|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **ETHICS AND GOVERNANCE ASSESSMENT (EGA) APPLICATION FORM** | | | | | | | |
|  | |  | |  | |  | |
| This form should be be used when applying for ethical and/or governance review of research projects eligible for review by the Central Adelaide Local Health Network (CALHN) Expedited Review Panel which incorporates both human ethics and governance review. Researchers are advised that formal determination of eligibility for expedited review is made by CALHN Research Services, and are strongly encouraged to read the Expedited Review Application guidelines prior to submitting an application.  **Submit to** [Health.CALHNResearchLNR@sa.gov.au](mailto:Health.CALHNResearchLNR@sa.gov.au) | | | | | | | |
|  | |  | |  | |  | |
| 1. **PRINCIPAL INVESTIGATOR** | | | | | | | |
|  | |  | |  | |  | |
| Name | | Enter text | | | | | |
|  | |  | |  | |  | |
| Department | | Enter text | | Site | | Enter text | |
|  | |  | |  | |  | |
| Email address | | Enter text | | Phone number | | Enter text | |
|  | |  | |  | |  | |
| Employing institution | | Enter text | | | | | |
|  | |  | |  | |  | |
| 1. **PROJECT DETAIL** | | | | | | | |
|  | |  | |  | |  | |
| Project title | | Enter text | | | | | |
|  | |  | |  | |  | |
| Project category | | Clinical research | | Review type | | Select one | |
|  | |  | |  | |  | |
| Institution responsible for protocol/results ownership | | | | Enter text | | | |
|  | |  | |  | |  | |
| Anticipated project duration e.g. 6 months, 12 months | | | | Enter text | | | |
|  | |  | |  | |  | |
| 1. **REGULATORY APPPROVALS** | | | | | | | |
|  | |  | |  | |  | |
| Reviewing Human Research Ethics Committee (HREC) | | | | Select one  Other: Enter text | | | |
|  | |  | |  | |  | |
| Reviewing animal ethics committee | | | | Select one | | | |
|  | |  | |  | |  | |
| Reviewing institutional biosafety committee | | | | Select one | | | |
|  | |  | |  | |  | |
| 1. **PARTICIPATING NETWORKS/SITES/SERVICES** | | | | | | | |
|  | |  | |  | |  | |
| Local Health Network | | Select one | | | | | |
|  | |  | |  | |  | |
| Site(s)/services | | Enter text | | | | | |
|  | |  | |  | |  | |
| Local Health Network | | Select one | | | | | |
|  | |  | |  | |  | |
| Site(s)/services | | Enter text | | | | | |
|  | |  | |  | |  | |
| 1. **DATA COLLECTION** | | | | | | | |
|  | |  | |  | |  | |
| Data to be collected | |  | | Select one | | | |
|  | |  | |  | |  | |
| Records to be accessed | | | |  | Electronic medical records | | |
|  | | | |  | Casenotes | | |
|  | | | |  | Departmental database | | |
|  | | | |  | Research database *– provide original ethics approval* | | |
|  | | | |  | Other: Enter text | | |
|  | | | |  | Not applicable | | |
|  | |  | |  | |  | |
| List investigators that will be accessing existing records | | | | Enter text | | | |
|  | |  | |  | |  | |
| Method of new data collection | | | | Select one | | | |
|  | |  | |  | |  | |
| Identifiability category | | | | Select one | | | |
|  | |  | |  | |  | |
| 1. **SPECIMEN COLLECTION** | | | | | | | |
|  | |  | |  | |  | |
| Specimens to be collected | | | | Select one | | | |
|  | |  | |  | |  | |
| Institution that owns existing specimens | | | | Enter text | | | |
|  | | > | |  | |  | |
| Institution that will own new specimens | | | | Enter text | | | |
|  | |  | |  | |  | |
| 1. **CONSENT PROCESS** | | | | | | | |
|  | |  | |  | |  | |
| Method of consent | | | | Select one | | | |
|  | |  | |  | |  | |
| 1. **FUNDING** | | | | | | | |
|  | |  | |  | |  | |
| How the project will be supported | | | | Select one | | | |
|  | |  | |  | |  | |
| 1. **IN-KIND SUPPORT** | | | | | | | |
|  | |  | |  | |  | |
| Summary of personnel and hours | | | | Enter text | | | |
|  | |  | |  | |  | |
| 1. **INTERNAL DEPARTMENTAL FUNDING** | | | | | | | |
|  | |  | |  | |  | |
| Institution and department providing funding | | | | Enter text | | | |
|  | |  | |  | |  | |
| Cost centre | | | | Enter number | | | |
|  | |  | |  | |  | |
| 1. **EXTERNAL FUNDING** | | | | | | | |
|  | |  | |  | |  | |
| Funding type | | | | Select one | |  | |
|  | |  | |  | |  | |
| If grant funded, is there a CALHN investigator named on the grant application? | | | | | | Select one | |
|  | | |  |  | | |  |
| If yes, list the investigators named on the grant application | | | | Enter text | | | |
|  | |  | |  | |  | |
| Will funds be paid to or from CAHLN? | | | | Select one | | | |
|  | |  | |  | |  | |
| 1. **CHECKLIST** | | | | | | | |
|  | |  | |  | |  | |
| **Mandatory documents** | | | | | | | |
|  | Protocol | | | | | | |
|  | Declaration by investigators | | | | | | |
|  | Declaration by the medical/nursing/allied health lead, clinical practice director or equivalent | | | | | | |
|  | Declaration by business manager | | | | | | |
|  | Curriculum vitae for each investigator (if not submitted in the previous 12 months) | | | | | | |
|  | Declaration of interests (email is sufficient) | | | | | | |
| **Supporting documents** | | | | | | | |
|  | Participant information sheet/consent form | | | | | | |
|  | Data collection sheet | | | | | | |
|  | Questionnaire/survey | | | | | | |
|  | Advertising materials | | | | | | |
|  | Regulatory approvals | | | | | | |
|  | Budget | | | | | | |
|  | Grant award letter and/or grant agreement | | | | | | |
|  | National Police Check or Working with Children Check | | | | | | |
|  | Confidentiality deed | | | | | | |
|  | Data custodian declaration | | | | | | |
|  | Specimen custodian declaration | | | | | | |
|  | Other: Enter text | | | | | | |
|  | |  | |  | |  | |
| 1. **ADDITIONAL INFORMATION** | | | | | | | |
|  | |  | |  | |  | |
| Include any additional information to assist with review | | | | Enter text | | | |
|  | |  | |  | |  | |
| **DECLARATION** | | | | | | | |
|  | |  | |  | |  | |
| **Declaration by all research personnel involved in the project** | | | | | |  | |
|  | |  | |  | |  | |
| Project title | | Enter text | | | | | |
|  | |  | |  | |  | |
| I/we certify that:   1. All information in this form is truthful and as complete as possible. 2. The protocol contains all required information for comprehensive ethical and scientific review. 3. I/we have read and understand the requirements of the [NHMRC *National Statement on Ethical Conduct in Human Research 2007* (Updated 2018)](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018) (the National Statement) and the [*Australian Code for the Responsible Conduct of Research 2018*](https://www.nhmrc.gov.au/sites/default/files/documents/attachments/grant%20documents/The-australian-code-for-the-responsible-conduct-of-research-2018.pdf) (the Code). 4. The research project will be undertaken in compliance with the approved proposal, and conducted in keeping with conditions of ethical approval and local governance, and subject to any changes subsequently approved. 5. All records will be maintained and stored in accordance with common law, legislative, ethical, and current best practice requirements. 6. Any confidential information, including but not limited to personal information of research project participants, CALHN patients, and CALHN staff will remain confidential and will not be disclosed to any third party except as required by law. 7. The project will be conducted in accordance with International Council for Harmonisation and NHMRC standards. 8. I/we have no conflicts of interest or have disclosed any conflicts of interest to the ethics review committee and CALHN Research Services and will manage them in accordance with the *National Statement* and the *Code*. 9. I/we will only commence this research project after obtaining project authorisation. | | | | | | | |
|  | |  | |  | |  | |
| **SA HEALTH EMPLOYEES** | | | | | | | |
| Name | | Main duties in the project | | Local Health Network | | Signature | |
| Enter text | | Select one | | Enter text | |  | |
| Enter text | | Select one | | Enter text | |  | |
| Enter text | | Select one | | Enter text | |  | |
| Enter text | | Select one | | Enter text | |  | |
| Enter text | | Select one | | Enter text | |  | |
| Enter text | | Select one | | Enter text | |  | |
| **NON-SA HEALTH EMPLOYEES**  *A confidentiality deed must be provided for any non-SA Health investigators accessing SA Health specimens or data. Non-SA Health investigators going onto an SA Health site, or accessing SA Health participants must also provide a National Police Check or Working with Children Check* | | | | | | | |
| Name | | Main duties in the project | | Employer/academic institution | | Signature | |
| Enter text | | Select one | | Enter text | |  | |
| Enter text | | Select one | | Enter text | |  | |
| Enter text | | Select one | | Enter text | |  | |
| Enter text | | Select one | | Enter text | |  | |
| Enter text | | Select one | | Enter text | |  | |
| Enter text | | Select one | | Enter text | |  | |
|  | |  | |  | |  | |

|  |  |  |  |
| --- | --- | --- | --- |
| **Declaration by medical/nursing/allied health lead/head of department/business manager** | | | |
|  |  |  |  |
| **All medical/nursing/allied health lead, head of department(s), business manager(s)** involved in supporting the project, must complete this declaration. Complete a separate declaration for each approval.  Where the principal investigator is also the medical/nursing/allied health lead, clinical practice director, or equivalent, certification must be sought from the person to whom the head of department is responsible. **Investigators cannot not approve their own research**. | | | |
|  |  |  |  |
| Project title | Enter text | | |
|  |  |  |  |
| I certify that:   1. I have read the referenced project application. 2. I have discussed this project and the resource implications with the principal investigator. 3. 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. There are suitable and adequate facilities and resources for the project to be conducted, and they are available for the duration of the project. 5. The research project has been costed appropriately and there are sufficient funds to cover the costs of conducting research.   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 | Enter text | Department | Enter text |
|  |  |  |  |
| Signature |  | Date | Enter date |
|  |  |  |  |