1. **Healthscope Hospital Details**

|  |
| --- |
| **1.1 Name of Healthscope Hospital(s)**  |
| Please provide details of the Healthscope hospital(s) to which this application applies. |
|  |

1. **Application Details**

|  |
| --- |
| **2.1 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**

|  |
| --- |
| **3.1 Applicant Details** |

|  |
| --- |
| It is the responsibility of the Principal Investigator (PI) to ensure that any staff member working on their research project at the Healthscope 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. |

|  |  |  |
| --- | --- | --- |
| **Principal Investigator:** | **Name:** |  |
| **Affiliation:** |  |
| **Phone:**  |  |
| **Email:** |  |
| **Accreditation:** | [ ]  Current CV *(within 2 years)* | [ ]  Current GCP certificate *(within 3 years)* |
| **Other Investigators:** | **Name:** |  |
| **Affiliation:** |  |
| **Phone:**  |  |
| **Email:** |  |
| *NB: All additional investigators involved in a research project at the Healthscope 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)*

|  |
| --- |
| **3.2 Contact details for correspondence** |
| **Study Coordinator:**(or Third party coordinating study if applicable) | **Name:** |  |
| **Affiliation:** |  |
| **Phone:**  |  |
| **Email:** |  |

1. **Study Details**

|  |
| --- |
| **4.1 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 |

|  |
| --- |
| * 1. **Study Duration (enrolment)**
 |
| Please provide the estimated Start and Finish dates for the enrolment period at the Healthscope hospital |
| **Start Date:** |  | **Finish Date:** |  |

|  |
| --- |
| * 1. **Patient Details**
 |
| **Patient Population (Target Group):** |  |
| **Estimated enrolment number** (at the Healthscope hospital)**:** |  |

|  |
| --- |
| **4.4 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**

|  |
| --- |
| * 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 this Healthscope 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**

|  |
| --- |
| **6.1 Participant’s consent to research activities (please tick all that apply):** |
| **6.1.1 The study requires** (please tick all that apply)**:** |
| [ ]  Written consent to participate in the specific research study[ ]  Consent for access to participants’ medical records[ ]  Consent for collection and use of patient’s tissue samples [ ]  Waiver of consent approval by HREC[ ]  Other, please specify |
| **6.1.2 If patient consent is required, please list below and attach copies of the master and the Healthscope hospital site-specific patient information & consent forms\*** |
|  |
| **6.1.3 If patient consent is required, how will participants be identified & approached?** |
|  |
| * *As required, the 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 medical record.*
 |

|  |
| --- |
| **6.2 Collection and Storage of Research Data** |
| **6.2.1 Is confidential information likely to be obtained in this study? If so, please indicate how confidential information will be protected.**  |
|  |

1. **Human Research Ethics Committee (HREC) Review**

|  |
| --- |
| **7.1 Human Research Ethics Committee Review** |
| **7.1.1 Ethics review application status**  |
| [ ]  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.**\*\* The ethics approval letter must list the name of the Hospital as a research site.*  |
| **HREC Reference Number:** |
|  |
| **Reviewing HREC Name:** |
|  |

1. **Hospital Site Resources**

|  |
| --- |
| **8.1 Facility Impact Summary** |
| **8.1.1 Please list the hospital resources that will be involved / impacted by this research?** |
| **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 |
|  |
| **Hospital 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 Hospital General Manager to discuss any special requirements to be considered for the conduct of the research project.**  |
|  |

1. **Financial and Legal Considerations**

|  |
| --- |
| **9.1 Financial considerations** |
| **9.1.1 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:** |
|  |
| **9.1.2 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\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

|  |
| --- |
| * 1. **Research Agreements:**
 |
| **9.2a Sponsored clinical trials** | [ ]  CTRA (Medicines Australia)[ ]  CTRA – Other \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_[ ]  Other Research Agreement, \_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **9.2b No research agreement required, please justify:** |
|  |

|  |
| --- |
| **9.3 Indemnity (only applicable to Sponsored Clinical Trials)** |
| **Has the Sponsor provided the Healthscope 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:** |
|  |

|  |
| --- |
| **9.4 Insurance** |
| **9.4a 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 |
| **9.4b 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**

|  |
| --- |
| **10.1 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 General Manager of the Healthscope hospital 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 the Healthscope 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:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

1. **Study Documents**

|  |
| --- |
| **11.1 Please list below all of the study documents requiring review and approval at NPH:** |
| **Document** | **Version and Date** | **Submission****Status** |
| **HREC approval/s**  |
|  |  | [ ]  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 |