1. **Application Details**

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| **1.1 Study Summary** | |
| **Study Title:** | |
|  | |
| **Study Acronym:** | |
|  | |
| **Study Sponsor:** | |
|  | |
| **Type of Sponsor:** | |
| Commercial sponsor | Collaborative Group  *(not for profit entity, medical research institute, university)* |
| Investigator Initiated | Other, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. **Research Staff**

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| **2.1 Newcastle Private Hospital Applicant Details** |

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| It is the responsibility of the Principal Investigator to ensure that any staff member working on their research project at Newcastle Private Hospital has the necessary experience for their role.  Research staff must participate in ongoing training and education appropriate to their role, and are strongly encouraged to complete and maintain ICH GCP training. |

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| **Principal Investigator:** | **Name:** |  | |
| **Affiliation:** |  | |
| **Phone:** |  | |
| **Email:** |  | |
| **Accreditation:** | Current CV *(within 2 years)* | Current GCP certificate *(within 3 years)* |

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| **Other Investigators:** | **Name:** |  |
| **Affiliation:** |  |
| **Phone:** |  |
| **Email:** |  |
| *NB: All additional investigators involved in a research project at Newcastle Private Hospital must have their own professional indemnity insurance that includes cover for Clinical Trials and Research in the private sector.* | | |

*(copy the below table to add additional investigators participating in the research project at Newcastle Private Hospital)*

|  |  |  |
| --- | --- | --- |
| **2.2 Newcastle Private Hospital - Contact details for correspondence** | | |
| **Study Coordinator:**  (or Third party coordinating study if applicable) | **Name:** |  |
| **Affiliation:** |  |
| **Phone:** |  |
| **Email:** |  |

1. **Study Details**

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| **3.1 Type of Study** | | | | | |
| Please select one of the following to best describe this research project: | | | | | |
| Clinical Trial - Drug | | Clinical Trial - Other | | Health Research | |
| Clinical Trial - Device | | Clinical Registry | | Other, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |
| Please select phase of the research project : | | | | | |
| Phase I | Phase II | | Phase III | | Phase IV |

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| * 1. **Study Duration (enrolment)** | | | |
| Please provide the estimated Start and Finish dates for the enrolment period at Newcastle Private Hospital | | | |
| **Start Date:** |  | **Finish Date:** |  |

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| * 1. **Patient Details** | |
| **Patient Population (Target Group):** |  |
| **Estimated NPH enrolment:** |  |

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| **3. 4 Summary of Research Activities** |
| **Why are you doing this study?** |
|  |
| **Study aims?** |
|  |
| **In practical terms what are you actually going to do with the subjects?** |
|  |
| **Is this a multicentre study? If yes, please advise the number of sites involved.** |
|  |

1. **Patient Safety**

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| * 1. **Research Interventions and Medical Investigations** | |
| **Please indicate which of the following treatments / procedures / interventions on participants this research project involves:** | Investigational Drug / Device  Procedure  Tissue Samples  Blood Samples  Others: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| *If the research involves investigational products or the experimental use of products, which was not yet approved by the TGA, please submit CTN/CTX acknowledgement, listing Newcastle Private Hospital.* | |
| **Please list the interventions / medical investigations involved in this study.** | |
|  | |
| **Please advise who is responsible for providing the investigational product(s) (study treatment) to be used in this study.** | |
|  | |
| **Are any of the interventions / medical investigations potentially harmful? If so, please describe.** | |
|  | |
| **If this study has commenced recruitment at another site, have there been any safety concerns reported?**  **If so, please describe.** | |
|  | |

1. **Patient Consent and Confidentiality**

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| **5.1 Participant’s consent to research activities (please tick all that apply):** |
| **5.1.1 The study requires** (please tick all that apply)**:** |
| Written consent to participate in the specific research study  Consent for access to participants’ NPH medical records  Consent for collection and use of patient’s tissue samples  Waiver of consent approval by HREC  Other, please specify |
| **5.1.2 If patient consent is required, please list below and attach copies of the master and NPH site-specific patient information & consent forms\*** |
|  |
| \*NB: All research approved by NPH governance must have the following NPH complaint statement included in any participant information sheet:  *“The conduct of this study at Newcastle Private Hospital has been authorised by the Newcastle Private Hospital Medical Advisory Committee (MAC). Any person with concerns or complaints about the conduct of this study may also contact the Hospital Quality and Risk Manager on 02 4941 8400.”* |
|  |
| **5.1.3 If patient consent is required, how will participants be identified & approached?** |
|  |
| * *As required, the Newcastle Private Hospital Health Information Manager; Medical Records should be contacted regarding requirements to access patient medical records.* * *Where applicable, the process by which consent for this research project is obtained must be documented in an appropriate place which may include filing a copy of the fully signed Participant Informed Consent Form (PICF) in the participant’s NPH medical record.* |

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| **5.2 Collection and Storage of Research Data** |
| **5.2.1 Is confidential information likely to be obtained in this study? If so, please indicate how confidential information will be protected.** |
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1. **Human Research Ethics Committee (HREC) Review**

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| **6.1 Human Research Ethics Committee Review** |
| **6.1.1 Ethics review application status for NPH** |
| Submitted to HREC for Review\*  HREC Approval Obtained\*\* |
| *\*Ethics approval letters can also be supplied after this form is submitted but must be provided prior to research governance approval being granted by Newcastle Private Hospital.*  *\*\* The ethics approval letter must list Newcastle Private Hospital as a research site.* |
| **HREC Reference Number:** |
|  |
| **Reviewing HREC Name:** |
|  |

1. **Newcastle Private Hospital Site Resources**

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| **7.1 Facility Impact Summary** | | | | |
| **7.1.1 Please list the NPH resources that will be involved / impacted by this research?** | | | | |
| **NPH admissions/ visits / procedures:** | Meeting room  Day Admissions  Outpatient Visits  Surgical Procedure | Overnight Hospital Stay  Pharmacy  Pathology  Radiology | |
| **Are any of these admissions/visits/procedures in addition to standard of care (if yes, please provide further detail?** | | YES | NO |
|  | | | | |
| **NPH staff:** | Clinical Trial Coordinators  Medical staff  Nursing staff | Allied Health staff  Administrative staff  Others,\_\_\_\_\_\_­­­­\_\_\_\_\_\_\_\_ | |
| **The PI and/or study team should make contact with the relevant NPH Manager(s) to discuss any special requirements to be considered for the conduct of the research project at NPH.**  **Please specify below any NPH Manager contacted for this project and any arrangements made.** | | | | |
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1. **Financial and Legal Considerations**

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| **8.1 Financial considerations** | |
| **8.1.1 How is this research to be funded?**  **- Please provide details of any funding that will be given to the facility as a part of the participation in this study;**  **- If funding for the research project is not provided, please provide justifications / arrangements:** | |
|  | |
| **8.1.2 If applicable, who will cover the cost of the investigational drug / device / procedure?**  *(NB: more than one answer may be applicable)* | Standard of care  Private Health Insurance  Sponsor  Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| * 1. **Research Agreements:** | |
| **8.2a Sponsored clinical trials** | CTRA (Medicines Australia)  CTRA – Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Other Research Agreement, \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **8.2b No research agreement required, please justify:** | |
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| **8.3 Indemnity (only applicable to Sponsored Clinical Trials)** | | | |
| **Has the Sponsor provided Newcastle Private Hospital with a Medicine Australia indemnity form?** | YES | NO | N/A |
| **If the Sponsor has not provided an indemnity in this form, please provide justification/context:** | | | |
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| **8.4 Insurance** | | | |
| **8.4a Sponsored clinical trials:**  Has the Sponsor provided a copy of a current certificate of insurance to cover the research activities?  ***If yes****, please attach a copy of a current certificate of insurance.* | YES | NO | N/A |
| **8.4b Research projects where no sponsor is nominated:**  Is the principal investigator covered by insurance for research activities?  ***If yes,*** *please attach a copy of your insurance policy or other evidence that you are covered for research activities* | YES | NO | N/A |
| **If no evidence of insurance is provided, please provide justification:** | | | |
|  | | | |

1. **Signature and Consent of Principal Investigator**

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| **9.1 Signature of Principal Investigator** |
| I certify that:   * The information in this form is truthful, accurate and complete to the best of my knowledge and belief. * If any information in this form changes, I will notify the Regulatory Coordinator at Newcastle Private Hospital ([NPHresearchgovernance@healthscope.com.au](mailto:NPHresearchgovernance@healthscope.com.au)) as soon as practicable and will provide details of the relevant changes.   I acknowledge that if this application for research governance approval is given, a letter of approval will be issued by the General Manager of Newcastle Private Hospital.  I understand that this letter of approval may be subject to conditions relating to the conduct of the research project at the facility.  **Name of the Principal Investigator / delegate:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_    **Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  **Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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| **9.2 NPH Research Governance Fee** | |
| **Where applicable, an invoice will be generated and sent to the study contact for payment once this governance application has been lodged** (*refer to the NPH Research Governance website for fees structure*) | |
| **Please provide the following invoice details:** | |
| **Company Name:** |  |
| **Company Address:** |  |
| **ABN:** |  |

1. **Study Documents**

|  |  |  |
| --- | --- | --- |
| **10.1 Please list below all of the study documents requiring review and approval at NPH:** | | |
| **Document** | **Version and Date** | **Submission**  **Status** |
| **HREC approval/s**  *(noting NPH as a trial site)* | | |
|  |  | included  pending |
|  |  | included  pending |
| **Study Protocols, Investigator Brochures** | | |
|  |  | included  pending |
|  |  | included  pending |
| **Participant Information Sheet and Consent form /s** | | |
|  |  | included  pending |
|  |  | included  pending |
| **CTN/ CTX** *(if applicable)* | | |
|  |  | included  pending |
| **Contracts / Finance / Indemnity** *(if applicable)* | | |
|  |  | included  pending |
|  |  | included  pending |
| **Other:** | | |
|  |  | included  pending |
|  |  | included  pending |