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| Project Title |  |
| Version Date | DD/MM/YYYY |
| **This document is a protocol for a research project.** This study will be conducted in compliance with the NHMRC National Statement on ethical Conduct in Human Research (2007), the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95) and any stipulations as outlined by the reviewing Human Research Ethics Committee. |
| Project Ethics Number(Office Use Only) | HREC/XXXXX/Austin-202X |

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1.1 – Project Classification

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| Please tick the correct classification for your project | [ ]  Intention to publish in scientific journal and any samples taken are part of standard of care. This is classified as research, therefore requiring approval from Ethics Committee or their delegate. |
| [ ]  No intention to publish, part of Organisation’s “Quality and Safety” continuous improvement processes and to be registered in the Projects and Improvements Database. This means you are exempt from Ethical Review but you cannot publish in a scientific forum. Register your QI project via Quality & Safety on the Projects and Improvements Database.  |

1.2- Site Specific Investigators

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| Name | Site Department | Role e.g. Associate Investigator | Email |
|  |  | Principal Investigator |  |
|  |  | Associate Investigator |  |
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1.3 - Will you be working with anyone outside of the lead Site?

Please add any collaborators or stakeholders who are not based at and clearly state who will be the principal investigator at each additional site.

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| Name | Institution | Role e.g. Associate Investigator | Email |
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1.4 - Conflicts of Interest

Is there any affiliation or financial interest for any researcher in this project which might represent a perceived, potential or actual conflict of interest?

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| [ ] Yes[ ] No | If yes, please explain. |

1.5 - Funding and Licence

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| Funding Source and Study Budget | [ ] No budget required as supported by site funds or in-kind support[ ] Budget required, funded via external competitive grant (NHMRC, ARC, MRFF) [ ] Budget required, funded by a commercial sponsor |
| Commercial in Confidence | [ ] Yes[ ] No |

1.6 – **Site Specific Authorisation**

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| **Situation** | **Agreements Required** |
| Data to be shared outside of Austin Health  | [ ]  Yes, please contact the Office for Research to discuss whether an agreement is needed[ ]  No  |
| PhD or Masters student using data towards their degree | [ ]  Yes, please contact the Office for Research to discuss whether an agreement is needed [ ]  No  |
| Access to biobank/ research database outside of Austin Health | [ ] Yes, I have a letter of support from the biobank/research database to use their data[ ] No, I am in the process of obtaining a letter of support to use their data[ ] No, I am not accessing a biobank/research database outside of Austin Health |

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2.1- Aims and Background

Use referenced literature to describe the gap in knowledge that your project will address.

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| Within our project we plan aim to [Insert a summary of the project using lay language in 150 words or less]. The current literature demonstrates that [Insert what the current research says about your topic. Please reference any publications mentioned]. |

2.2 – Project Description

This section is in line with National Statement 1.1 (b), (d), (e) and (f) to demonstrate that the research has merit.

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| This project uses a [qualitative/quantitative/other] research methodology that will include the following data collection method/s: [list data collection methods]1. Retrospective audit of medical records

This methodology is appropriate to answer the research questions/meet the research aims because [insert justification for the methodology].**Retrospective audit of medical records**Data will be collected using review of [electronic/paper medical records/medical databases etc..]. Medical Records and/or Medical databases will be accessed by [named investigators reviewing medical records/medical databases] [insert location for in person] and will be stored in [list data storage location e.g., RedCap, Excel etc..]. The following data points will be obtained:* [insert list of datapoints]

**Data & Statistical Analysis Plan** The total sample size for the project is [insert number of participants/medical records to be accessed/biosamples to be obtained].[If more than one participant group/medical record/biospecimen type] Specifically, this sample size is comprised of the following samples from each of the participant groups:1. Participant Group 1 [NAME/DESCRIPTION]: [SAMPLE SIZE]
2. Participant Group 2 [NAME/DESCRIPTION]: [SAMPLE SIZE]
3. [Add additional participant groups]

This sample size is sufficient to meet the research aims and answer the research questions because [e.g. this study does not intend to generalise to broader populations, but to gain an in-depth understanding of the topic; e.g. This sample size will allow for broad representation of perspectives on the topic; e.g. Research studies examining similar topics with sample sizes ranging from [minimum-maximum] participants have allowed the researchers to reach saturation of themes during data analysis; e.g. the power calculation reveals that this sample size will allow for statistically significant results]. |

**2.3 Sustainability and Scalability Plan**

Please state how, if successful, the project can be embedded into business as usual and/or how it would benefit other clinical groups.

This project will be able to inform [please describe what standard practices the information from the project could help to improve and how that will benefit patient care].

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3.1 – **Inclusion and Exclusion Criteria**

Please outline the criteria that will be used to select potential participants. In line with the National Statement, items 1.4 (a) 3.1.12 and 3.1.14.

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| **Selection/Inclusion criteria for this study include**:1. E.g., Over the age of 18 years and visited Austin Health between June 2019 and June 2021.
2. Etc.

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3.2- Recruitment

Please outline the methods used to recruit participants to the study. The information must outline the following to address National Statement items 3.1.12-3.1.22.

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| **Medical Records**The research team will access patient records at [Insert site].  |

3.3- Consent

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| **Medical Records** As part of recruitment, we will view patient medical records to determine suitable participants for this study. This data was collected as part of routine standard of care. We will access the information from the participants medical record as per section 2.2. **Waiver of Consent for Medical Records** We are requesting to access retrospective records/samples from the electronic medical records. We plan to access records/samples that were taken from the participant between MM/YYYY to MM/YYYY.Therefore, as per section 2.3.10 of the National Statement we are requesting a waiver of consent due to the following reasons:* it is impracticable to obtain consent [Insert justification, e.g., due to the quantity, age or the accessibility of records, patients may be lost to follow up or deceased]
* the benefits from the research justify any risks of harm associated with not seeking consent because [Insert justification]
* there is sufficient protection of their privacy. All data will be stored, as per Section 3.4 and 3.5 of this document. When the data is the shared via publication or presentation it will be deidentified and aggregated to ensure that no singular individual can be identified.
* there is an adequate plan to protect the confidentiality of data, as per Section 3.4 and 3.5 of this document.

Additionally, the project also meets the following voluntary requirements:[ ]  involvement in the research carries no more than low risk to participants.[ ]  there is no known or likely reason for thinking that participants would not have consented if they had been asked[ ]  in case the results have significance for the participants’ welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media). As there is no patient contact as part of this project, patients will not be individually informed of the outcome of this project. However, we do intend to publish the results to the public. [ ]  there is no possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled. [ ]  the waiver is not prohibited by State, federal, or international law. |

* 1. – Risks

This is to address National Statement 2.2.1 – 2.1.8. Examples of discomforts include: minor side-effects of participating in the research in general (e.g., headaches), discomforts related to being asked about particular aspects of one’s personal or social lives, and/or anxiety induced by providing answers during an interview or in answering a survey.

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| **Risk Management to access Medical Records**The medical record review will not pose any risk because medical records will be accessed by a named investigator on this project, who has rightful access to the medical records. Identifying information such as hospital number and date of birth will not be collected. This means the data will be collected in a [de-identified or re-identified] format. |

* 1. – Data & Confidentiality Management

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| Data will be stored at: [Insert Institution and Department or online database]As per section 1.3 and 1.6, data will be shared between: Sending Information: [Insert Institution and Department]Receiving Information: [Insert Institution and Department]Please select one of the following:[ ] De-identified data will be stored for this project. Individual identifiers will be removed from the data upon collection to ensure that all data stored for this project is de-identified. Data will be kept secure at all times by being either password protected or securely locked away at the institution as stated above. All data, both electronic and paper, will be kept for a maximum of 7 years from the time of collection. After 7 years, all data will be destroyed through deletion of electronic files or through shredding or placing files into confidential waste bins for paper data.[ ] Re-identifiable data will be stored for this project. Upon collection, participant data will be allocated a unique identifier which will allow for re-identification if needed. The data coding document containing the key for re-identification will be kept secure at all times with only named investigators having access. The participant will only be identified by investigators if deemed crucial to the study’s function. Data will be kept secure at all times by being either password protected or securely locked away at the institution as stated above. All data analysed and published from this project will not allow for patient identification. Participant information will be stored for a maximum of 7 years from the time of collection. All data will be destroyed after 7 years through deletion of electronic files or through shredding or placing files into confidential waste bins for paper data. [ ] Neither of the above. Please clarify below how data will be collected and stored securely.  |

* 1. Publications & Dissemination of Results

This section will answer the sections addressed in the National Statement item, 1.1 (d).

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| **Publication & Dissemination of Results for Medical Record Review** The person whose data and/or biospecimens are used will not be provided with a summary of findings. This is because [insert correct option (1) original consent to use data and/or biospecimens was obtained and noted that future research projects would not contact the original participant or (2) there is no patient contact as part of this study]. |

* 1. – Declaration

By submitting this application **all** investigators declare that they have:

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| [ ]  (Please tick this box to confirm your declaration) | By submitting this application, we, the Principal Investigator, Co-Investigators and Student Investigators, declare the following:* All information in this application and supporting documentation is correct and as complete as possible;
* I have read and addressed in this application the requirements of the National Statement and any other relevant guidelines;
* I have familiarised myself with, considered and addressed in this application any relevant legislation, regulations, research guidelines and organisational policies;
* All relevant financial and non-financial interests of the project team have been disclosed; and

understand that we cannot commence data collection until we receive a formal approval letter from Austin Health Human Research Ethics Committee or one of its Low-Risk Committee;* I will abide by the terms and conditions set by the Austin Health Human Research Ethics Committee or on of its Low-Risk Committee;
* I will ensure that the qualifications and/or experience of all Austin Health personnel involved in the project are appropriate to their role and/or to the procedures performed;
* I will ensure that appropriate approvals and/or approvals from external organisations or agencies will be obtained and that any imposed conditions will be observed;
* In the capacity of principal investigator, I have reviewed this application and I will provide appropriate supervision to the student(s) in accordance with the arrangements specified in this application and those associated with the student’s educational program.
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