# NH research template documents

# The following documents are meant as templates and can be adapted for individual study needs.

**Specific studies may require some or all of the following documents depending on the type of research being conducted.**

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NOTE: a Site Master File is also known as essential documents folder or binder, master file, Investigator site file or site file.

# Table of contents

|  |  |
| --- | --- |
| **Section\*** | **Site Master File/ Essential documents****Study documents must be available for audit or inspection****Chapter 8 of ICH-GCP provides further detail regarding essential documents**  |
|  | **Study team** |
|  | Study team contact list |
|  | Authority log or site staff delegation list |
|  | CV’s, licenses, financial disclosure, certifications |
|  | **Protocol and amendments** |
|  | Tracked changes versions & clean versions |
|  | **Investigation Brochure**  |
|  | Tracked changes versions & clean versions |
|  | **Ethics/regulatory/governance** |
|  | Approval letters |
|  | Amendment submissions |
|  | Correspondence |
|  | Clinical trial notifications |
|  | **Consent** |
|  | PICF – master & NH site specific approved, tracked changed and clean |
|  | **Study site specific forms** |
|  | Screening log template |
|  | Enrolment log template |
|  | Participant visit schedule/workflow |
|  | **Adverse events** |
|  | [AE reports](https://www2.health.vic.gov.au/about/publications/researchandreports/ae-and-sae-report) if not included in participant files |
|  | [Protocol deviation](https://www2.health.vic.gov.au/about/publications/researchandreports/protocol-deviation-or-violation-report) logs |
|  | **Monitoring** |
|  | NH CPF Consent Form/Monitoring log |
|  | Monitoring reports |
|  | **Correspondence** |
|  | **Contractual and financial documents** |
|  | Clinical trial agreement |
|  | Budget |
|  | Financial expenditure records (sundry debtor, invoicing) |
|  | Study meeting minutes  |
|  | **Other documents** |

**Definition of Site Master Files ‘Table of contents’**

 **This ‘Table of contents’ is a guide if sections are not pertinent to your study they can be deleted and/or other sections added. The idea is that it is clear where documents are located. If the documents are stored elsewhere then a ‘note to file’ needs to be completed. This is a statement indicating where that file is kept, e.g. File is stored electronically on the NH S drive in the research department folder. If internal or external monitoring or auditing is carried out this is the file that will be requested.**

1. **Study team** – List the study team and contact detail of all study team personnel. An authority log or delegation list is a list of duties that the study personnel will complete. This lists individually the duties for each person involved in the study. It is a good idea to establish this prior to start-up of the study. Each study personnel can sign to indicate understanding of their role indicating a start and stop time. **CV’s licenses, financial disclosures, certifications** should be included for key personnel involved with the study at your site. CV’s need to be updated annually and signed and dated. Store here any financial disclosures that need to be completed as well as any certifications, such as copies of medical licenses and nursing registration. Department licenses such as laboratory licenses can be stored here also.
2. **Protocol –** keep versions of the protocol here, often these documents are large and space occupying. If they are not going to be printed and kept here then a note to file should be completed indicating where they are kept. If a protocol is superseded it is a good idea to mark in some way that it is not a current protocol being used. For example write on with red pen ‘Superseded by version 2, 15/6/2016’.
3. **Investigation Brochure** – An Investigation Brochure (IB) is the information regarding a drug or device, it summarises the body of information about the product. Principal investigators will need to sign and date the document indicting receipt of the information. If an IB is superseded it is a good idea to mark in some way that it is not a current. For example write on with red pen ‘Superseded by version 2, 15/6/2016’.
4. **Ethics /regulatory –** copies or the originals of approval or submission letters submitted to the ethics or governance department. Include any key correspondence. If clinical trial notification is completed then store related files here.
5. **Consent** – This is the ethically & governance approved versions of the consent. It is a good idea to mark all superseded versions as superseded. Can also keep any ‘tracked changes’ version in this section. May be necessary to mark clearly the current version especially if copies that are being used to consent participants is being taken from here.
6. **Study site specific templates –** templated forms if supplied or created can be stored here.
7. **Adverse events –** Any documentation in regards to adverse events can be stored here. If any identifiable participant detail is included then restricted access to this folder needs to be ensured. It is a good idea to put any detail with identifiable participant information in participant specific files.
8. **Monitoring –** File any monitoring specific detail here, internal or external monitoring.
9. **Correspondence –** Any study specific key correspondence including emails can be stored here.
10. **Contractual and financial documents –** Any study specific contract or financial documentscan be filed here
11. **Other documents –** file any other miscellaneous documents here, these maybe equipment manuals, publications/manuscripts of use or interest, scoring templates, case report form templates.

**For questions or concerns regarding setting up your site file please contact** **nh.research@nh.org.au**

**CONTACTS LIST**

|  |
| --- |
| **HREC Number: SSA Number:**  |
| **Study Title:**  |
| **Role and Name** | **Means of Contact** | **Contact Information** |
| Principal Investigator: | Phone: |  |
| Mobile: |  |
| Fax: |  |
| Email: |  |
| Pager: |  |
| Study Coordinator/Research Nurse: | Phone: |  |
| Mobile: |  |
| Fax: |  |
| Email: |  |
| Associate Investigator: | Phone: |  |
| Mobile: |  |
| Fax: |  |
| Email: |  |
| Pager: |  |
| Associate Investigator: | Phone: |  |
| Mobile: |  |
| Fax: |  |
| Email: |  |
| Pager: |  |
| Pharmacist *(if, applicable)*: | Phone: |  |
| Mobile: |  |
| Fax: |  |
| Email: |  |
| Pager: |  |
| Sponsor *(if applicable):* | Phone: |  |
| Mobile: |  |
| Fax: |  |
| Email: |  |
| CRO *(if applicable):* | Phone: |  |
| Mobile: |  |
| Fax: |  |
| Email: |  |
| Laboratory: | Phone: |  |
| Mobile: |  |
| Email: |  |
| Pager: |  |
|  |  |

**Authority log / site staff delegation of duties**

**HREC No.:**

**Study Title:**

**Principal Investigator: Sponsor:**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Name** | **Initials** | **Role in Study** | **Start Date** | **End Date** | **Responsibilities** | **PI Signature** |
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**List of Responsibilities:**

|  |  |
| --- | --- |
| 1. Identification, screening
 | 1. Obtaining informed consent
 |
| 1. Adverse event reporting
 | 1. Randomisation
 |
| 1. Maintenance of Investigator Site File & project documents
 | 1. Data collection & input
 |
| 1. Ethics & governance documents/reports
 | 1. Blood Sample Collection
 |
| 1. Training
 | 1. Spinning blood samples
 |

**Participant Screening & Enrolment Log**

|  |
| --- |
| **HREC Number:****Study Title:** |
| **Protocol Version/Date:**  | **Principal Investigator Name:**  | **Study Coordinator Name(s):**  |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Screening Number** | **Date Screened***(MM/DD/YY)* | **Eligibility Criteria Met***(Yes/No)* | **Participant Initials** | **Gender***(M/F)* | **Ethnicity** | **Informed Consent Signed:** *(Date or N/A**Copy to participant)* | **Reason for Exclusion***(Screen Fail, Refused to Participate)* | **Participant****Number****Assigned** *(Randomisation)* |
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**Site training Log**

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| --- |
| **HREC Number:****Study Title:****Principal Investigator:** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Date of Training** | **Training Documentation (include version & date)**  | **Training summary** | **Trainer Name** **Trainer Signature** | **Trainee Name** **Trainee Signature** |
|  |  |  | Print name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Print name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
|  |  |  | Print name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Print name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
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|  |  |  | Print name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Print name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**NOTE TO FILE**

**STUDY:**

**SITE NAME/NUMBER**

**HREC NUMBER:**

**PI:**

|  |  |
| --- | --- |
| **Description** | **Signature (Coordinator, PI, or coinvestigator ) date and time of note** |
|  |  |
|  |  |
|  |  |

**NOTE TO FILE**

|  |
| --- |
| **STUDY PROTOCOL #/NAME:** |
| **SITE NAME/NUMBER:** |
| **PARTICIPANT ID** *(if this Note to File pertains to a participant)***:** |
| **ISSUE:**  |

|  |
| --- |
| *Record information here (i.e. issue description, action taken, resolution)*  |

**REPORTED BY:****ROLE IN STUDY:**

**SIGNATURE: DATE:**

SITE INITIATION CHECK-LIST

|  |  |
| --- | --- |
| Activity | Complete  |
| Ensure the Site Initiation Meeting is scheduled and all relevant staff is able to attend - (Investigator, Clinical Research Coordinator, Sponsor or CRA, Pharmacist, other relevant people such as laboratory staff). It is usual to confirm the initiation by letter. |  |
| Review Investigational Product overview and background |  |
| Review with investigator and relevant staff their understanding of the protocol, study procedures, investigational product, randomization procedures, un-blinding procedures and timelines |  |
| Review that site resources are adequate to conduct the trial  |  |
| Review with investigator and relevant staff Safety Reporting procedures and principles of Good Clinical Practice (ICH-GCP), including informed consent procedures, investigator responsibilities, record keeping and ethics reporting. |  |
| Review contents of Site Master File to ensure that: * The current approved copy of the Protocol, Informed Consent Form & Investigational Brochure are present and align with the ethics committee approval
* the HREC Approval and Governance Authorisation documentation are present and signed
* a copy of the CTN/CTX form is present and complete
* all necessary agreements are present and signed ( Clinical Trial Agreement, Indemnities, Insurance)
* all site staff CVs are present and signed
* Laboratory normal ranges and relevant accreditation are present
 |  |
| Complete staff delegations log |  |
| Review investigational product shipment records |  |

CLOSE-OUT CHECK LIST

|  |  |
| --- | --- |
| Activity | Complete  |
| Ensure all protocol required data has been collected |  |
| Finalise accountability and disposition of test drug |  |
| Verify that all study files are complete |  |
| Discuss overall study conduct at the site  |  |
| Collect final signatures for any data queries, signature logs or reports |  |
| Discuss archiving of original data and documents |  |
| Dispose of or return any remaining trial specific supplies |  |
| Formally close the site |  |
| Notify the HREC and site Governance Office that the study has been closed, and study materials archived. Complete and submit final report. |  |

**RESEARCH SITE FILE**



HREC/LNR:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

STUDY NAME:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

PI:

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**RESEARCH SITE FILE**



HREC/LNR:

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STUDY NAME:

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PI:

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**RESEARCH SITE FILE**



HREC/LNR:

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STUDY NAME:

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PI:

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