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|  All SSA Submissions & amendments should be made via email (healthnalhnrgo@sa.gov.au)**Preparing an SSA**To avoid delays, it is highly recommended that Principal Investigators/Project Managers contact the relevant supporting departments prior HREC submission to ensure that the services/samples etc., can be provided by the department. PI’s should also request a quote from the department/service where resources are required. Each supporting department must sign the declaration pages on the SSA. **Submitting an amendment**All amendments must include a statement advising the RGO what the variation involves. Please see submission EXAMPLE below:*Protocol Version 4 has been amended to:** *Extend the treatment period, offering an open label phase for those participants already on study and who give consent to continue on open label treatment for an additional 6 cycles.*
* *Extend the screening period to 28 days*
* *Clarify treatment of hyperglycaemic episodes*
* *Clarify the timing of bloods samples during the mixed meal tolerance test (MMTT)*
* *Clarify that hyperglycaemic events related to the MMTT are not AEs’*
* *Clarify that out of range lab results related to the diagnosis under study can be considered not clinically significant*
* *Add new wording regarding safety data*

*The study assessments required for each additional treatment cycle have remained unchanged. All participants wishing to continue open label treatment in the extension phase will be consented with the extension PICF.**The contract has been amended in line with the protocol amendment resulting in an increase to the study budget in order to account for the additional 6 cycles of treatment and will be submitted on receipt of the executed documents from the sponsor. The sponsor has also changed their invoicing details. It is anticipated that the first patient will roll over into open label treatment in March.* |
|  **Document** | **Initial governance submission** | **Post governance approval** |
| **Confidentiality Deed (CDA)** | Must be provided before site feasibility is conducted[CDA checklist](https://www.sahealth.sa.gov.au/wps/wcm/connect/public%2Bcontent/sa%2Bhealth%2Binternet/resources/nalhn%2Brgo%2Bconfidentiality%2Bagreement%2Bchecklist)   | N/A |
| **Fee Form** | See current [SA Health Fees Policy](https://www.sahealth.sa.gov.au/wps/wcm/connect/public%2Bcontent/sa%2Bhealth%2Binternet/resources/policies/fees%2Bpolicy%2Bfor%2Bthe%2Breview%2Bof%2Bresearch%2Bethics%2Band%2Bgovernance%2Bapplications) to check whether your submission has associated submission fees  | See current [SA Health Fees Policy](https://www.sahealth.sa.gov.au/wps/wcm/connect/public%2Bcontent/sa%2Bhealth%2Binternet/resources/policies/fees%2Bpolicy%2Bfor%2Bthe%2Breview%2Bof%2Bresearch%2Bethics%2Band%2Bgovernance%2Bapplications) to check whether your amendment requires a fee  |
| **Completed SSA** | Must be signed by all relevant persons Divisional Director, Finance Delegate, Pharmacy, with supporting emails from Head(s) of Unit, Business Consultant, Medical Records and any other relevant units. | N/A |
| **HREC Approval Letter** | HREC letter/s must list the site and current approved documents. | HREC letter must list the current approved documents. |
| **Ethics Application Form** | NEAF/HREA/Other. Copy must be provided. Must also be listed on HREC approval letter | N/A |
| **TGA CTN Acknowledgement** | Provided to RGO after CTN lodgment by sponsor | Provided to RGO after CTN lodgment by sponsor. Any amendments to the CTN must be provided to the RGO. |
| **Study Protocol** | Must be listed on HREC approval letterMust have version/dateMust be a .docx format | Must be listed on HREC approval letterMust have version/dateSummary of changesCovering letter to state site and participant impact (e.g. does protocol amendment require an update to the PICF?)  |
| **Investigator Brochure** | Must be listed on HREC approval letterMust have version/date | Must be listed on HREC approval letterCovering letter to state if the update required a change to the PISCF |
| **Master PISCF** | Must be listed on HREC approval letterMust have version/date | Must be listed on HREC approval letterTracked and clean versions Must have version/date |
| **Site Specific PISCF** | Site Specific details entered (SA Health Logo, local PI/Coordinator details and local complaints details)Must have version/dateStudies involving radiation: Site specific PICF must include radiation safety wording that mirrors report approved by HREC) | Site Specific details entered (SA Health Logo, local PI/Coordinator details and local complaints details)Tracked and clean versions Must have version/dateCovering letter to state site and participant impactStudies involving radiation: Site specific PICF must include radiation safety wording that mirrors report approved by HREC). |
| **Radiation Safety Report/Standard of Care declaration by PI** | Must be listed on HREC approval letterAttach declaration/report | Updates are required if protocol amendment results in changes to radiation assessments and hence change in dose*. E.G. increase in frequency in MUGA scans for safety or CT for efficacy.*Must be listed on HREC approval letterAttach declaration/report |
| **Advertising** | Must be listed on HREC approval letterMust have version/dateAll radio advertising, social media, or anything including the SA Health logo must receive approval from Media & Communications HEALTH.NorthernCommunication@sa.gov.au  | Must be listed on HREC approval letterMust have version/dateAll radio advertising, social media, or anything including the SA Health logo must receive approval from Media & Communications HEALTH.NorthernCommunication@sa.gov.au  |
| **Legal Documentation** |
| **Insurance Certificate** | From Third Party Sponsor/University/Employer outside of SA Health, must be current | From Third Party Sponsor/University/Employer outside of SA Health, must be current |
| **Medicines Australia Clinical Trial Agreement** | 3x Originals partially executed by Sponsor and PIMust include correct Institution details (see bottom of form) | 3x Original amendments partially executed by Sponsor and PIMust include correct Institution details (see bottom of form)Covering letter must state reason for amendment |
| **Other form of Research Agreement** | Must be reviewed by the research office prior to submission (send in word format). Agreements are executed by the delegated Executive of the Institution and not by the individual researcher.Must include correct Institution details (see below) | Must be reviewed by the research office prior to submission (send in word format). Agreements are executed by the delegated Executive of the Institution and not by the individual researcher.Must include correct Institution details (see below)Covering letter must state reason for amendment |
| **Medicines Australia Form of Indemnity** | 3x Originals partially executed by Sponsor and PIMust include correct Institution details (see bottom of form) | 3x Originals partially executed by Sponsor and PIMust include correct Institution details (see bottom of form)Covering letter must state reason for amendment |
| **Research Personnel** |
| **CV of Principal Investigator** | CV dated within last 2 years (if previously submitted within last 2 years, please ignore) | CV dated within last 2 years (if previously submitted within last 2 years, please ignore) |
| **Research Coordinator Form (Clinical Trials Only)** | To be completed for all research coordinators on the current[template](https://www.sahealth.sa.gov.au/wps/wcm/connect/public%2Bcontent/sa%2Bhealth%2Binternet/resources/nalhn%2Brgo%2Bresearch%2Bcoordinator%2Bauthorisation%2Bform)  | For all new staff post original approval on the [current template](https://www.sahealth.sa.gov.au/wps/wcm/connect/public%2Bcontent/sa%2Bhealth%2Binternet/resources/nalhn%2Brgo%2Bresearch%2Bcoordinator%2Bauthorisation%2Bform) |
|  **ICH-GCP Certificate** | PI must provide GCP Certificate dated within 3 years of start date of clinical trial (if previously submitted within last 3 years, please ignore)It is the PI’s responsibility to ensure all study staff have appropriate GCP and IATA certification before they undertake any research tasks. | PI must provide GCP Certificate dated within 3 years of start date of clinical trial (if previously submitted within last 3 years, please ignore)It is the PI’s responsibility to ensure all study staff have appropriate GCP and IATA certification before they undertake any research tasks. |
| **Police Clearances** | [https://screening.sa.gov.au](https://www.sahealth.sa.gov.au/wps/wcm/connect/public%2Bcontent/sa%2Bhealth%2Binternet/resources/nalhn%2Brgo%2Bresearch%2Bcoordinator%2Bauthorisation%2Bform)Required for researchers whose study involves children (or records of children <18 years); aged care or disability sector. | [https://screening.sa.gov.au](https://www.sahealth.sa.gov.au/wps/wcm/connect/public%2Bcontent/sa%2Bhealth%2Binternet/resources/nalhn%2Brgo%2Bresearch%2Bcoordinator%2Bauthorisation%2Bform)Required for researchers whose study involves children (or records of children <18 years); aged care or disability sector. |
| **Confidentiality agreement for non-SA Health staff** | [For all non – SA Health staff that will access site or any form of confidential data](https://www.sahealth.sa.gov.au/wps/wcm/connect/public%2Bcontent/sa%2Bhealth%2Binternet/resources/nalhn%2Brgo%2Bconfidentiality-deed-non%2Bnalhn%2Bemployee) | For all new staff post original approval [Non – SA Health staff that will access site or any form of confidential data](https://www.sahealth.sa.gov.au/wps/wcm/connect/public%2Bcontent/sa%2Bhealth%2Binternet/resources/nalhn%2Brgo%2Bconfidentiality-deed-non%2Bnalhn%2Bemployee) |
| **Change in Principal Investigator** | N/A | Email HREC approval noting the change, CV of new PI and credentialing details (as applicable) |
| **Change in Associate Investigator**  | N/A | Email RGO with change and credentialing details (as applicable)  |
| **Safety Documentation** |
| **Safety Reports** | N/A | Site based SUSAR/USADE (related to IP or Device and unexpected) (send within 72 hours)Urgent Safety Measures (USMs) Any measure required to be taken to eliminate immediate hazard to participant health/safety (send within 72 hours)Annual Safety Report - DSMB report submitted to RGO as available\* Site SAE (not related) ; Site SAR (related but expected); 6 monthly line listings are not required for RGO submission |
| **Protocol Deviation** | N/A | Major deviations and protocol violations which pose a risk to patient safety, or have ethical or significant administrative implications must be reported.Minor deviations which do not carry significant ethical / administrative implications or consequences should be reported to the RGO for review/acknowledgement |
| **Reporting** |
| **Annual Report** | N/A | Due on the anniversary date specified by the lead HREC.Report must be site specific and must go to lead HREC via CPI.See reviewing HREC site for relevant template. |
| **Study Closure/Suspension** | N/A | Email notification to RGO within 14 days |
| **Final Report** | N/A | Email report to RGO within 30 days of completion |
| **Audit documentation** | N/A | If the study is audited by the HREC, Sponsor or other regulatory body, the RGO must be informed and the final report provided |
| **Publications** | N/A | All study publications must also be sent to the RGO. |
| **Complaints** | N/A | PI must send the RGO a report on any complaint from participants (within 72 hours). It must contain a description of what occurred and the steps taken to address or resolve the complaint.  |

**Institution details for inclusion on CTRA/Indemnity**

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| **Name of Institution**: Northern Adelaide Local Health Network Incorporated, operating as **Lyell McEwin Hospital****Address:** Haydown Road, Elizabeth Vale, South Australia, 5112**ABN:** 46 371 200 573 | **Name of Institution:** Northern Adelaide Local Health Network Incorporated, operating as **Modbury Hospital****Address**: 41-69 Smart Road, Modbury, South Australia 5092**ABN:** 46 371 200 573 |

**NALHN banking details must be included in Schedule 2 of CTRA:**

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| All payments listed in this schedule will be made by the Sponsor to Institution upon receipt of a tax invoice by direct credit.**Bank:** Commonwealth Bank of Australia **Branch:** 96 King William St, Adelaide**BSB:** 065 266      **Account Number:** 10020646**Account Nam**e: NALHN Oracle Operating**ABN:** 46 371 200 573**Swift Code:** CTBAAU2S |

**Document Naming & Version Control**

Ensure that documents provided to the RGO are appropriately named with the document title, version number, version date (e.g. Protocol\_V3\_16Jan2018) and that documents are not locked. Do not send unnamed documents (e.g. files from a scanner titled 20188476565).

Versions must correspond with the HREC approval.

Participation Information Sheets and Consent Forms should be provided as .docx files. Both the tracked and clean versions for each document should be provided. Both Master and Site Specific versions should be identified in the document name, and reflected in the document footer eg:

* Master\_Main\_PISCF\_v1.0\_16Jan18\_tracked.docx
* Master\_Main\_PISCF\_v1.0\_16Jan18\_clean.docx
* LMH\_Main\_PISCF\_v1.0\_28Feb18\_tracked.docx
* LMH\_Main\_PISCF\_v1.0\_28Feb18\_clean.docx

Attach each document separately to one email (e.g. a separate file for the cover letter, protocol, PICF). Do not combine files into a single PDF.

For assistance in understanding version control, please refer to NALHN Research Secretariat Procedure OWI04336 – *Research Version Control* available on PPG.

Documents with insufficient naming/version control or that do not match the HREC approval will be returned to the researcher without review.