Checklist for Site Specific Assessment submissions to the Research Governance Officer

Site Specific Assessments (SSA) can be submitted before or after receiving ethics approval, however both submissions are encouraged to be done in parallel. SSA applications are to be submitted via the Research Ethics and Governance Information System (REGIS). Quick reference guides for REGIS can be found here, or please contact the ISLHD Research Governance Office on the details provided below.

Cover Letter (recommended – template provided on page 4)

- ☐ Identify if Human Research Ethics Committee (HREC) approval has been granted (include date and HREC reference number) or is pending
- ☐ List all documents enclosed in the application (for multi-site projects, if some HREC approved documents are not being used at ISLHD please specify these in the cover letter)

Site Specific Assessment Form (SSA)

- ☐ All questions completed
- ☐ Relevant ISLHD Head(s) of Department(s) are listed in Part C: Departments and Services – Principal Investigators who are Heads of Department **must not** sign off on their own SSA applications but must obtain support from their direct manager.
- ☐ Relevant ISLHD Head(s) of Supporting Department(s) (eg. Pharmacy if dispensing drugs) (if applicable) are listed in Part C: Departments and Services

Documents to be included with the SSA submission

- ☐ Site Specific Participant Information Sheet and Consent Form (must include the ISLHD logo and each page must have the date and version number in the footer)
- ☐ Letter of approval from the HREC
- ☐ HREC Amendment Approval Letters (if applicable)
- ☐ Human Research Ethics Application (HREA)
- ☐ Research protocol
- ☐ Master Participant Information Sheet and Consent Form (each page must have the date and version number in the footer)
- ☐ Advertisements, patient diaries, etc
- ☐ Investigator brochure (if applicable)
- ☐ Radiation safety report and approval (if applicable)
- ☐ Study budget summary completed and signed by the person completing the form and ISLHD Cost Centre Manager (if your project involves funding)
- ☐ Letter of approval from data custodians (if applicable)

Clinical Trials

- ☐ Clinical Trial Notification (CTN) Form (if applicable) (https://www.tga.gov.au/clinical-trials)

Pharmaceutical/Medical Device Industry Sponsored Studies

- ☐ Medicines Australia Form of Indemnity on Australian company letterhead (http://medicinesaustralia.com.au/issues-information/clinical-trials/indemity-and-compensation-guidelines/) signed by sponsor and principal investigator

- ☐ Certificate of Insurance ($20,000,000) identifying the research project and period of currency.

- ☐ Medicines Australia Clinical Trials Research Agreement (http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements/) which is endorsed by NSW Health. Please feel welcome to send through a draft copy of the CTRA to the ISLHD Research Governance Office for review prior to submission and partial execution.
  - Ensure the legal name of the organisation is used as follows:
    Name of Institution: Illawarra Shoalhaven Local Health District
    Address: Illawarra Shoalhaven Local Health District Executive Office, Suite 2, Level 2, 67-71 King Street, Warrawong, NSW 2502 Australia
    ABN: 13 567 011 035
  - Specify Name, Address and ABN of Sponsor
  - Specify Name, Address and ABN of Clinical Research Organisation (CRO) (if applicable)
  - Indicate whether the Sponsor or CRO is to be invoiced
  - Signed by sponsor and principal investigator

Please note:
ISLHD incorporates the Wollongong Hospital, Coledale Hospital, Bulli Hospital, Port Kembla Hospital, Shellharbour Hospital, David Berry Hospital, Shoalhaven District Memorial Hospital and Milton-Ulladulla Hospital and other public health facilities within the District. If your research is being conducted across more than one site, please select ISLHD as a site when completing your SSA. Please check with the Research Governance Officer if you are unsure.

Enquiries:
ISLHD Research Governance Office
Block C, Level 8, Wollongong Hospital
Locked Mail Bag 8808,
South Coast Mail Centre NSW 2521
Ph: (02) 4253 4819
Email: ISLHD-ResearchGovernance@health.nsw.gov.au

A list of handy tips and cover letter template is provided on the following pages.

Handy tips

For submitting your SSA in REGIS

- The Principal Investigator (PI) must submit the SSA on behalf of the research team. As such, the PI must have a REGIS account.
- The head of department cannot be an investigator of the study as this would be a conflict of interest. Please contact the office if you are unsure of the correct head of departments to list in the application.
- If your project involves non-NSW Health staff accessing ISLHD sites or patients, please notify the Research Governance Office prior to submission for clarification regarding any additional requirements.

Site specific documents

These are study documents that are site specific to ISLHD for multi-site projects e.g. Participant information sheets, consent forms, posters, flyers etc. Please upload site specific documents with the SSA application in REGIS if applicable (this is in addition to the master document approved by the lead HREC).

Please ensure the following is included on the site specific versions:

- A site specific version number/date must be included **in addition to** the master version number/date. There should be two version numbers/dates, *e.g. Wollongong Hospital, Version 1.0, 10 January 2021, MASTER Version 1.0, 8 January 2020*
- Illawarra Shoalhaven Local Health District logo must be used. This is available on request from the office.
- For participant information sheets the ISLHD Research Governance Office complaints paragraph must be used in addition to the lead HREC complaints paragraph. Please insert the following:
  "The conduct of this study at [insert Hospital name] has been authorised by the Illawarra Shoalhaven Local Health District. Any person with concerns or complaints about the conduct of this study may also may also contact the Research Governance Officer on Phone: 02 4253 4819, email: ISLHD-ResearchGovernance@health.nsw.gov.au and quote project number "2022/STEXXX"

Research Governance Submission Cover Letter

Research Governance Officer
ISLHD Research Office
Wollongong Hospital, Block C, Level 8

[Date]

Ethics Application number: [YEAR/ETHXXXXX] or [HREC/xx/xx/xxx] or [HREC unique reference number]
Name of Approving HREC: [Approving HREC Name]
Governance Application number: [YEAR/STEXXXXX]
Project Title: [Project Title]
Co-ordinating Principal Investigator: [Co-ordinating Principal Investigator]
HREC Approval Period: [DAY / MONTH / YEAR] - [DAY / MONTH / YEAR]

Dear Governance

Please find enclosed the Site Specific (SSA/STE) application and relevant documents for the above referenced study. The following documents have been uploaded with this application into REGIS (this includes all final HREC approved documents – Documents must be listed as per the HREC approval notification and uploaded into REGIS with matching naming convention):

- [Protocol, version & date]
- [Master PISCFs, version & date]
- [Document filename, version & date]

In addition, please find the Site Specific documents listed below as uploaded with the application in REGIS:

- [Site Specific PISCFs, version & date based on Master X, Version X, Dated X]
- [Site Specific document filename, version & date based on Master X, Version X, Dated X]

ISLHD Departments supporting this project:
- [Imaging]
- [Pharmacy]
- [other]

Research Agreements:
- [Medicines Australia Clinical Trial Research Agreement - Standard]
- [Medicines Australia Clinical Trial Research Agreement - Collaborative]
- [Medicines Australia Indemnity - Standard]
- [Material Transfer Data Agreement]
- [Service Level Agreement]
- [other]

Other
- [Insurance Certificate (if required)]

Special comments/consideration:
- [if applicable - please add any comments for the ISLHD RGO to consider]

Please do not hesitate to contact myself or [Administrative Contact] on [contact number/email].
Thank you for your time and consideration of this study.

Yours sincerely,

[Site Principal Investigator]
[Telephone]
[Institutional Email]