## PROJECT OVERVIEW

### **Project title**

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### **Description of proposed activity**

Prospective collection of data from:

[ ]  Routine clinical data

[ ]  Survey or questionnaire

[ ]  Interview or focus group

AND/OR

Collection of data from existing records:

[ ]  Clinical data (non-identifiable/anonymous);

[ ]  Clinical data (to be de-identified by clinical team); or

[ ]  Research data

[ ]  Other (please specify) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

### **Project plan**

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| --- | --- |
| **Version Date:**  | **Version Number:**  |
| **Project Protocol** * **Attach or include a detailed description of the project comprising of:**
* *Background & rationale*
* *Aims & objectives*
* *Methodology for the collection of data*
* *Recruitment details (if prospective data collection)*
* *Privacy, storage and disposal of data*
* *Data use and analysis*
* *Risks & Ethical Issues (including mitigation and management)*
* *Dissemination plans*
 |
| **Data Details (use, collection, storage and disposal)*** **Type of data to be collected and used**

[ ]  Personal Information[ ]  Health Information[ ]  Sensitive Information* **Provide a description of the data that will be collected.**

*If applicable, also describe the details of collection and/or use of information, if data is being sought from a third party.* * **Source of the data**

[ ]  Epworth Medical Records[ ]  Private practice [ ]  Other (please clarify) * **In what form will data be accessed?**

[ ]  Identifiable (or potentially identifiable) [ ]  Re-Identifiable [ ]  Non-identifiable/anonymous* **In what form will data be used and stored?**

[ ]  Identifiable (or potentially identifiable) [ ]  Re-Identifiable [ ]  Non-identifiable/anonymous* **When data is NOT being accessed, used and/or stored in a non-identifiable form, provide detail and justification for needing to be identifiable or re-identifiable (and to whom).**
* **If project team members will be accessing identifiable health information, do they have regular access to the data as part of their employment at Epworth?**

[ ]  Yes[ ]  No* **What type of consent will be sought?**

[ ]  No consent required (accessing non-identifiable data only) [ ]  Impracticable to obtain consent (for identifiable data, or data that willbe de-identified by the clinical team), **justify:**[ ]  Consent from participant (implied consent, verbal, written consent) [ ]  Other, provide details:* **How many participants (or records) will be recruited/accessed?**

*Express as a specific (maximum) number or as a range.** **How, where and for how long will data be stored?**

*Ensuring compliance with the Health Records Act (Vic) (2001) & Australian Code for the Responsible Conduct if Research as applicable.** **What will happen to the data at the end of the retention period?**

*e.g. how or will it be destroyed* |

## ETHICAL CONSIDERATIONS

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| * **What are the public benefits of this project and relevance to clinical care?**

*i.e. will this project generate new information that will have direct implications for patient clinical management?** **What are the possible risks, burdens or inconveniences that the participants may experience?**

*Describe any foreseeable ethical issues and how they will be addressed, including any risks to privacy.* |

## GOVERNANCE CONSIDERATIONS

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| * **Are other organisations involved in this project?**

[ ]  No [ ]  Yes; please list:* **Have all organisations involved, as listed above, agreed to participate in the project and have/will obtain local ethics and governance authorisation?**

[ ]  Yes [ ]  In progress[ ]  No; please explain: [ ]  N/A* **Will Epworth data be provided to a third party (external) organisation?**

*If there is a transfer of data, ensure that the site-information is completed and an appropriate agreement is put in place.*[ ]  Yes [ ]  No [ ]  N/A* **If yes, in what format will that data be provided to the third party?**

[ ]  Identifiable (or potentially identifiable) [ ]  Re-Identifiable [ ]  Non-identifiable/anonymous[ ]  N/A* **Are there any resourcing or financial implications associated with undertaking this project?**

[ ]  No [ ]  Yes\*; please provide details:* **Have you discussed the project with and sought support from the relevant directors/managers/clinicians at Epworth?**

[ ]  Yes, please provide names [ ]  Not applicable; please explain: |

## INVESTIGATIONAL TEAM

**Principal Investigator**

|  |  |
| --- | --- |
| **Title and name** |  |
| **Epworth appointment** |  |
| **Epworth site(s)** |  |
| **Phone** |  |
| **Email** |  |
| **Researcher Credentialed** | [ ]  Yes [ ]  No  |

**Co-Investigator/Author** *(Copy/paste cells as required for additional investigators)*

|  |  |
| --- | --- |
| **Title and name** |  |
| **Epworth appointment** |  |
| **Epworth site(s)** |  |
| **Phone** |  |
| **Email** |  |
| **Researcher Credentialed** | [ ]  Yes [ ]  No |

*Note: A representative from each department involved in the project should be included.*

**Student Investigator/Author** *(If applicable)*

|  |  |
| --- | --- |
| **Name**  |  |
| **University** |  |
| **Role in this project** |  |
| **Email address** |  |
| **Epworth supervisor**  |  |
| **Qualification being undertaken** |  |
| **Has a student confidentiality agreement been signed?** | [ ]  Yes [ ]  No, provide details: |

## DECLARATION AND SIGNATURES

**I/We, the authors identified below, undertake:**

1. To observe the principles laid down in National Clinical Trials Governance Framework (NCTGF), the most recent NHMRC Statement on Ethical Conduct in Human Research, Australian Code for the Responsible Conduct of Research and The Declaration of Helsinki.
2. All Investigators/authors listed in this form have read, reviewed, and approved the submission of this project.
3. The project will not commence until institutional ethical approval and governance authorisation is obtained from the RDGU.
4. To provide additional information about the project, for the purposes of ensuring patient privacy and ethical conduct, if requested by the RDGU.
5. To notify the RDGU in writing immediately if any changes to the project are proposed that would impact on its ethical consideration and await approval before proceeding.
6. That no data capable of identifying a particular individual will be published without the specific written consent of the participant or person(s) with authority to consent on behalf of patient(s) lacking capacity.
7. That any patient personal information collected, used and disclosed will be done so in accordance with the Epworth Privacy Policy ([www.epworth.org.au/privacy](http://www.epworth.org.au/privacy))

**Signature of Principal Investigator\*:**

|  |  |
| --- | --- |
| **Signature:** |  |
| **Name (in block letters):** |  |
| **Date:** |  |

*\*If the PI intends to use clinical data collected for standard of care purposes by other medical practitioners or departments, written authorisation must be obtained from said medical practitioners or departments and must be submitted to the RDGU with this form.*

**Submitting your Application:**

Please email a copy of the completed and signed form and any relevant documents to research@epworth.org.au