

**Attachment 3**

Application for Ethical Review of single site Low or Negligible Risk

|  |
| --- |
| **1. GENERAL INFORMATION** |
| **PROJECT TITLE** |  |
| **Project Category**  | **🞏** Negligible Risk Research**🞏** Low Risk**🞏** Clinical Audit/QA |
| **PRINCIPAL****INVESTIGATOR** | Name & Title/Position: |
| Phone: Mobile: | Mobile: |
| Email:  |
| Department:  |
| Calvary Health Care Status: [ ]  Staff Member [ ]  Honorary Staff Member*(if applicable)* |
| **STUDENT INVESTIGATOR & STUDENT PLACEMENT DETAILS** | Name:  | University:  |
| Email:  | Mobile:  |
| Course title/qualification |
| Is this research project being used towards that qualification? Yes [ ]  No [ ] Provide details: |
| Is the student an employee of Calvary Health Care Bethlehem? Yes [ ]  No [ ] If ‘Yes’, what position & department/unit:  |
| Is there a *Student Placement Agreement* between Calvary Health Care Bethlehem and the student’s tertiary institution? Yes [ ]  No [ ]  |

**Additional Investigators/Assistants** *(Copy & paste cells as required)*

|  |  |
| --- | --- |
| Name & Title/Position:  | Department/Institution:  |
| Email:  | Phone: |
| Role on this project: |

|  |  |
| --- | --- |
| Name & Title/Position:  | Department/Institution:  |
| Email:  | Phone: |
| Role on this project: |

|  |
| --- |
| **2. PROJECT DETAILS** |
| **2.1** | **Please complete each section of this form to give a detailed description of the project** |
|  | **Version and Date:**  |
| **2.2** | **Project time-frame** | **From Month / Year to Month / Year** |
| **2.3** | **Background and Rationale** |  |
| **2.4** | **Aims and Objectives** |  |
| **2.5** | **Methodology**  |  |
| **2.6** | **Selection and Recruitment methods:*** **Explain how you will identify participants**
* **How will you invite participants to participate**
* **How will participants be informed about the project in order to give valid consent**
* **What method of consent is to be used** *(Tick box and attach relevant information)*

**[ ]**  **A Participant Information & Consent Form (PICF) will be used**[ ]  **An Information Statement will be provided and consent implied by participation e.g. the return of a questionnaire; participation in an on-line activity.** [ ]  **An Information Statement will be provided and verbal consent obtained.**[ ]  **An Information Statement will be provided via an ‘Opt-out’ process.****[ ]**  **The project involves access, collection and use of only non-identifiable data from a register or database so consent is not required.****[ ]**  **Other (please explain)**  |  |
| **2.7** | **Data Collection Methods:*** **The method that you will use to collect or gain access to the data/samples that you will use in the research.**
* **The method you will use to record the data during collection**
* **How you intend to analyse the information**
 |  |
| **2.8** | **Risks and Ethical Issues/Considerations*** **What are the public benefits of this project and relevance to clinical care?**
* **What are the possible risks, burdens or inconvenience that the participants may experience? How will they be addressed? Are there any risks to privacy?**
 |  |
| **2.9** | **Publication and reporting of results*** **Provide a short description on how and where you intend to report the results of the research.**
* **Please explain how the research participants will be provided with a copy of the results.**

**If they will not be provided a copy of the results, explain why.** |  |
| **2.10** | **Funding/budget (if applicable)** | 1. **Amount:**
2. **Source of funding/funding body:** (e.g. departmental funds, grant, commercial sponsor)
3. **Fees:** (Review fees may be applicable, refer to the research guidelines

[**https://www.calvarycare.org.au/public-hospital-bethlehem/wp-content/uploads/sites/5/2016/05/CHCB-Research-application-guidelines-for-researchers\_2017.pdf**](https://www.calvarycare.org.au/public-hospital-bethlehem/wp-content/uploads/sites/5/2016/05/CHCB-Research-application-guidelines-for-researchers_2017.pdf)**Not applicable (no payment form required) [ ]** **Yes, payment form attached [ ]**  |
| **2.11** | **Research Coordinator involvement** | **Will the research be conducted by research nurses, use research nursing resources):****Yes [ ]  No [ ]** **If ‘Yes’ please include evidence of Nursing Research approval.** |

|  |
| --- |
| **3. PRIVACY Access & collection, identifiers, use, disclosure, storage and publication of information** |
| **3.1** | **Description of the type of data to be collected and used****Provide a description of the data that will be collected.** | **🞏 Personal Information****🞏 Health Information****🞏 Sensitive Information** |
| **3.2** | **In what form will data be used or stored?** **If potentially identifiable, provide justification.** **Does the project team have regular access to the record?** | **🞏 Identifiable or potentially identifiable****🞏 Re-identifiable****🞏 Non-identifiable/anonymous** |
| **3.3** | **How, where and for how long will data be stored?**  |  |
| **3.4** | **What will happen to the data at the end of the retention period? How will data be destroyed?** |  |
|  |  |  |
| **4. Governance Considerations** |
| **4.1** | **Are other organisations involved in the project?** | **🞏 Yes; please list:****🞏 No** |
| **4.2** | **Have all organisations involved agreed to provide relevant information?**  | **🞏 Yes****🞏 No** |
| **4.3** | **Will non-identifiable data be provided from or to a third party?** *(If applicable, ensure that a material transfer agreement is put in place)* | **🞏 Yes****🞏 No** |

**6. SIGNATURES**

|  |
| --- |
| **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 Calvary Health Care, the National Statement on Ethical Conduct in Human Research 2007 and the Calvary Health Care Bethlehem Research Ethics and Ethics Committee, including any special ethical conditions.** |
|  |  |  |  |  |
| **NAME: (block letters)** |  | **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 Calvary Health Care Bethlehem standards, policies and codes of practice; has research merit; has adequate resources and appropriate leadership/supervision.** |
|  |
|  |  |  |  |  |
| **NAME & POSITION: (block letters)** |  | **SIGNATURE:** |  | **DATE:** |

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

**7. APPLICATION CHECKLIST**

Please complete this application checklist before submitting your application and attach the relevant documents to your email. Refer to the [Research Ethics and Ethics Committee](https://www.calvarycare.org.au/public-hospital-bethlehem/services-and-clinics/research/) website for document templates and forms.

|  |  |  |  |
| --- | --- | --- | --- |
| **Document to be used in the project** | **Yes** | **No** | **N/A** |
| Data collection sheet | **[ ]**  | **[ ]**  | **[ ]**  |
| Questionnaire/s | **[ ]**  | **[ ]**  | **[ ]**  |
| Participant Information Sheet | **[ ]**  | **[ ]**  | **[ ]**  |
| Participant Information & Consent Form | **[ ]**  | **[ ]**  | **[ ]**  |
| Cover letter &/or email (to participants) | **[ ]**  | **[ ]**  | **[ ]**  |
| Advertisement | **[ ]**  | **[ ]**  | **[ ]**  |
| Flyer &/or brochure | **[ ]**  | **[ ]**  | **[ ]**  |
| **Additional application documents** | **Yes** | **No** | **N/A** |
| Services form and Declarations | **[ ]**  | **[ ]**  | **[ ]**  |
| Research Agreement | **[ ]**  | **[ ]**  | **[ ]**  |
| Ethics & Governance payment form | **[ ]**  | **[ ]**  | **[ ]**  |
| Other *(specify)*: | **[ ]**  | **[ ]**  | **[ ]**  |

**SUBMITTING YOUR APPLICATION:**

* Please email the completed form/s and any relevant documents to BET-REEC@calvarycare.org.au

and send one hard copy to Executive Assistant, CHCB, 152 Como Parade West, Parkdale 3195