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| **Human Research Ethics Committee Submission Covering Letter**  **Phase 1 Clinical Drug Trial** | | | |
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| This form must be completed by the sponsor or the coordinating Principal Investigator (CPI) for all multi-site projects or the Principal Investigator (PI) for single site projects when submitting a new Phase 1 clinical trial of an investigational drug and/or device to the Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) for ethical and scientific review. All phase 1 drug studies will undertake a Clinical Pharmacology review. \*Asterisk denotes mandatory fields  **Submit as supplementary documentation with application via** [**Research GEMS**](https://gems.sahealth.sa.gov.au/Account/SignIn) | | | |

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| |  |  |  |  |  | | --- | --- | --- | --- | --- | | CPI Name: Enter text | | Protocol No: Enter text | | Phase:Enter text | | \*Program: Enter text | | \*Department: Enter text | | | | Study title: | Enter text | | | | | **\***Institution responsible for protocol/results ownership | | | Enter text | |   Study sites must be listed in the submitted HREA under M6.2.1.2.6 Provide the following details for each site where the clinical trial will be conducted.  For non-sponsored clinical trial phase 1 drug studies complete the below table listing all the study sites   |  |  |  |  | | --- | --- | --- | --- | | Study Site/s | Public  Private | State | Site Principal Investigator | | Enter text | Enter text | Enter text | Enter text | | Enter text | Enter text | Enter text | Enter text | | Enter text | Enter text | Enter text | Enter text | | Enter text | Enter text | Enter text | Enter text | | Enter text | Enter text | Enter text | Enter text | | Enter text | Enter text | Enter text | Enter text | | Enter text | Enter text | Enter text | Enter text | | Enter text | Enter text | Enter text | Enter text | | **\***Have investigators accessed consumer engagement during the development and review of the above protocol? Enter text | | | | |
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| 1. **RADIATION\*** |

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| |  |  | | --- | --- | | All research involving any form of radiation must comply with relevant National and State legislation, organisational policies and procedures, and codes and standards of practice provided by the NHMRC and the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).  SA Medical Imaging now has online system to determine if you will be required to submit a Radiation Safety Report for your study.  You can access the new form via [https://redcap.link/SAMIethicsrequest](https://aus01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fredcap.link%2FSAMIethicsrequest&data=05%7C01%7CHealth.CALHNResearchEthics%40sa.gov.au%7C50842f265183491c924808dbb8b8811e%7Cbda528f7fca9432fbc98bd7e90d40906%7C1%7C0%7C638306874794731360%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=nmJ9lSnVVzQSElhoaosumjVdEAyN8D%2BXu9qymBuAJck%3D&reserved=0) - enter your contact details and you will receive an email with a link to the new form.  Provide a copy of the outcome of your REDCap submission as part of your submission to CALHN HREC. (Either a copy of the email stating you do not require Radiation Safety Report or a copy of the Radiation Safety Report) If multisite a radiation report or a standard of care statement must be provided for **all** sites.  *If you have troubles with accessing the REDCap system contact SA Medical Imaging at* [*radiationsafety@sa.gov.au*](mailto:radiationsafety@sa.gov.au)  **\*JUSTIFICATION IF RADIATION IS STANDARD OF CARE**  That is, if a patient was not enrolled in the above study, they would still receive an equivalent number of exams involving the use of ionising radiation at the specified intervals as stated in the research protocol. In making this determination investigators have considered:   1. The body region being examined. 2. The modality being identical to that used as part of standard care. 3. Frequency or number of the exams proposed. 4. Differing cancers of potential patients.  |  | | --- | | \*Provide a justification statement (include number of exams involving the use of ionising radiation Enter text | | |

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| 1. **\*CLINICAL PHARMACOLOGY REVIEW** |

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| **All drug details must be included in the submitted HREA for Clinical Pharmacology/HREC review** | |
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| Is the drug manufactured under Good Manufacturing Practice (GMP) | Select one |
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| Specify total number of participants to be recruited at lead site: | Enter text |
| Specify total number of participants to be recruited per site under this approval: | Enter text |
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| 1. **DATA** |

An individual’s right to privacy is a fundamental human right. This is recognised in a number of international

instruments, in particular, the *International Covenant on Civil and Political Rights (Article 17)* and the *OECD*

*Guidelines on the Protection of Privacy and Transborder Flows of Personal Data.* Australia adopted the

OECD Guidelines in 1984 and the principles in those guidelines were incorporated in the Commonwealth

*Privacy Act 1988* (Privacy Act), which deals with personal information privacy protection, a component of

the broader concept of privacy. However, the right to privacy is not an absolute right. In some circumstances, it must be weighed against the equally justified rights of others and against matters that benefit society as a whole.

The conduct of medical research presents one of these circumstances. Medical research is important

for providing information to help the community make decisions that have an impact on the health

of individuals and the community. However, it should be carried out in such a way as to minimise the

intrusion on people’s privacy. Optimally, this is done by obtaining the informed consent of participants

prior to using their personal information. Where this is not practicable, de-identified information should be

used. Where neither of these options are available, it may be that identified information needs to be used,

even though consent of the individual or individuals has not been obtained, in order for the medical

research to proceed. For further information refer to *Guidelines under Section 95 of the Privacy Act 1988, 2014*

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| **\*** **s95 Guidelines — Commonwealth Agency/ies -** With respect to the above protocol, will data be collected from a Commonwealth agency? If yes, list the commonwealth agency/ies | | | |
| Enter text | | | |
| **\*s95a Guidelines — Private Sector -** With respect to the above protocol, will data be collected from a private sector agency? If yes, list the private sector agency/ies | | | |
| Enter text | | | |
| **\*Clarify what data is being collected and how the data will be used.** | | | |
| Enter text | | | |

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| 1. **CALHN’s ROLE IN THE PROJECT\*** |

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| Provide information regarding CALHN’s role in the project. For example, recruitment requirements, services or departments that will be accessed. (Question must be answered in full not just reference to other documents.) | | | |
| Enter text | | | |

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| 1. **INVESTIGATOR STATEMENT\*** |

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| The Investigator Statement must be submitted together with the protocol submission. The following questions must be addressed in the statement. | | | |
| **\*What is the current standard treatment for this patient population at CALHN/NALHN?** | | | |
| Enter text | | | |
| **What are the overall benefits to the project participant?** | | | |
| Enter text | | | |
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| **What are the risks to the project participant?** | | | |
| Enter text | | | |
| **Are there any other trials in the unit which recruit a similar participant population? If so, how will it be determined as to which project the participant will be recruited into?** | | | |
| Enter text | | | |