**CENTRAL ADELAIDE LOCAL HEALTH NETWORK**

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| **Human Research Ethics Committee Submission Covering Letter**  **Clinical Trials (Phase 2/3/4)** | | | |
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| Sections 1 and 2 of this form must be completed by the coordinating Principal Investigator (CPI) for all multi-site projects or the Principal Investigator (PI) for single site projects when submitting a new no phase, Phase 2/3/4/ clinical trial of an investigational drug and or device study to the Central Adelaide Local Health Network Human Research Ethics Committee (CALHN HREC) for ethical and scientific 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 (include title): Enter text | | Protocol No: Enter text | | Phase:Enter text | | Study title: | Enter text | | | | | Institution responsible for protocol/results ownership | | | 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 | |
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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. **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 | | | | |
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