**CENTRAL ADELAIDE LOCAL HEALTH NETWORK**

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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 under a review by the Investigational drug and Safety Sub-Committee. (see part 2 and complete  **Submit as supplementary documentation with application via** [**Research GEMS**](https://gems.sahealth.sa.gov.au/Account/SignIn) | | | |

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| |  |  |  |  | | --- | --- | --- | --- | | CPI Name (include title): Enter text | | Protocol No: Enter text | Phase:Enter text | | Study title: | Enter text | | |  |  |  |  | | --- | --- | --- | | Study Site/s | 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 | |
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| 1. **RADIATION** (Q1 - Radiation exposure must be justified by investigators) |

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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 Health HRECs assessing research proposals involving exposure of participants to ionising radiation must be provided with a written report from an accredited medical physicist.   * **If the proposal requires exposure of humans to radiation which is additional to that which would be received as part of their normal clinical management, then this report must contain radiation dose and risk assessment from an accredited medical physicist** as per the Code of Practice for the Exposure of Humans to Ionising Radiation for Research Purposes (2005). * Otherwise the report should confirm the investigator’s statement that all radiation exposure is part of normal clinical management of all participants in the study. | | | | | | **Does the Project involve the use of ionising radiation?** | | | Select one | | |  | | | | | | **Type and site of procedure:** *(PA Chest X-Ray, Brain CT, NM bone scan, FDG PET/CT, Coronary Angio)* | | **Where:** (*TQEH, Jones & Partners Nth Tce, LMH)* | | **How many and when:***(4 total, at screening, weeks 6,12,36)* | | A | Enter text | Enter text | | Enter text | | B | Enter text | Enter text | | Enter text | | C | Enter text | Enter text | | Enter text | |

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| 1. Provide justification for radiation exposure to participants. For example, if exposure is part of SOC or additional to particpants normal clinical management? |
| Enter text |
| 1. Is there the likelihood of any radiation exposure to people other than participants (eg: carers, family or members of the public)? Select one |
| If yes, give the reasons why it is necessary to expose these people for the purposes of research. Provide or reference evidence that investigators are taking precautions to minimise the dose to these people. |
| Enter text |

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| **Certification:** As the CPI/PI/site PI for the above site I have taken into account the body region, type of procedure and the frequency and number of procedures which will be performed on each participant in the project and I certify that: | | | | |
|  | | All participants would receive all the procedures using ionising radiation required by this project even if they were not participating in the project. | | |
|  | | Some/all participants will receive exposure to ionising radiation in addition to that which would be received as part of normal clinical management. | | |
| Name | | Enter text | Phone | Enter text |

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| 1. **INVESTIGATIONAL DRUG SUB-COMMITTEE DRUG CHECKLIST** | | | |

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| **Drug Details or Product Information Sheet attached** | | | | | | Select one | | |
|  | | | | | | | | |
| DRUG | | Generic name | | Trade name | | | Manufacturer | |
| Drug 1 | | Enter text | | Enter text | | | Enter text | |
| Drug 2 | | Enter text | | Enter text | | | Enter text | |
| Drug 3 | | Enter text | | Enter text | | | Enter text | |
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| Will the Sponsor supply the drug for the duration of the Project at no charge to the Hospital? | | | | | | | | Select one |
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| Is there an arrangement for access to the drug after completion of the project? | | | | | | | | Select one |
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| Is the drug marketed by a Regulatory Agency? | | | | | | | | |
|  | Select one | | | | | | | |
|  | Enter text | | | | | | | |
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| Is the proposed indication of the drug used in this project the same as the marketed indication? | | | | | | | | Select one |
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| Does the Investigator’s Brochure contain a large number of individual patient safety reports? | | | | | | | | Select one |
|  | If **Yes**, is there any new safety information in these reports that would alter the overall assessment of safety, as described in the main body of the Investigator’s Brochure, the protocol and the Patient Information sheet? | | | | | | | Select one |
|  | Enter text | | | | | | | |
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| **Formulation/description of drug (include dissolution data for bioequivalence studies)**  Indicate the page number(s) in protocol/ Investigator’s Brochure or provide details: | | | | | | | | |
|  | Enter text | | | | | | | |
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| Is the drug manufactured under Good Manufacturing Practice (GMP) | | | | | | | | Select one |
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| Is the assessment of renal function for inclusion/exclusion criteria defined by estimated creatinine clearance using Cockcroft-Gault equation, rather than serum creatinine?  **If NO, This is a mandatory requirement and may be a site specific amendment** | | | | | | | | 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. **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 | | | | |
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