety reports or CRFs) where signature attribution/verification is necessary. **Rationale:** To reduce unnecessary duplication.
Delegation Log	The study team should only provide if combined with the signature log and the signature log is provided (see above). **Rationale:** Site specific so only required to be held by the site.
Training Log, Certificates (such as GCP or IATA) and CVs	The study team should only provide the training log if it is for (or includes) the PI or Sub-Investigators (Sub-I) or records training that has been delivered by the Sponsor. The study team should only provide the certificates and CVs for the PI or Sub-I(s) – not for other study team members. **Rationale:** The Sponsor should have a copy of records for the study team they have delegated tasks to (i.e. PI or Sub-I(s)) or that documents tasks the Sponsor has done. Other records are site specific and are only required be held by the site.
CRF	Originals usually filed in the Sponsor TMF and copies retained in the Investigator section of the TMF. The site must retain a legible, independent copy of the CRF. When CRFs are sent to the Sponsor, this should be tracked. **Rationale:** To protect data integrity.
Source Data (e.g. medical notes, study diary/questionnaire)	Should not be provided – particularly must not be provided for Sponsor/CRO to complete CRF (this must be done by the site). **Rationale:** To protect data integrity.
Other Site Logs or Records	(E.g. Temperature or deviation logs, or calibration records for site equipment). Should not usually be provided. **Rationale:** Site specific so only required to be held by the site.

Exceptions:

- Study teams should provide documents as have been agreed in the study contract.
- Documents may be provides ad hoc if supporting a communication to the Sponsor (e.g. temperature records provided as part of temperature deviation report, or training log provided as proof of amendment training in order for Sponsor to give 'green light').
- Documents that show the Sponsor's and/or CRO's work.
- Documents that have been agreed by the R&I QA Manager/Head of Governance, Clinical Trials and Contracts (requests generally responded to within 3 working days).