

**CABRINI RESEARCH GOVERNANCE**

LOW RISK & GOVERNANCE REVIEW APPLICATION FORM

**Prior to completing this form, please read the** [**CRGO Handbook**](http://cabrini.com.au/research-and-education/research-ethics/) **and complete a level of risk checklist (**[**Attachment 4**](http://cabrini.com.au/research-and-education/research-ethics/)**).**

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| **1.** | **ADMINISTRATIVE INFORMATION** | | | | | |
|  | **1.1** | **Project Title:** |  | | | |
|  | **1.2** | **Principal Investigator:** | |  | | |
|  | | | | | **Yes** | **No** |
| **Is the Principal Investigator a Cabrini accredited Medical Practitioner?** | | | | |  |  |
|  | | | | | **Yes** | **No** |
| **Is the Principal Investigator a Cabrini staff member?** | | | | |  |  |
|  | | | | |  |  |
| **Note: If** NO**, please provide insurance/indemnity certificate which covers research** | | | | | **Yes** | **No** |
| **Is current certification of GCP training provided?** | | | | |  |  |
| **Note**: All Investigators need to provide evidence of current Good Clinical Practice (GCP) training.  Visit <https://monashpartners.org.au/research-facilitation/good-clinical-practice/> for more information. | | | | | | |

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| **Qualifications:** |  |
| **Project tasks:** |  |
| **Address:** |  |
| **Email:** |  |
| **Telephone:** |  |

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|  | **1.3** | **Student Researcher (if applicable):**  (A student researcher must list a Cabrini supervisor as Principal Investigator above.) |

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| **Name:** |  |
| **Qualifications:** |  |
| **Project tasks:** |  |
| **Address:** |  |
| **Email:** |  |
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|  | **1.4** | **Associate Investigator/s** | | |
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| **Name:** |  |
| **Qualifications:** |  |
| **Project tasks:** |  |
| **Address:** |  |
| **Email:** |  |
| **Telephone:** |  |
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***Repeat table for each additional investigator and provide a CV of all investigator(s)***

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|  | **1.5** | **Study Co-ordinator / Contact for correspondence** | |
| **Name:** | | |  |
| **Project tasks:** | | |  |
| **Qualifications:** | | |  |
| **Address:** | | |  |
| **Email:** | | |  |
| **Telephone:** | | |  |

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|  | **1.6** | **Payment Details** | | | | | | | | | | | | |
|  |  |  | | |  | | | | | | | | | |
|  |  | **If your project is billable, please provide details of the person responsible for payments. An invoice for submission fee will be sent during the review process.** | | | | | | | | | | | | |
| Person responsible for payments: | |  | | | | | | | | | | |
|  |  | **Name:** | |  | | | | | | | | | | |
|  |  | **Position/Title:** | |  | | | | | | | | | | |
|  |  | **Company/organisation:** | |  | | | | | | | | | | |
|  |  | **Address:** | |  | | | | | | | | | | |
|  |  | **Contact phone number:** | |  | | | | | | | | | | |
|  |  | **Contact email:** | |  | | | | | | | | | | |
|  |  |  | | | | | | | **Yes** | | | **No** | | |
|  | **1.7** | **Will the research be conducted at Cabrini?** | | | | | | |  | | |  | | |
|  |  | ***If yes, which site(s)? If no, where will the research be conducted?*** | | | | | | | | | | | | |
|  |  |  | | |  | | | | | | | | | |
|  | **1.8** | **Proposed commencement date** | | | |  | | | |  | |  | | |
|  |  |  | | | | **( dd / mm / yyyy )** | | | | | | | | |
|  | **1.9** | **Expected completion date** | | | |  | | | |  | |  | | |
|  |  |  | | | | **( dd / mm / yyyy )** | | | | | | | | |
|  | **1.10** | **Other information** | | | |  |  | | | | | |  | |
|  |  |  |  | | | | | | **Yes** | | | **No** | | |
|  |  | **1.10.1** | **Is there anything in this project that may conflict with Cabrini Health’s Mission Statement?** | | | | | |  | | |  | | |
|  |  |  |  | | | | | | **Yes** | | | **No** | | |
|  |  | **1.10.2** | **Is there anything in this project which is contrary to the NHMRC *National Statement on Ethical Conduct in Human Research*?** | | | | | |  | | |  | | |
|  |  |  | | | | | | **Yes** | | | **No** | | |
|  |  | **1.10.3** | **Is there anything in the project that may contravene Catholic Health**  **Australia’s Code of Ethical Standards for research?** | | | | |  | | |  | | |
|  |  | ***Ensure that your wording regarding prevention of conception complies with our Guidelines -***  ***Refer to CRGO Handbook.***  ***If the answer to any of the above questions is yes, the application will be considered only when the researcher clarifies why this is necessary.*** | | | | | |  | | |  | | |

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|  |  |  |  | | | | **Yes** | **No** |
|  |  | **1.10.4** | **Have you sought approval to conduct this research from the relevant**   1. **Cabrini Research Academic Head of Department; and** 2. **Cabrini Clinical Craft Group Head?** | | | |  |  |
|  |  | ***If YES, provide evidence of their support. If NO, indicate why. 2 x YES/NO tick boxes*** | | | | |  |  |
|  |  |  | | | | | **Yes** | **No** |
|  |  | **1.10.5** | **Has this project been peer reviewed?** | | | |  |  |
|  |  | ***If YES, indicate who conducted the peer review, advise if recommendations were adopted, and provide evidence. If NO, indicate why. Retrospective data audits do not require peer review.*** | | | | |  |  |
|  |  |  | | | | | **Yes** | **No** |
|  |  | **1.10.6** | **If this is a clinical trial, have you registered?** | | | |  |  |
|  |  | ***All drug or device clinical trials must be registered with the*** [***Therapeutic Goods Administration***](http://www.tga.gov.au/)***. Clinical trials must also be published on a WHO Registry Network public platform e.g.*** [***https://clinicaltrials.gov/***](https://clinicaltrials.gov/) ***or*** [***www.anzctr.org.au***](http://www.anzctr.org.au)***. Attach evidence of registration for both, ensuring Cabrini is listed as a recruitment site. A CTN acknowledgement must be provided once issued by the TGA.***  **CTN / CTX Number**   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   **Date (dd/mm/yy)**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |   **Clinical Trials Registration Number (clinical trial public registry)**   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |   **Date (dd/mm/yy)**   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  | | | | | | | |
|  |  |  |  | | | | **Yes** | **No** |
|  | **1.11** | **Have other HRECs considered this project?** | | | | |  |  |
|  |  | ***Provide details of the progress of each approval and attach approval letter(s).*** | | | | |  |  |
|  |  | **Single Site Study** | | 🞏 **Yes** 🞏 **No** | **Multi site study** | 🞏 **Yes** 🞏 **No** | | |
|  |  | **Lead Site** | |  | **Coordinating Principal Investigator** |  | | |
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|  |  | **HREC** | | | **Status of Approval (e.g. ‘Approved [date]’ or ‘Pending’)** | | | |
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|  |  | ***Add or delete rows as needed*** | | |  | | | |

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| **2.** | **RESOURCES** | | | | | |
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|  | **2.1** | **How is the project being financed? *If funded by an internal or external grant, provide a copy of the offer letter or funding agreement and a Cabrini finance reference code if already assigned, otherwise a finance reference code will be arranged).*** | | | |  |
|  |  | | | | | |
|  |  |  | | **Yes** | **No** | |
|  | **2.2** | **Is Cabrini Health expected to provide any funding for this project?** | |  |  | |
|  |  | | | **Yes** | **No** | |
|  | **2.3** | **Is Cabrini Health expected to provide any staff time for this project?** | |  |  | |
|  |  | | | **Yes** | **No** | |
|  | **2.4** | **Is Cabrini Health expected to provide any facilities for this project?** | |  |  | |
|  | ***If the answer to any of these questions is yes, attach a completed project resourcing and costing template (Attachment 3) from the authorised person indicating her/his willingness to make the necessary resources available.*** | | | | | |
|  | **2.5** | | **Please attach a project budget. *Include any anticipated costs and income such as per patient payments, if applicable.*** | | | |

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| **3.** | **PROJECT SUMMARY** | | | | | | | | | | | | |
|  | **Give a brief plain language summary of the project including aim/hypothesis and rationale relating to current literature. If there is more than one arm or multiples phases, provide a flow chart to illustrate project progression.**  ***The summary should be in plain (grade 8 level) language suitable to be read and understood by laypersons.***  ***Applications will not be considered by the Committee if the language is complex.*** | | | | | | | | | | | | |
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| **4.** | **PROJECT DETAILS** | | | | | | | | |
|  | **4.1** | **Recruitment** | | | | | | | | | | | |
|  |  |  | | | | | | | | **Yes** | | **No** | |
|  |  | **4.1.1** | **Can this study be undertaken without using human participants?** Refer to the National Statement’s definition of ‘human participation in research’ which includes involvement in surveys / interviews / focus groups, psychological / physiological / medical testing, observation, researcher access to a participant’s personal documents and information, and collection / use of body organs / tissues / fluid. HREC approved waiver of consent still constitutes human participation. | | | | | | |  | |  | |
|  |  | ***If yes, please explain why this approach is not being adopted.*** | | | | | | | | | | | |
|  |  | **4.1.2** | **Please provide details of the participants in the table below:** | | | | | | | | | | |
|  |  |  | | | | | | | | | | |  |
|  |  | **Number at this site** | |  | **Number across all sites** |  | **Age**  **Range** |  | **Gender**  **(M/F)** | |  | | |
|  |  | **Source of recruitment**  e.g. Researcher’s rooms, nursing staff, inpatient, other | | | | | | | | | | | |
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|  |  | **Inclusion Criteria** | | | | | **Exclusion Criteria** | | | | | | |
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|  |  | ***Add or delete rows as needed*** | | | | |  | | | | | | |
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|  | **4.2** | **Informed consent** | | | | | | | |  | |  | |
|  |  |  | | | | | | | | **Yes** | | **No** | |
|  |  | **4.2.1** | **Does the study involve using identified or potentially identifiable information?** | | | | | | |  | |  | |
|  |  | ***If yes, please explain why.*** | | | | | | | | | | | |
|  |  |
|  |  | **4.2.2** | **How will the names of potential participants be obtained?** | | | | | | | | | | |
|  |  | ***If through medical records, hospital or other databases, how will permission to review such records/databases be obtained?*** | | | | | | | | | | | |
|  |  |  |  | | | | | | | **Yes** | | **No** | |
|  |  | **4.2.3** | **Will you be seeking consent from all participants of the project**  **(including patients whose records are to be reviewed)?** | | | | | | |  | |  | |
|  |  | ***If no, provide justification for a waiver of consent by addressing each point under 2.3.10 of the National Statement.*** | | | | | | | | | | | |

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|  |  |  |  | **Yes** | **No** |
|  |  | **4.2.4** | **Will each participant be capable of giving informed consent?** |  |  |
|  |  | ***If no, the project is not low risk. For minors, refer to Chapter 4.2 of the National Statement.*** | | | |
|  |  |  | | | |
|  |  | **4.2.5** | **Please attach a participant information and consent form** | | |
|  |  | ***Please note that the form should have a footer with the name of the document, version number, date, page number and number of pages on each page.*** | | | |
|  |  | **4.2.6** | **Describe the process for obtaining consent including when and how the explanation of the project will be given to potential participants, who will conduct the consenting process and how they will ensure that participants are able to make a free and informed decision to participate** | | |
|  |  |  | | | |
|  | | **Yes** | **No** |
|  |  | **4.2.7** | **Will any special relationship exist between the recruiter and the participants?** e.g. doctor/patient, employer/employee, supervisor/worker/student |  |  |
|  | | ***If yes, how will this be managed?*** | | | |
|  | | | | **Yes** | **No** |
|  |  | **4.2.8** | **Is it clearly documented that participants may withdraw from the project at any time?** |  |  |
|  | | ***If not, why not?*** | | | |
|  |  | **4.2.9** | **How will this provision be drawn to the attention of participants?** | | |
|  | |  | | | |
|  | **4.3** | **Demands on participants** | | | |
|  |  | **4.3.1** | **Describe all the procedures to be conducted with participants which are specifically for this project (i.e. outside of standard of care)** | | |
|  |  |  | | | |
|  |  | **4.3.2** | **What demands, inconvenience or discomfort will be involved for the participants?** | | |
|  |  | ***Explain the number of visits, surveys etc., time commitment, possible dangers, risks, side effects of the procedures and compare this to standard of care*** | | | |
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| **5.** | **ETHICAL COMMITTEE ISSUES – data storage and protection** | | | | |
|  | **5.1** | **Storage of information about participants during and after completion of the project** | | | |
|  |  |  | | | |
|  |  | **5.1.1** | **In what formats and where will the information be stored during and after the research project and who will have access?** | | |
|  |  |  | | | |
|  |  |  | | **Yes** | **No** |
|  |  | **5.1.2** | **Will the information stored at the completion of the project be identifiable?** |  |  |
|  |  | ***If yes, explain why?***  ***If no, describe how it will be de-identified.*** | | | |
|  |  | **5.1.3** | **For how long will the information be stored after the completion of the project and why has this period been chosen?** | | |
|  |  |  | | | |
|  |  | **5.1.4** | **How do you intend to disseminate the results of the project?** | | |
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**Please note: Sections 6 and 7 may not apply to your project.**

* **If the project involves any drug or therapeutic device or use of human tissue, complete the relevant section(s).**
* **If a section does not apply, select ‘No’ at the start, delete the rest of the section and go to the next section.**
* **If the project involves human genetic research or ionising radiation, the project is not low risk and full HREC review will be required by a registered ethics committee.**
* **Section 8 (Declaration) must be completed and submitted with all investigator signature(s).**

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| **6.** | **DRUGS AND THERAPEUTIC DEVICES** | | | | |
|  |  |  |  | **Yes** | **No** |
|  | **6.1** | **Does this project involve trial of a drug?** | |  |  |
|  |  | | | **Yes** | **No** |
|  | **6.2** | **Does this project involve trial of a therapeutic device?** | |  |  |
|  |  | | | | |
|  |  |  |  | **Yes** | **No** |
|  | **6.3** | **Does the research involve a practice or intervention which is an alternative to a standard practice or intervention?** | |  |  |
|  |  | | |  | |
|  | **6.4** | **What drug(s) or device(s) is/are involved in the project?** | | | |
|  |  | | | | |
|  | **6.5** | **What is the status of registration of the drug or device with the Therapeutic Drugs Administration?** | | | |
|  | ***If the drug(s)/device(s) is/are registered, indicate under what name*** | | | | |

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| **7.** | **HUMAN BIOSPECIMENS** | | | |
|  |  |  | **Yes** | **No** |
|  | **7.1** | **Does this project involve the collection and use of human biospecimens such as skin, saliva, hair, blood, bone, tissue and urine?** |  |  |
|  | ***If yes, complete Section 6***  ***If no, delete the rest of Section 6 and go to Section 7*** | |  | |
|  | **7.2** | **How will the collected biospecimens be labelled i.e. will any identifying information such as name or UR be included?** | | |
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|  | **7.3** | **Will any identifying information be recorded elsewhere?** | | |
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| **8.** | **DECLARATION** | | | | | |
|  | **I/we the undersigned, have read the Cabrini Health Mission Statement, the current NHMRC National Statement on Ethical Conduct in Human Research, the Catholic Health Australia Code of Ethical Standards for Catholic Health and Aged Care Services in Australia, and the Cabrini Research Governance Handbook, and accept responsibility for the conduct of the research detailed above, in accordance with the principles contained therein and any other conditions laid down.**  **Where appropriate, the Associate Investigator will assume responsibility for the project in the absence of the Principal Investigator.**  **I/we agree to the project documentation being audited by the Cabrini Research Governance Committee from time to time.**  **I/we agree to notify the Committee immediately in writing of any changes to the protocol, plain language statement or project personnel after it has been approved.** | | | | | |
|  |  |  | | | |  |
|  | | | **NAME:** | **SIGNATURE:** | **DATE:** | |
| **Principal Investigator** | | |  |  |  | |
| **Associate Investigator** | | |  |  |  | |
| **Student Investigator** | | |  |  |  | |
| ***Add or delete rows as needed*** | | |  |  |  | |