The following slides are a template to be used for Site Initiation Visit presentations. They can be edited or rearranged to suit your specific study.

Please fill in all [red marked] sections with your study specific details

Please **remove this slide** before SIV presentation

SOP 410 App4 SIV slides
Author: Poppy Howard
Approved by: Julie Dawson/Sarah Ruthven
Available via Trust Docs v1

Author title: Clinical Trial Monitor
Date approved: 25/09/2024 Review date 25/09/2027
Trust Docs ID: 23576

Site Initiation Visit

[Study Title]

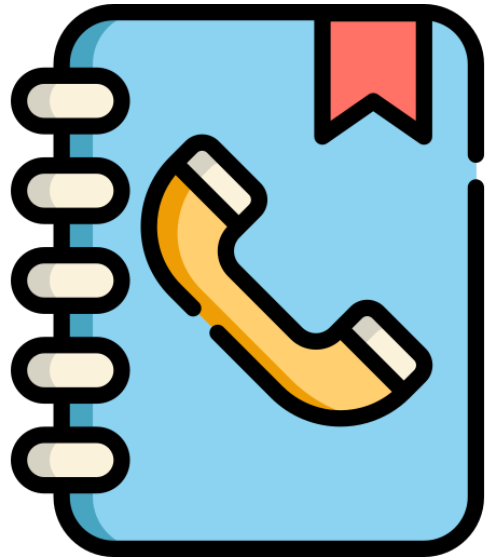
Chief Investigator: [Name of Chief Investigator]
Trial Manager: [Name of Trial Manager/Study Coordinator]
Date of SIV: [SIV date]

Agenda [edit or rearrange for your study]

- Key contacts
- Trial overview
- Trial background
- Outcomes
- Study documentation
- Amendments
- Participant screening
- Informed consent
- Randomisation
- Visit schedule
- Study assessments
- Source data & CRF completion
- IMP information
- Concomitant medication
- Safety reporting
- Monitoring & audit
- Reports & end of trial
- Archiving

Key contacts

- [Trial key contacts]
- [E.g., CI/PI, Research Nurses, Trial Manager]



Trial Overview

Insert trial logo

- [Trial overview details]
- [E.g., interventions, follow-up times, number of sites, target recruitment and date]

Trial Background

Insert trial logo

- [Trial background]
- [E.g., details of condition/disease, previous relevant studies, rationale for study]

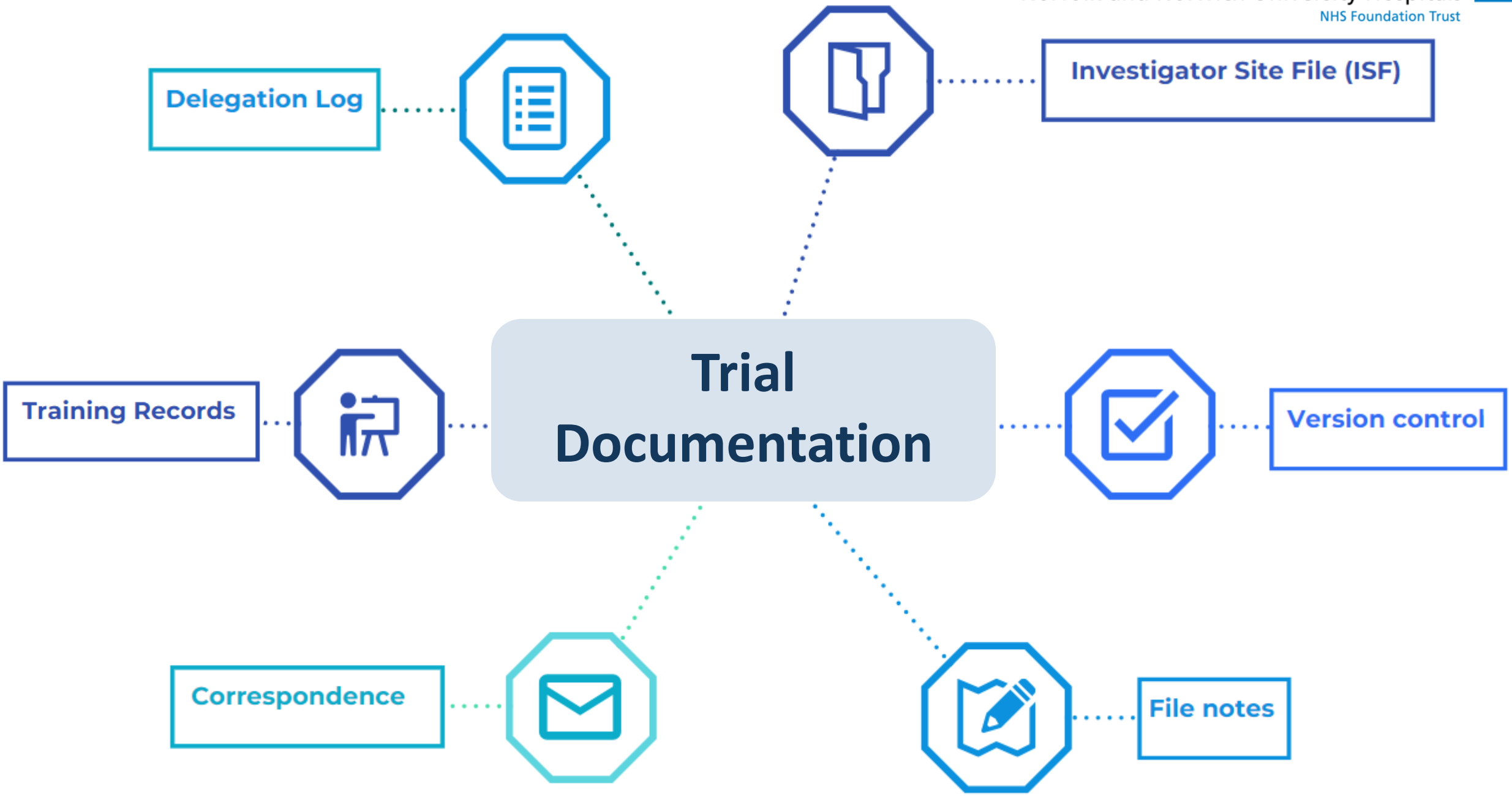
Trial Outcomes

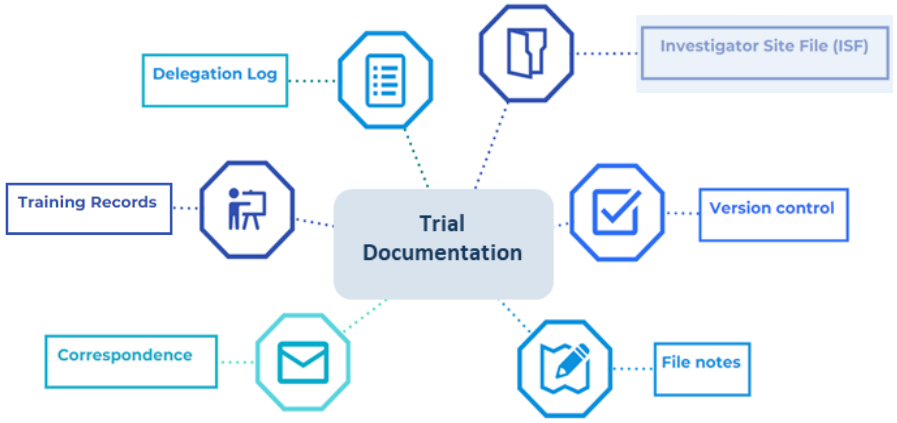
Primary Outcome

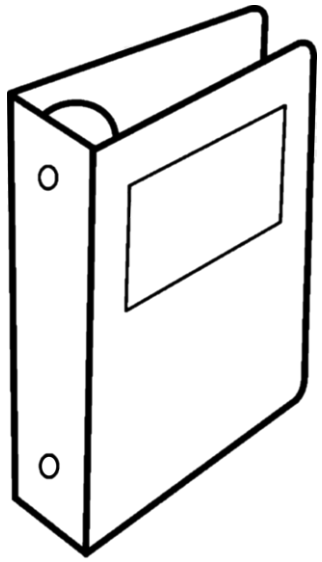
[trial primary outcome]

Secondary Outcomes

[trial secondary outcomes]

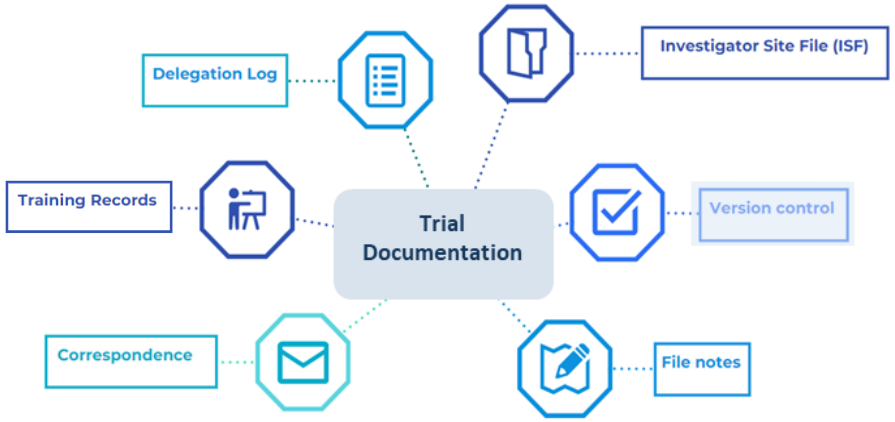

Delegation Log
Investigator Site File (ISF)
Training Records
Trial Documentation
Version control
Correspondence
File notes

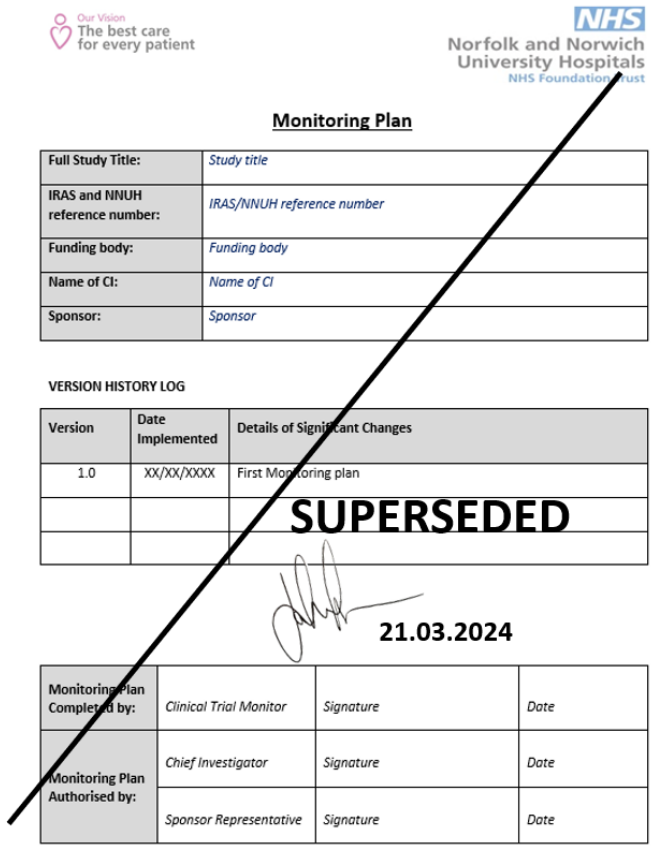




Investigator Site File (ISF)

- The ISF will be maintained by the CI/PI or delegated study team member and will reside with the study team
- May contain participant information such as completed consent forms, questionnaires and diaries
- Must be kept securely as per trust policy and regulatory guidelines
- Filing in the ISF should be done in reverse chronological order





Our Vision
The best care for every patient

NHS
Norfolk and Norwich University Hospitals
NHS Foundation Trust

Monitoring Plan

Full Study Title:	*Study title*
IRAS and NNUH reference number:	*IRAS/NNUH reference number*
Funding body:	*Funding body*
Name of CI:	*Name of CI*
Sponsor:	*Sponsor*

VERSION HISTORY LOG

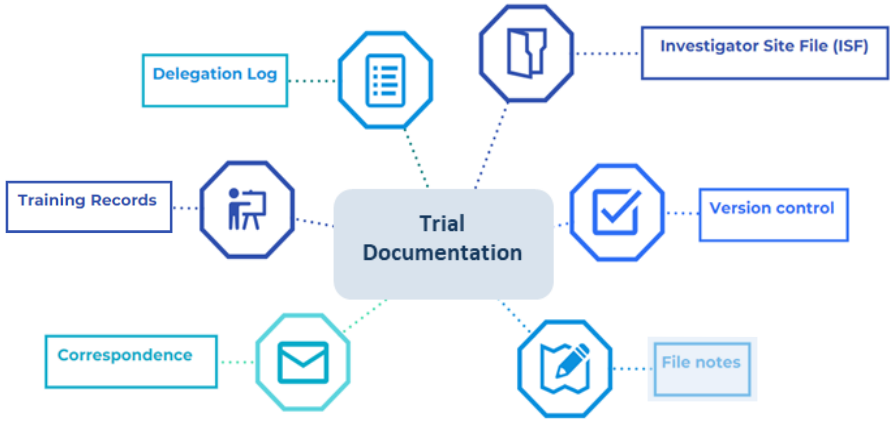
Version	Date Implemented	Details of Significant Changes
1.0	XX/XX/XXXX	First Monitoring plan
		SUPERSEDED

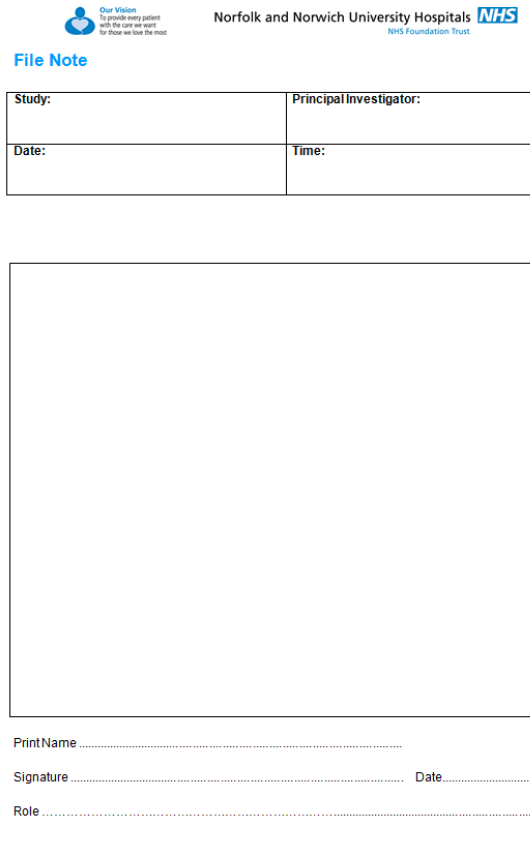
21.03.2024

Monitoring Plan Completed by:	*Clinical Trial Monitor*	*Signature*	*Date*
Monitoring Plan Authorised by:	*Chief Investigator*	*Signature*	*Date*
	Sponsor Representative	*Signature*	*Date*

Version control

- Only approved (REC, MHRA, HRA and R&D) documents should be used
- Documents should contain a version number, date and page number
- Superseded documents should be filed in the ISF and labelled as superseded, struck through, signed and dated
- This ensures the correct version of the document is being used





Our Vision To provide every patient with the care we want for those we love the most

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

File Note

Study:	Principal Investigator:
Date:	Time:

Print Name .....

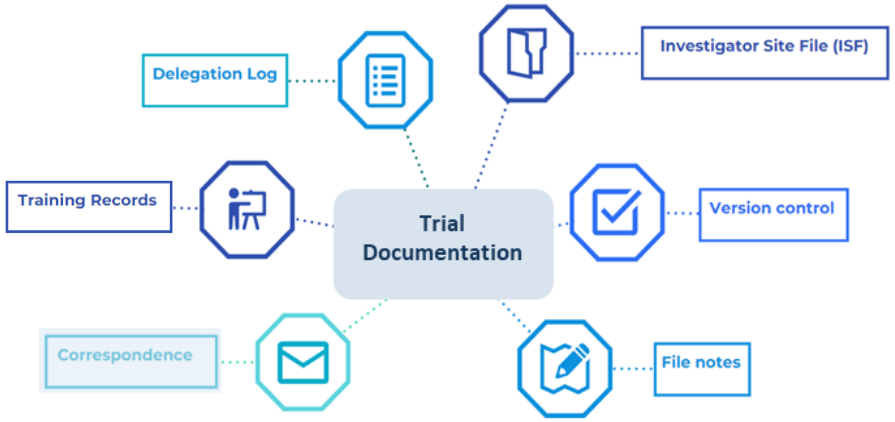
Signature ..... Date .....

Role .....

1

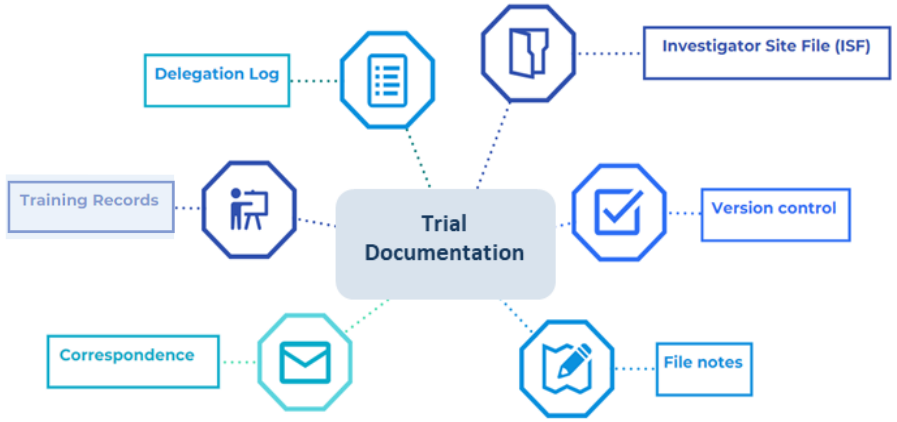
File notes

- File notes can be used to:
  - Record discrepancies that may occur to clarify any issues
  - Identify the location of a document not stored in the site file/case report form
  - Record conversations
- File notes can be added to the site file retrospectively
- It is the PI's responsibility to ensure file notes are recorded accurately. It is good practice to maintain a log of file notes in the ISF



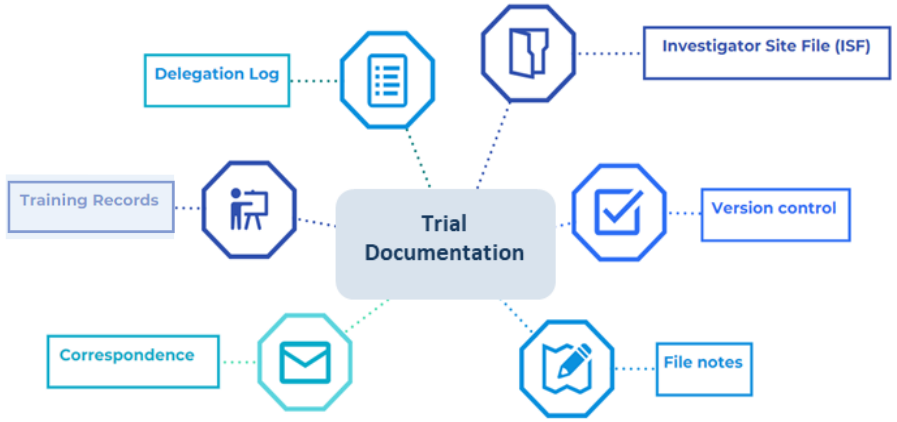
Correspondence

- The study team should file correspondence between the sponsor, study team and other sites that are relevant to the trial
- Records of meeting discussions (e.g., minutes) can be kept in the ISF
- Documents containing patient identifiable information should be stored separately from anonymised data (typically in a separate folder, with a note in the ISF indicating their location)



Training records

- Each individual involved in the study must be qualified by education, training and experience to perform the tasks they have been delegated
- Documentation must be maintained and retained for all staff involved, to demonstrate training has occurred
- For more information see:
  - SOP 002: Good Clinical Practice
  - SOP 505: Training Requirements and creating and maintaining training records



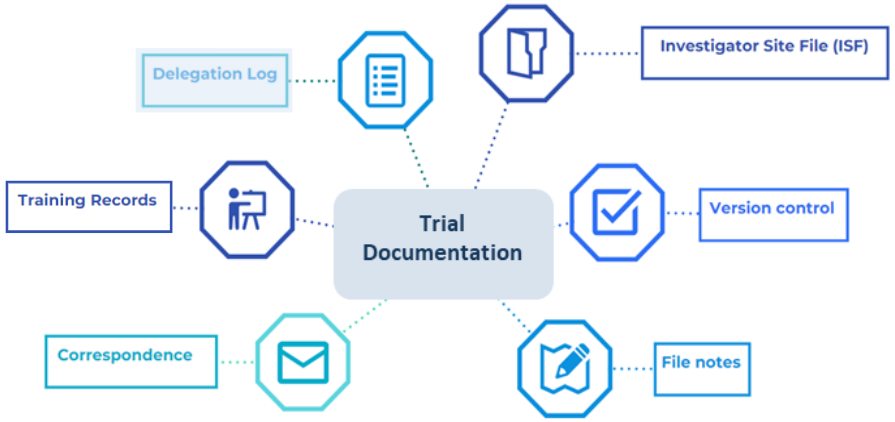
EXAMPLE Study Training Log

It is the responsibility of the site Principal Investigator to confirm staff at their site are appropriately trained by education, experience and training to perform their role in line with Good Clinical Practice.

Name	Date Protocol Training Completed	Signature	Date

Training records

- For each member of the research team you will need to collect:
  - Good Clinical Practice training certificate from within the last 3 years
  - CV (signed and dated by the individual)
  - Any other study specific documentation
- Training documents should be filed in the Trial Master File and updated as required
- All staff must be trained on the study protocol, and this must be documented (e.g., via a Training Log)



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NHS Foundation Trust
Joint Arrangements for Research

Appendix 2: Example of Study Delegation log

Study Title			R&D Reference				
Principle Investigator			Site				
Name	Responsibilities (See Key below)	Initials (as used in clinical or patient notes)	Signature	Start Date	Date of signature	Date and Signature of PI	Date of leaving

Key	*To be adapted to suit the study*	5	Checking eligibility criteria	10	Taking bloods
1	Screening subjects for eligibility	6	Data collection and entry	11	Sample transport
2	Taking informed consent	7	Reporting SAEs	12	Performing study training
3	Maintaining regulatory documentation	8	Source document entries (Medical notes)	13	Other: Specify
4	Patient enrolment and follow-up	9	Data validation	14	Other specify

Delegation Log

- A list of appropriately qualified personnel to whom the investigator has delegated trial related duties
- This must be kept up to date as members of staff join and leave the research team
- The PI is required to sign off each person listed on the delegation log

Amendments

Substantial amendment

Changes to the application, protocol or study document that significantly affects:

- The safety, physical or mental integrity of trial subjects
- Conduct or management of the trial
- Scientific value of the trial
- Quality of safety of any IMP/device used in the trial

Non-substantial amendment

Any change that does not fit the criteria for a substantial amendment

All amendments must be submitted to R&D and signed off by Sponsor Representative.
Substantial amendments must be submitted to the relevant regulatory bodies.

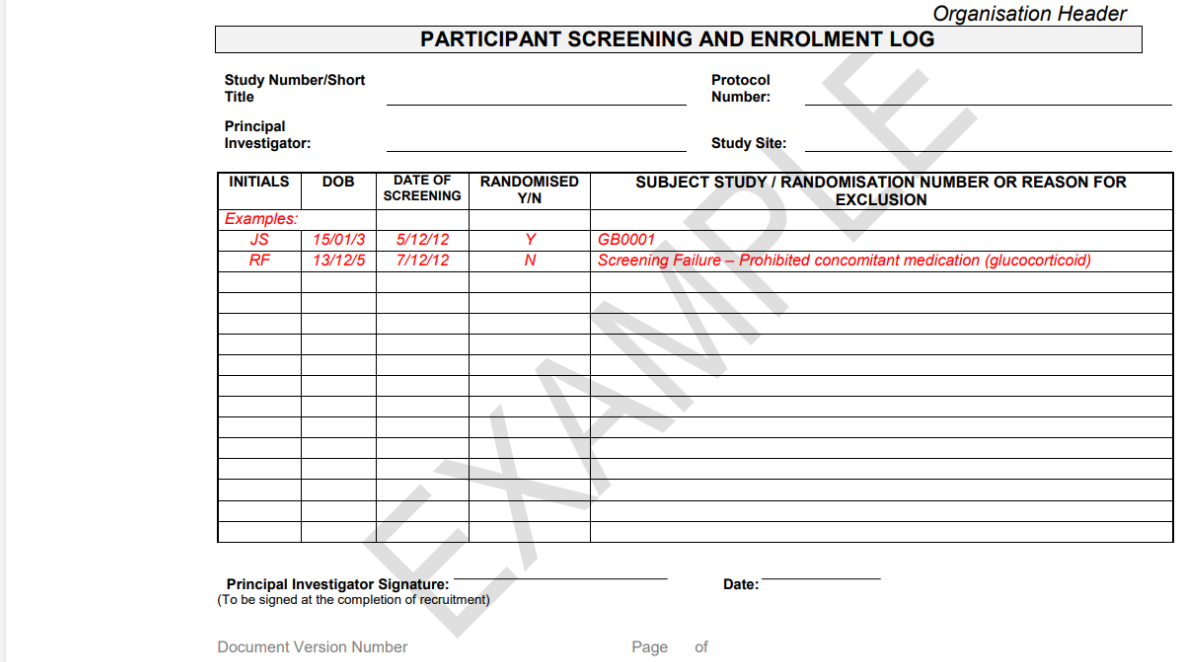
Participant Screening

Screening flow chart

- [Inclusion criteria]
- [Exclusion criteria]
- [Participant screening information]

Screening Log

- A Screening Log should be used to track all patients that are seen
- Patients that provide informed consent and are randomised/enrolled into the trial can be assigned a study/randomisation number, which should be recorded here
- Alternatively, reasons for exclusion should be recorded if patients do not meet eligibility criteria



Organisation Header

PARTICIPANT SCREENING AND ENROLMENT LOG

Study Number/Short Title _____ **Protocol Number:** _____

Principal Investigator: _____ **Study Site:** _____

INITIALS	DOB	DATE OF SCREENING	RANDOMISED Y/N	SUBJECT STUDY / RANDOMISATION NUMBER OR REASON FOR EXCLUSION
Examples:				
JS	*15/01/3*	*5/12/12*	*Y*	*GB0001*
RF	*13/12/5*	*7/12/12*	*N*	*Screening Failure – Prohibited concomitant medication (glucocorticoid)*

Principal Investigator Signature: _____ **Date:** _____
(To be signed at the completion of recruitment)

Document Version Number Page of

EXAMPLE

Informed consent

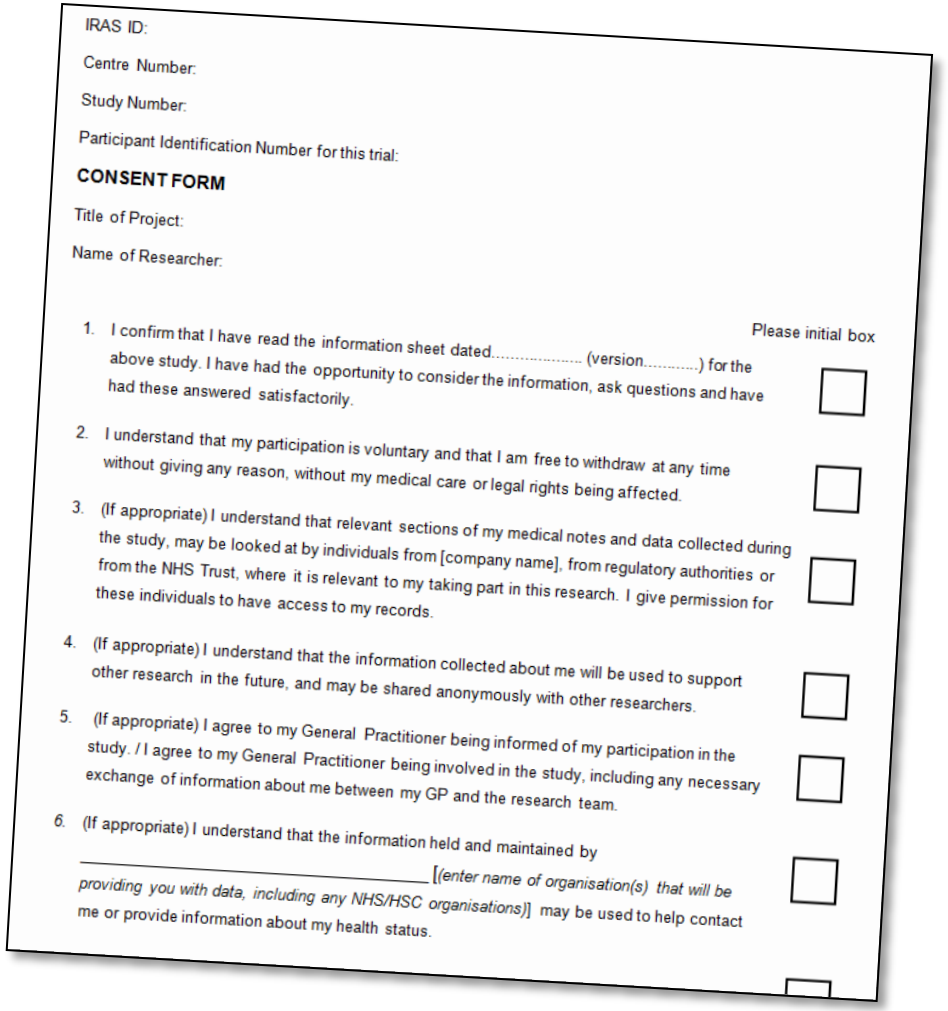
- ‘Informed consent’ requires patients to have sufficient information and understanding before making a decision about trial participation
- Only trained staff can obtain informed consent (investigators or staff named on the Delegation Log)
- Informed consent is an ongoing process: it must be reaffirmed on each study visit

Must be confident that the participant:

- Has been informed about a condition or given a diagnosis of the condition to be investigated
- Fully understands what they are agreeing to
- Is aware they may receive a control intervention rather than active treatment
- Understands the implications of any decisions that may be made during the research

Informed consent

- Completed consent forms must be retained
- Template consent forms and patient information sheets can be found at https://www.hra-decisiontools.org.uk/consent/examples.html
- **SOP 310** – Development of Participant Information Sheet and Informed Consent Form
- [Include any study-specific consent information]



IRAS ID:

Centre Number:

Study Number:

Participant Identification Number for this trial:

CONSENT FORM

Title of Project:

Name of Researcher:

Please initial box

1. I confirm that I have read the information sheet dated..... (version.....) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐
3. (If appropriate) I understand that relevant sections of my medical notes and data collected during the study, may be looked at by individuals from [company name], from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. (If appropriate) I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers. ☐
5. (If appropriate) I agree to my General Practitioner being informed of my participation in the study. / I agree to my General Practitioner being involved in the study, including any necessary exchange of information about me between my GP and the research team. ☐
6. (If appropriate) I understand that the information held and maintained by _____ *[(enter name of organisation(s) that will be providing you with data, including any NHS/HSC organisations)]* may be used to help contact me or provide information about my health status. ☐

Randomisation

- [Study specific randomisation information – e.g., pre-randomisation baselines, when to randomise, who to inform, post-randomisation process]

Visit Schedule

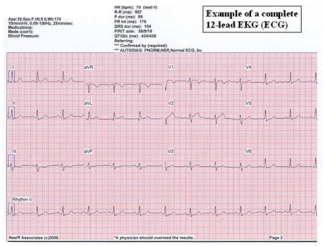
[Study Visit Schedule for participants]

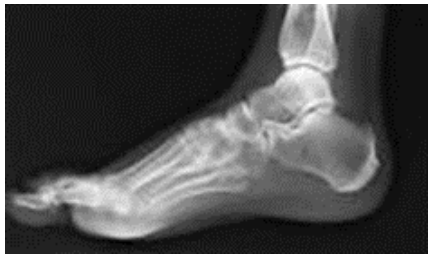
Study Assessments

- [Study specific Assessments – e.g., specifics of blood tests, sample collection and storage, information on questionnaires, variables to be recorded]

Source Data

- Information collected from, or certified copies of, clinical findings observations or other activities needed to reconstruct and evaluate a study
- E.g., ECGs, X-Rays, pathology reports, or scans
- Each study visit should be recorded in the medical notes, including confirmation of ongoing consent
- Source data verification is usually performed by the Clinical Trials Monitor during a Monitoring Visit, but may also be carried out by a Study Officer for Sponsor Oversight





Completion of Case Report Forms (CRFs)

Should be reviewed and signed by PI (or delegated individual) following completion

CRFs should contain only anonymised data (unless specified in the protocol that CRFs are source documents)

Ensure entries are clear and legible

Use black ballpoint pen

Do not create any additional fields on the CRF

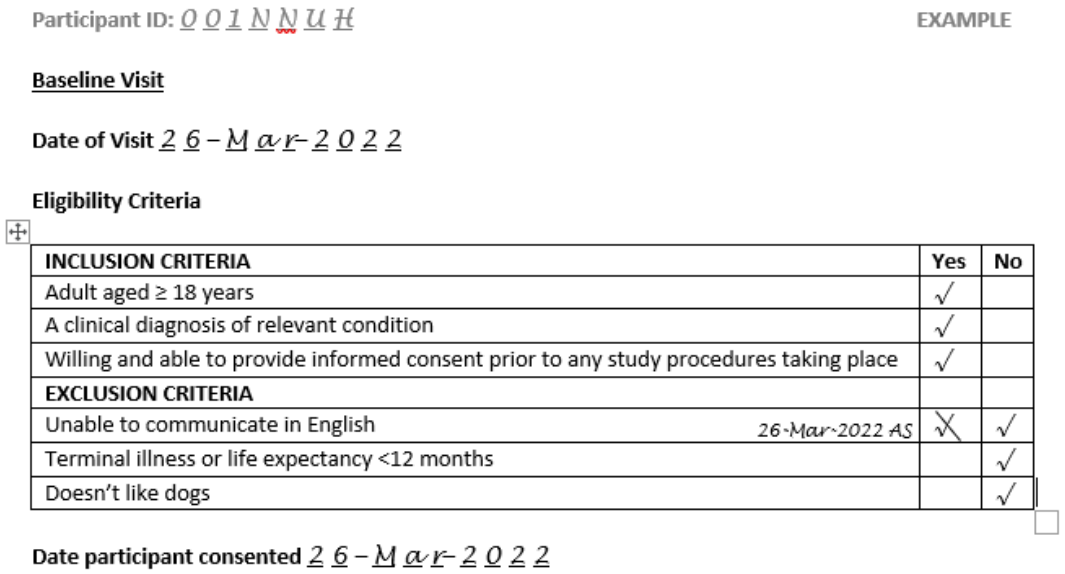
Ensure data entry is as complete as possible. If data is unavailable, write 'unknown' or N/A, do not leave blank spaces

See SOP 350 and SOP 351 for more details

Case Report Forms: Corrections

- Corrections should be made by:
  - Crossing through the incorrect entry with a single line, leaving the original entry legible
  - Entering the correct data
  - Initialling and dating the correction

- Do not use correction fluid – the original entry should still be readable
- When all entries and corrections are completed, the CRF should be reviewed and signed by the PI or a delegated individual



Participant ID: 0 0 1 N N U H EXAMPLE

Baseline Visit

Date of Visit 2 6 – M a r – 2 0 2 2

Eligibility Criteria

INCLUSION CRITERIA	Yes	No
Adult aged ≥ 18 years	√	
A clinical diagnosis of relevant condition	√	
Willing and able to provide informed consent prior to any study procedures taking place	√	
EXCLUSION CRITERIA		
Unable to communicate in English 26-Mar-2022 AS	X	√
Terminal illness or life expectancy <12 months		√
Doesn't like dogs		√

Date participant consented 2 6 – M a r – 2 0 2 2

Case Report Forms

- [Study specific CRF details]

[Study name]: IMP/Medical device/Intervention

- [Study specific IMP/Medical device/Intervention details, e.g., dosage, frequency, dose interruptions/treatment discontinuations, etc]

Concomitant Medication

- [Standard care, non-permitted medication, medications that require additional participant monitoring]

Safety Reporting

Adverse Event (AE)

An unfavourable or unintended sign or symptom

Adverse Reaction (AR)

An unfavourable response to an IMP

Serious Adverse Event/Reaction (SAE/R)

Results in death, is life-threatening, requires hospitalisation, results in disability, causes congenital anomaly or birth defect

Suspected Unexpected Serious Adverse Reaction (SUSAR)

Serious adverse reaction that is suspected to be caused by the IMP

Suspected Serious Adverse Reaction (SSAR)

Serious adverse reaction that is consistent with information in the RSI

Please see SOP 205 & 206 for further information and guidelines on reporting and responsibilities

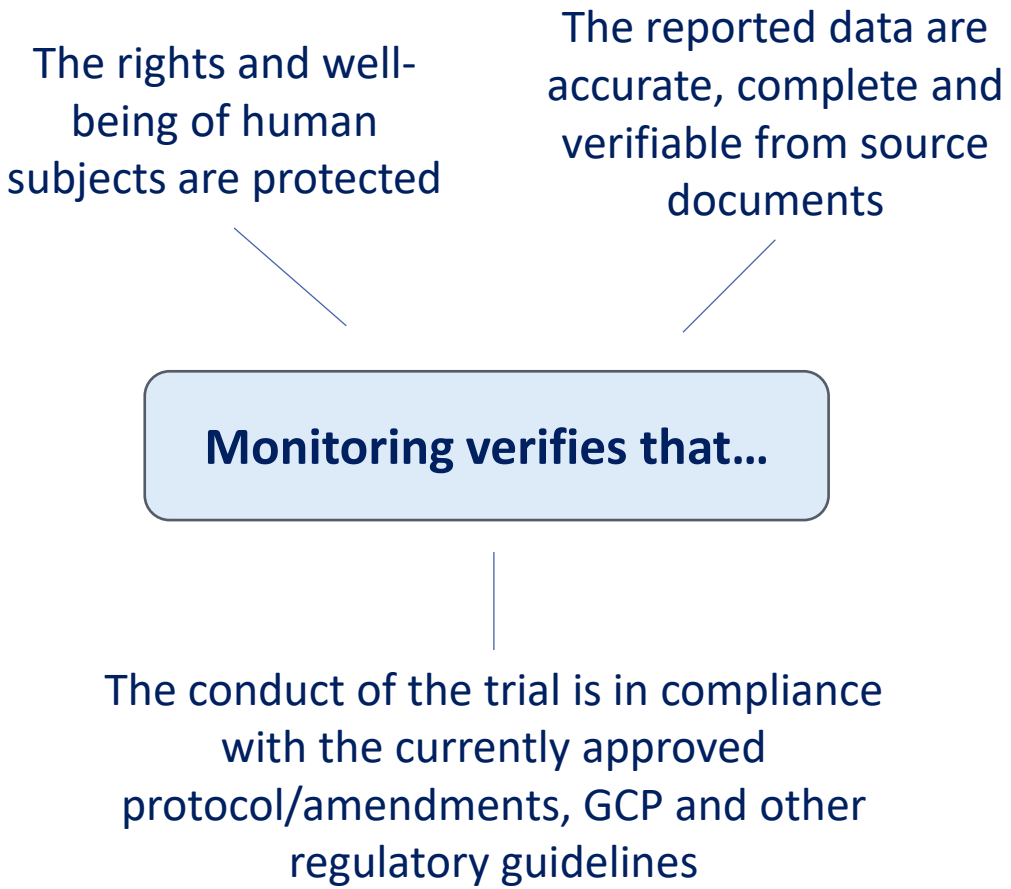
Safety Reporting

- If actions relating to SAEs are undertaken by the study nurse/trial co-ordinator, the SAE should be discussed with the Investigator as soon as reasonably possible
- It is the responsibility of the CI to report all SAEs within agreed timelines to the Sponsor, REC and relevant NHS Trust R&D
  - See SOP 205/207 [delete as appropriate] for this process

Insert study-specific SAE form template if applicable

Monitoring

- CTIMPs or Device Trials sponsored by NNUH may be subject to Monitoring
- Conducted to oversee the progress of a trial, ensuring that it is conducted, recorded and reported in accordance with the trial protocol, local SOPs, GCP principles and other regulations (e.g., MHRA guidelines)



Monitoring

Monitor creates Monitoring Plan to outline proposed monitoring activities and timelines

Monitor informs trial team of Monitoring Visit and documentation to prepare in advance

Visit is conducted – at least one study team member should be available to assist the Monitor

Other support departments (e.g., pharmacy/laboratory may also be visited)

A Monitoring Report will be provided after the visit listing the findings and any actions required

The study team should respond to required actions promptly (as per Monitoring Plan)

Please see SOP 330 for more information

Monitoring

- [Study specific Monitoring details, e.g., the trial Monitoring Plan, specific triggers for Monitoring Visits outside of schedule, typically on-site or remote monitoring]

Audit

- Studies sponsored by NNUH also may be subject to audit by the R&D Department
- This may be a routine scheduled audit, or triggered by a specific cause

Please see SOP 710 for more information

Reports & End of Trial

End of Study Declaration

- Declaration of End of Study Form available at www.hra.nhs.uk section 'End of Study and Beyond'
- Copy to be sent to the REC and R&D

Final Study Report

- A final report should be submitted to the REC within 12 months of end of study.
- For CTIMPs, the final report should be submitted in the new part of IRAS.
- For all other research, the final report should be submitted via the HRA webform.
- Copy to be sent to R&D

Publications

- Please send any publications to R&D
- Ensure the role of host NHS organisation is acknowledged in any such publication (staff affiliated with UEA to list both NNUH and UEA as organisations)

Archiving

- [Study specific archiving requirements should be detailed in the protocol]

- Guidance on archiving procedures can be found in SOP 900
- Please contact R&D Research Governance Administrator for more information

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Research Delivery Team Archiving Checklist

Please complete the appropriate column on the right once each step has been completed.

Step	Instruction	Completed
DELIVERY TEAM ACTIONS		
1	Contact R&D to request archiving at rdoffice@nnuh.nhs.uk Heading "Request for Archiving and IRAS/R&D study number" Attach permission to archive and retention period provided by Sponsor or evidence of two attempts to contact the Sponsor with no response received	
2	Ensure supplies available - Powergate order no. Archive E-Clips - KF02282 Archive boxes are available by emailing storage@archive-vault.co.uk	
3	Prepare documents for Archiving as per Archiving Process Map (SOP 900 Appendix 1)	
4	Complete the Archiving Inventory (SOP 900 Appendix 3)	
5	Add the study information to the Archiving Chain of Custody form (SOP 900 Appendix 4), sign and date.	
6	Request Quality Check via rdoffice@nnuh.nhs.uk Heading "Request for Archiving and IRAS/R&D study number"	
7	Post Quality Check, if collection is NOT from R&D office: Obtain collection driver's signatures on Chain of Custody form. Scan and email signed form to rdoffice@nnuh.nhs.uk	