## NALHN LNR Ethics and Governance Application Form

**Instructions:**

Please note: responses must be typed into this form – **do not** write responses by hand. Invalid forms will be returned to the Researcher.

Step 1. Complete this form, and get it signed by the Divisional Business Consultant and Divisional Director

Step 2. Submit form and supporting documents to RGO for validity check HealthNALHNRGO@sa.gov.au

Step 3. RGO will confirm validity

Step 4. Researcher to submit form and supporting documents to **one** of the Human Research Ethics Committee offices for expedited review:

CALHN HREC: CALHNResearchLNR@sa.gov.au

SALHN HREC: Health.SALHNOfficeforResearch@sa.gov.au

Step 5. HREC committee will approve ethics

Step 6. Researcher provides RGO with copy of HREC approval to HealthNALHNRGO@sa.gov.au

Step 7 **RGO will provide authorisation to commence the project (please note the study is not able to commence at the NALHN site/s until you have received the RGO authorisation letter of approval)**

|  |  |
| --- | --- |
| Project full title |  |
| Term of the study | Start date:  | End date:  |
| Principal investigator | Name: Department: Employer: Work email: Telephone:  |
| Reviewing Human Research Ethics Committee (HREC) | [ ] Central Adelaide Local Health Network HREC[ ] Southern Adelaide Clinical HREC[ ] SA Health HREC | [ ] Aboriginal Health HREC[ ] Women’s and Children’s Health Network HREC[ ] Other: |
| Other Committee approvals | [ ] Animal Ethics Committee[ ] Institutional Biosafety Committee | [ ] Radiation Safety Report[ ] Other:  |
| Type of application | [ ] Low Risk[ ] Negligible Risk | [ ] Access Request[ ] Other: |
| **SA Health sites involved in study****e.g. NALHN – LMH, MH, NCMHS, Watto Purunna** |  |
| Non SA Health sites involved in the study e.g. SAHMRI, University of Adelaide AHMS, UniSA HIB  |  |
| **Conflicts of interest** | [ ]  Yes [ ]  NoIf yes, please provide details in the protocol |
| **Existing data** (further details to be provided in the protocol) | Will access to patient data be required in the study? [ ]  Yes [ ]  No |
| Has participant consent been obtained? [ ]  Yes [ ]  No |
| If access is required outside of your normal duties attach approval from person / department responsible for authorising access |
| **New Data collection** (further details to be provided in the protocol) | Will there be collection of data? [ ]  Yes [ ]  NoWill participant consent be obtained? [ ]  Yes [ ]  NoWill a databank be established? [ ]  Yes [ ]  No  |
| **Existing tissue/samples** (further details to be provided in the protocol) | Will access to tissue / samples be required in the study? [ ]  Yes [ ]  NoAre the tissue/samples held within your department? [ ]  Yes [ ]  NoHas participant consent been obtained? [ ]  Yes [ ]  No |
| If access is required outside of your department attach approval from person /department responsible for access to tissue/sample e.g. manager of tissue bank |
| **New sample collection** (further details to be provided in the protocol) | Will there be collection of samples? [ ]  Yes [ ]  No |
| Will a tissue bank be established? [ ]  Yes [ ]  No |
| Will participant consent be obtained? [ ]  Yes [ ]  No |
| **Peer review (e.g. grant application)** | [ ]  Yes [ ]  NoIf yes, provide details |
| **Funding/Budget**To be discussed with the Divisional Business Consultant | [ ] **In-kind.** **Provide details**: personnel and hours of support for NALHN staff. |
| [ ] Internal department fundingIf yes, NALHN [ ]  / University [ ]  / SAHMRI [ ]  / Other [ ]  **Provide details** of funding and cost centre for NALHN only |
| [ ]  External Funding [ ] Grant [ ] Company sponsored[ ] Research Services**Provide details** of funding to be provided to or from NALHN |
| **Agreements/Contracts** | If funds are to be paid to or from NALHN, services or samples are being provided to another organisation, the research project involves intellectual property, an agreement must be in place. Agreements must be reviewed by the RGO and signed by the EDMS.Will there be an agreement associated with this study? [ ]  Yes [ ]  NoIf yes please attach |
| **Non SA Health investigators** | Where the project is being conducted within NALHN or accessing NALHN participants, their tissue or data:Are all members of the project team employees of SA Health? [ ]  Yes [ ]  NoIf No, confirmation of Admin/HR/Laboratory Manager that non-SA Health investigators have approval to be on NALHN site(s) is requiredIf not previously submitted to this Research Office please attach |
| If the project involves team members who are not SA Health employees, confirmation of insurance and indemnity cover for the study by the non SA Health organisation is required |
| **CV/GCP** | A copy of a CV for all researchers / students involved in the study must be registered with the Research Office. Good Clinical Practice (GCP) certificates are required by the site PI for all LNR studies.If not previously submitted this to the Research Office please attach  |
| **Study Protocol (Mandatory)** | Attach the Study Protocol and all additional documents (Patient Information and Consent Forms, questionnaires, recruitment flyers etc). |
| **Additional information to assist with the review:** (please provide as much information as possible as to what is being undertaken at this site) |

**RESEARCHERS:**

Project title:

#### Declaration by all research personnel involved in the study at this site

I/we certify that:

1. All information in this form is truthful and as complete as possible.
2. I/we have had access to and read the *NHMRC National Statement on Ethical Conduct in Human Research 2007* (National Statement) and the *Australian Code for the Responsible Conduct of Research 2018* (the Code).
3. The research will be conducted in accordance with all ethical and research governance arrangements of the organisations involved.
4. I/we have no conflicts of interest or have disclosed any conflicts of interest to the ethics review committee and NALHN Research Office and will manage them in accordance with the National Statement and the Code.
5. I/we will maintain the confidentiality, integrity, privacy and security of information in accordance with the *SA Health Code of Fair Information Practice 2004* and *Australian Privacy Principles 2014*.
6. I/we have consulted any relevant legislation and regulations, and the project will be conducted in accordance with these.
7. I/we will only commence this research project after obtaining ethics approval and governance authorisation.

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Role**e.g. PI/ student/ supervisor  | **Employer/Affiliation** | **Signature** |
|   |   |  |  |
|   |   |  |  |
|  |  |  |  |

(insert additional lines if necessary)

**Submission Check list**:

[ ]  Protocol

[ ] :Participant Information Sheet and Consent Form

[ ]  Data collection tool

[ ]  Questionnaires

[ ]  Recruitment Script

[ ]  Interview Focus Group guide

[ ]  Advertising

[ ]  Divisional Business Consultant approval

[ ]  Divisional Director approval

[ ]  Supporting email from Medical Records (if study is accessing patient records)

[ ]  CV and GCP attached for all investigators

[ ]  Insurance certificates of currency attached for all non-SA Health employees

[ ]  Confidentiality deed attached for all non-SA Health employees/students

[ ]  Police checks attached for all non-SA Health employees/students (on site or accessing identifiable data)

[ ]  Confirmation of Student IP Deed poll for HDR students

[ ]  Copies of all agreements (grant contracts, collaboration agreements, material transfer agreements, etc)

**DIVISIONAL APPROVAL:**

Project title:

**Declaration by the NALHN Divisional Business Consultant**

I certify that the site Principal Investigator has discussed the research project named above with me, and I am satisfied that the financial impacts on the Division have been adequately addressed.

|  |  |
| --- | --- |
| Name of Divisional Business Consultant |  |
| Signature  | Date |

Supporting e-mails will be accepted in lieu of signatures

**Declaration by the NALHN Divisional Director**

*This declaration must be completed by* ***all NALHN*** *Divisional Directors (or facility, location or service) involved in supporting the project.. Attach a separate declaration for the head of* ***each*** *department involved in the project at this site.*

*Where the principal investigator for the study is also the head of department, certification must be sought from the person to whom the head of department is responsible. Investigators must not approve their own research on behalf of the department.*

1. I certify that I have read the project application named above.
2. I certify that I have discussed this project and the resource implications for this department with the principal investigator.
3. I certify that the principal investigator and other investigators involved in the project have the necessary skills, training and experience to undertake their role, and where necessary, appropriate training and supervision has been arranged.
4. I certify that there are suitable and adequate facilities and resources for the project to be conducted at this site as proposed, and they are available for the duration of the project.
5. I certify that the research project has been costed appropriately and there are sufficient funds to cover the costs of conducting research at the site.
6. I certify that I am signing after discussion and agreement on behalf of the nursing and medical component of the relevant division

My signature indicates that I support this project being carried out using the required resources, based on the information provided by the principal investigator.

|  |  |
| --- | --- |
| Name of Division |  |
| Name of Divisional Director |  |
| Signature  | Date |

#### RESEARCH OFFICE USE ONLY

**Declaration by Research Office**

Project title**:**

Our Reference

HREC:

SSA:

This application has been reviewed and is:

[ ] Supported

[ ] Not Supported

|  |  |
| --- | --- |
| Name  |  |
| Position |  |
| Signature  | Date  |
| Comments |

**Final Authorisation**

Noting the endorsement provided above, I hereby recommend this project is:

[ ] Authorised

[ ] Not Authorised

|  |  |
| --- | --- |
| Name  |  |
| Position |  |
| Signature  | Date |
| Comments |