ALFRED HOSPITAL ETHICS COMMITTEE

Application for Ethical Review of single site Low Risk Projects

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| **A. GENERAL INFORMATION** | |
| **PROJECT TITLE** |  |
| **Sponsor** | **Nominate the organization responsible for the conduct of this project:**  **Alfred Health**  **Monash University**  **Baker Heart & Diabetes Institute**  **Burnet Institute**  **Other: (provide details)** |

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| **PRINCIPAL INVESTIGATOR** | Name & Title/Position: | |
| Phone:  Mobile: | Mobile: |
| Email: | |
| Department & Campus: | |
| Monash University appointment:  Staff Member  Honorary Staff Member  *(if applicable)* | |

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| **STUDENT INVESTIGATOR** | Name: | University: |
| Email: | Mobile: |
| Course title and course code | |
| Describe what the student will do in the context of this project | |
| **ONLY COMPLETE FOR STUDENT INVESTIGTOR AT ALFRED HEALTH (refer to the** [**website**](https://www.alfredhealth.org.au/research/ethics-research-governance/essential-elements-for-research-applications/being-a-researcher-at-Alfred-Health)**)**  Is the student also an employee of Alfred Health? Yes  No  If ‘Yes’, what position & department/unit:  There is a Student Clinical Placement Agreement between Alfred Health and the student’s tertiary institution: Yes  No  **If “no” refer to the link above for further instructions**  If “yes”, is the student’s course included in the Student Clinical Placement Agreement via a Schedule?  Yes  No  **If “no”, this will need to be arranged, refer to the link above**  If “yes” confirm the student has completed a [*Student Undertaking*](https://www.health.vic.gov.au/education-and-training/standardised-student-induction-protocol)*.* Yes | | |

**Additional investigators/assistants** *(Duplicate as required)*

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| Name & Title/Position: | Department/Institution: |
| Email: | Phone: |
| Describe what this person will do in the context of this project | |

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| **Do any members of the research team have any financial or non-financial interests related to this research?** Alfred Health researchers can refer to institutional policy and guidelines on competing interests via PROMPT  **Yes**  **No**  (If yes, provide details) |

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| **Has there been consumer engagement in the research design? Yes**  **No**  If “yes” tick all that apply:  **Committee membership**  **Survey**  **Consumer association**  **Other (provide details)** |

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| **B. PROJECT DETAILS/PROPOSAL** |
| **1 Aims and objectives:** |
| **2 Explain the proposed research procedures and outcome measures.**  *(Include justification for why this is ‘low risk’ if the project involves activities from the Low Risk Guideline, Checklist 2)* |
| **3 Human Biospecimens\***  **For projects that involve use of biospecimens (e.g. body fluids or tissue)**  **Biospecimen Addendum included** **Not applicable**  *\*Biospecimens may be fresh, stored/banked, or left-over clinical/surgical/autopsy samples* |
| **4 Proposed project time-frame: Commence Month / Year to Month / Year** |
| **5 Participant details**  **Age**:  **Gender**:  **Participant Type/ Diagnostic group**:  **Number of participants/Records/Samples**:  *Duplicate this section if there is more than one participant group.* |
| **6 Selection and/or Recruitment**  i) how the number of participants/records/samples was decided ii) how they are selected iii) how they are identified iv) if there will be recruitment of participants, how they will be approached and by whom.  *Duplicate as required.* |
| **7 Possible risks to participants, investigators, clinicians, research assistants or the institution?**  **Describe any perceived risks and the measures to be taken to minimise these.** |
| **8 Anticipated benefits**  **Describe the potential benefit/s to participants, profession, the institution, society etc.** |
| **9 Impact of findings**  **Describe the likely impact, if any, of negative or positive findings.** |
| **10 Alteration to routine care**  **Describe any alteration to routine care or service provided to individuals and how it may affect them.** |
| **11 If the research/activity involves randomisation, placebo control or withholding/ substitution of treatment, programs or services (health, educational, commercial, other), please describe.** |
| **12 Other ethical issues** |

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| **C. DATA MANAGEMENT AND PRIVACY (Refer to the** [National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)**, Section 3, Element 4)** |
| **1. Data sources**  **(a)** **List all sources of information/data for this project:**  **(b) If the project involves accessing and/or collecting health information (e.g. medical records), who will access this?**  Name/s:  **(NB For research involving accessing Alfred Health medical records, complete the** [**Health Information Services request form**](https://www.alfredhealth.org.au/research/ethics-research-governance/use-of-hospital-resources-for-research) **and submit the fully signed form with this application)**  **(c) Would the person accessing the information normally have access to these data sources through their daily work?** **Yes**  **No**  *(Provide details)* |
| **2. Privacy**  **(a) At the time of data collection, the dataset will be:**  **Identifiable** *Go to (b) & (c) below*  **Coded/re-identifiable** *Go to (c) below*  **Non-identifiable/anonymous** *Go to 3*  **(b) Explain how the identifiable data will be dealt with once data has been collected:**  **(c) Who will retain the document containing the identifiable data connected to the study code and where will it be stored?**  *If relevant, provide a copy of the data collection form or a data dictionary with the application.* |
| **3. Provide a detailed data management plan**  **Include detailed information about:**   * *Data collection (how the information will be collected and by whom)* * *Data management (how and where information will be stored, who will have access, disclosure and use, plans for sharing and data transfer* * *Proposed data linkage – sources of information and who will link the data* * *Data analysis* * *Any plans for future use of data and/or follow up research* * *Plans for* [*archiving*](https://www.alfredhealth.org.au/research/ethics-research-governance/post-approval-project-management/archive-a-project) *and secure destruction(usually 7 years for low risk projects)* * *This section should include details of all software/IT that will be used for all aspects of the data management. If data sharing is proposed, state the proposed data transfer method.* |
| **4. Plans for publication or sharing the findings**  **(a) What, if any, publication (conference, news media, academic journal, etc.) is planned?**  **(b) Will participants be informed about any envisaged research publication/outcome? If yes, how?**  **(c) Will any participants be able to be identified through the publication of research findings? If so, explain why this is necessary.** |

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| **D. CONSENT** *Note: for consent relating to already-collected biospecimens see Biospecimen Addendum* |
| **How will participants be informed about the project in order to give valid consent and what method of consent is to be used?**  *Check the process that applies by double clicking on the box icon.*  *If there is more than one participant group/consent process please click on the box icon and insert the participant group.*   1. A Participant Information & Consent Form (PICF) will be used. 2. An Information Statement will be provided and consent implied by participation e.g. the return of a questionnaire, participation in an on-line activity. 3. An Information Statement will be provided and verbal consent obtained. *Explain how and why*: 4. An Information Statement will be provided via an ‘Opt-out’ process. *Explain how and why with reference to the criteria in Section 2.3 of the* [*National Statement*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)*.* 5. Verbal advice and verbal consent. *Explain how and why*: 6. Participants previously provided consent in another research project for future use of the data for research. *State the project number and/or title & attach a copy of the PICF/s used in that project*: 7. A waiver of the requirement of providing information and obtaining consent is requested. *Applicants should justify the request with reference to the relevant criteria in Section 2.3 of the* [*National Statement*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023) 8. The project involves **access, collection and use of only non-identifiable** data from a registry or database so consent is not required.   *State who is the custodian of the Registry/database & what arrangements are in place for the provision of the non-identifiable data:*   1. This is an **Alfred Health project that involves previously collected clinical information** (Health Privacy Principle 2, [Health Records Act 2001](https://www.legislation.vic.gov.au/in-force/acts/health-records-act-2001/046))**.** It is impracticable to obtain consent AND the purpose of this project is to address one or more of the following internal health service provision purposes:   funding of the health service  management of the health service  planning of the health service  monitoring of the health service  improvement of the health service  evaluation of the health service  *State the original reason the data was collected and why it is impracticable to obtain patients’ consent.* |

**E. FUNDING, AGREEMENTS & OTHER RESOURCES**

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| **1** | **Is there going to be collaboration or involvement of researchers from other organisations?** | **Yes  Name of institution/organisation:**  **Details of involvement**:  **Is there a research agreement?**  **Yes  No**  **If “yes” provide a draft of the research agreement with the application (for projects involving Alfred Health only).** |
| **2** | **Funding/resources** | 1. **Amount: (specify or state “in kind”)** 2. **Source of funding/resources:** (e.g. departmental, grant, commercial sponsor) 3. **Fees:** (Review fees may be applicable, refer to the [fee schedule](https://www.alfredhealth.org.au/research/ethics-research-governance/research-fees-payment)   **Not applicable (no payment form required)**  **Yes, payment form attached** |
| **3** | **Nurses involvement (for Alfred Health projects only)**  ***Note that*** [*Nursing Review*](https://www.alfredhealth.org.au/research/ethics-research-governance/use-of-hospital-resources-for-research) ***is required BEFORE the project is submitted for ethics review*** | **Will the research use nursing resources, or involve nurses as research subjects?**  **Yes  No**  **If ‘Yes’ please include the fully signed Nursing Resource form** |
| **4** | **Research IT Security review**  **(Complete this section for all projects involving Alfred Health)** | **Will the research involve use of systems with an Information Technology component? Examples include hardware, software, transcription services, data analysis software, data transfer software, apps.**  **Yes  No**  **If ‘Yes’ please refer to the ‘Research Information Technology (IT) guideline in PROMPT.**  **Is the ‘Research IT Security Clearance form’ required?**  **Yes  No**  **If “yes” complete and submit the application for review.**  **Note the ethics review can proceed with the IT review pending.** |
| **5** | **Other resources/departments supporting the research.** | **List and provide the evidence of support/approval with the application.**  **Note that some departments have a specific** [**form or application**](https://www.alfredhealth.org.au/research/ethics-research-governance/use-of-hospital-resources-for-research)**.**  **Otherwise provide evidence of support via Section F.** |

**F. SIGNATURES**

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| **PROJECT TITLE** |  |

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| **Principal Investigator Declaration** | | | | |
| **The information supplied in this application is a true and accurate account of the project and is provided with sufficient clarity to enable review. I agree to take full responsibility for this project and to undertake the research activity and handle data confidentially in accordance with the requirements of [*insert name of relevant institution e.g. Alfred Health*] the National Statement on Ethical Conduct in Human Research 2023 and the Alfred Hospital Ethics Committee, including any special ethical conditions.** | | | | |
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| **NAME** |  | **SIGNATURE:** |  | **DATE:** |
| **Head of Department Statement**  ***If the HoD is named as an investigator on this project then independent sign-off must be provided.***  **I have read the application and confirm that this project: has been developed and will be conducted in accordance with relevant [*Insert name of institution e.g. Alfred Health, Burnet Institute*] standards, policies and codes of practice; has research merit; has adequate resources and appropriate leadership/supervision.** | | | | |
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| **NAME & POSITION** |  | **SIGNATURE:** |  | **DATE:** |

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| **Endorsement by Head of Supporting Department (if applicable)**  ***Duplicate this section as required.***  **I have discussed this project with the Principal Researcher and have considered the relevant application documents and protocol. I endorse this research project.** | | | | |
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| **NAME & POSITION** |  | **SIGNATURE:** |  | **DATE:** |