**Investigator Initiated Study Site File**

**Table of Contents**

**Protocol name and number: { }**

**Site name / number (if applicable) { }**

**Principal Investigator name: { }**

**Department: { }**

|  |  |  |  |
| --- | --- | --- | --- |
| **SECTION** | **DOCMENTATION** | **PRESENT** | **COMMENTS** |
| **1** | **Contact Details** |  |  |
| 1.1 | Contact list of study personnel | **□** |  |
|  |  |  |  |
| **2** | **Investigator’s Brochure (IB) / Product Information sheet / Instruction for Use (IFU) or Intervention** |  |  |
| 2.1 | Current Approved Version(s) | **□** |  |
| 2.2 | All Previous Submitted and Approved Version(s) | **□**  **□ N/A** |  |
|  |  |  |  |
| **3** | **Protocol** |  |  |
| 3.1 | Current Approved Version(s) | **□** |  |
| 3.2 | All Previous Submitted and Approved Version(s) | **□**  **□ N/A** |  |
| 3.3 | Protocol Signature Page(s) | **□** |  |
|  |  |  |  |
| **4** | **Participant Information & Consent Form (PICF)** |  |  |
| 4.1 | Current Approved Version(s) | **□** |  |
| 4.2 | All Previous Submitted and Approved Version(s) | **□**  **□ N/A** |  |
| 4.3 | Signed Informed Consent Forms | **□** |  |
|  |  |  |  |
| **5** | **Participant Tools** |  |  |
|  | Participant Diary/Participant Card/Participant Questionnaires / instruction leaflets (if applicable) |  |  |
| 5.1 | Current Approved Version(s)  Including all applicable translations | **□** |  |
| 5.2 | All Previous Submitted and Approved Version(s) including all applicable translations | **□**  **□ N/A** |  |
|  |  |  |  |
| **SECTION** | **DOCUMENTATION** | **PRESENT** | **COMMENTS** |
| **6** | **Advertisements** | **□ N/A** |  |
| 6.1 | Current Approved Version(s) | **□** |  |
| 6.2 | All Previous Submitted and Approved Versions | **□** |  |
|  |  |  |  |
| **7** | **Data collection forms/ Case Report Forms (CRF)** |  |  |
| 7.1 | Current data collection form Version (Blank)  **For CALHN-initiated studies, REDCap Database is mandatory as per Research** [SOP 032](https://ecentral.had.sa.gov.au/ViewDoc.aspx?ID=18631) | **□** | <https://ecentral.had.sa.gov.au/>  ecentral reference: ResearchSOP06079 |
| 7.2 | Data collection Completion Guidelines | **□** |  |
|  |  |  |  |
| **8** | **Ethics** |  | <https://www.rah.sa.gov.au/research> |
| 8.1 | [Initial Submission](https://www.rah.sa.gov.au/research/for-researchers/clinical-trial-submissions) (including advertising, radiation safety report, Office of the Gene Technology Regulator (OGTR) license and approval from biosafety committee, aboriginal ethics committee submission if applicable) | **□** |  |
| 8.2 | Human Research Ethics Committee (HREC) approval letter | **□** |  |
| 8.3 | Amendment submission(s) | **□**  **□ N/A** |  |
| 8.4  See note 1 | [Annual Progress Reports](https://www.rah.sa.gov.au/research/for-researchers/post-approval-monitoring) | **□**  **□ N/A** |  |
| 8.5 | [Notification of Safety Reports](https://www.rah.sa.gov.au/research/for-researchers/post-approval-monitoring)  (Caused by the clinical trial / intervention) | **□**  **□ N/A** |  |
| 8.6 | Notification of Non-compliance / Protocol Deviations  <https://www.rah.sa.gov.au/research/for-researchers/post-approval-monitoring> | **□**  **□ N/A** |  |
| 8.7 | Correspondence | **□** |  |
|  |  |  |  |
| **9.0** | **Governance** |  |  |
| 9.1 | [Clinical Trial Submissions | Royal Adelaide Hospital (rah.sa.gov.au)](https://www.rah.sa.gov.au/research/for-researchers/clinical-trial-submissions)  - Governance Authorisation letter | **□** |  |
| 9.2 | Post submission/authorisation letters | **□** |  |
|  |  |  |  |
| **10.0** | **Regulatory Documents** |  |  |
| 10.1  See note 2. | Clinical Trial Notification (CTN) | **□**  **□ N/A** |  |
| **SECTION** | **DOCUMENTATION** | **PRESENT** | **COMMENTS** |
| **11** | **Study Personnel** |  |  |
| 11.1 | Curriculum Vitae (including Medical License if applicable) | **□** |  |
| 11.2 | Good Clinical Practice (GCP) Certificate | **□** |  |
| 11.3 | Training Log / Documentation | **□** |  |
| 11.4 | Signature and delegation log | **□** |  |
|  |  |  |  |
| **12** | **Agreements** |  |  |
| 12.1 | Signed Clinical Trial/Sponsorship/Grant/Other Agreement | **□**  **□ N/A** |  |
| 12.2 | Other relevant Agreement / Contracts (including work orders if applicable) | **□**  **□ N/A** |  |
| 12.3 | Insurance Certificate | **□**  **□ N/A** |  |
| 12.4 | Indemnity  (only required where external collaborators are involved in project) | **□**  **□ N/A** |  |
|  |  |  |  |
| **13** | **Participant Logs** |  |  |
| 13.1  See note 3. | Participant Screening and Enrolment Log | **□** |  |
| 13.2 | Participant Identification Log | **□** |  |
|  |  |  |  |
| **14** | **Investigational Product (IP)** | **□ N/A** |  |
| 14.1 | De-coding and Unblinding Procedure | **□**  **□ N/A** |  |
| 14.2 | IP temperature Log | **□** |  |
|  |  |  |  |
| **15** | **Randomisation** |  |  |
| 15.1 | Instructions | **□** |  |
| 15.2 | Unblinding procedure | **□** |  |
|  |  |  |  |
| **16** | **Monitoring** | **□ N/A** |  |
| 16.1 | Site Visit Log | **□** |  |
| 16.2 | Correspondence | **□** |  |
|  |  |  |  |
| **SECTION** | **DOCUMENTATION** | **PRESENT** | **COMMENTS** |
| **17** | **Audit** |  |  |
| 17.1 | Report  To be submitted to lead HREC/Research Governance Office (RGO) | **□**  **□ N/A** |  |
| 17.2 | Correspondence (eg visit confirmation / follow up letters) | **□**  **□ N/A** |  |
|  |  |  |  |
| **18** | **Laboratory** | **□ N/A** |  |
| 18.1 | Reference Ranges (signed and current) | **□** |  |
| 18.2 | Certification / Accreditation (NATA/Medicare) | **□** |  |
|  |  |  |  |
| **19** | **Biological Samples** | **□ N/A** |  |
| 19.1 | Biological samples storage log | **□** |  |
| 19.2 | Biological samples shipping records and materials (waybills, customs declaration) | **□** |  |
| 19.3 | Laboratory manual  (if information not included in protocol) | **□** |  |
|  |  |  |  |
| **20**  See note 4 | **Safety Reports** | **□ N/A** |  |
| 20.1 | Serious Adverse Event (SAE) log | **□** |  |
| 20.2 | SAE / Significant Safety Issue (SSI) reports submitted to Sponsor/ Reviewing Ethics Committee | **□** |  |
| 20.3 | Copy of blank safety report document | **□** |  |
|  |  |  |  |
|  |  |  |  |
| **21** | **Study Reports / Publications** |  |  |
| 21.1 | Interim Report | **□**  **□ N/A** |  |
| 21.2 | Final Clinical Study Report | **□**  **□ N/A** |  |
| 21.3 | Relevant Study Publications/ References | **□**  **□ N/A** |  |
|  |  |  |  |
| **22** | **Study Meetings** |  |  |
| 22.1 | Relevant Meeting Documentation | **□** |  |
|  |  |  |  |
| **23** | **Correspondence** |  |  |
| 23.1 | Correspondence | **□**  **□ N/A** |  |
| 23.2 | Newsletters | **□**  **□ N/A** |  |
|  |  |  |  |

Notes:

1. Annual reports: - reporting form can be found in link below.

<https://www.rah.sa.gov.au/research/for-researchers/post-approval-monitoring>

Handy hint: it is the investigators responsibility to provide reports on the progress of approved research. Add annual report due date to outlook calendar as a reminder. Report is due within 2 weeks of the due date (HREC or RGO approval) to ensure continuity of ethics and governance approval.

1. Where CALHN is the sponsor the research services office will submit the CTN/CTA as provided by the site. Where an external organisation is the sponsor, CALHN Research Office will ask for a copy of the CTN as part of ethics/governance review.
2. Documents listed are available on request [Health.CALHNClinicalTrials@sa.gov.au](mailto:Health.CALHNClinicalTrials@sa.gov.au)
3. Safety reporting:

Serious Adverse Events (as defined in the protocol) can relate to medication, device

or intervention.

Significant Safety Issues (SSI) are defined as issues that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial. SSI’s should be reported to the sponsor, HREC and other Investigators

**Glossary**

IB- Investigator Brochure

IFU – Instruction for Use

CRF – Case Report Form

PICF - Participant Information & Consent Form

HREC – Human Research Ethics Committee

SSA- Site Specific Assessment

CTN – Clinical Trial Notification

CTA – Clinical Trial Application

OGTR Office of the Gene Technology Regulator

GCP – Good Clinical Practice

SAE – Serious Adverse Event

IP – Investigational Product

RGO – Research Governance Office

SAE – Serious Adverse Event

SSI – Significant Safety Issue