|  |  |  |
| --- | --- | --- |
| 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 |

|  |
| --- |
|  |

1.1 – Project Classification

|  |  |
| --- | --- |
| 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

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Site Department | Role e.g. Associate Investigator | Email |
|  |  | Principal Investigator |  |
|  |  | Associate Investigator |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

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.

|  |  |  |  |
| --- | --- | --- | --- |
| Name | Institution | Role e.g. Associate Investigator | Email |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

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?

|  |  |
| --- | --- |
| Yes  No | If yes, please explain. |

1.5 - Funding and Licence

|  |  |
| --- | --- |
| 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**

|  |  |
| --- | --- |
| **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 |
| Investigator competency check | **Only provide the following if you are recruiting patients and/or staff:**  CVs attached or submitted in the last 2 years  [Good Clinical Practice (GCP)](https://genesisresearchservices.com/education/gcp-ich-course/) certificates attached or submitted in the last 2 years  Working with Children’s Check attached for projects working with people under 18 years of age |

|  |
| --- |
|  |

2.1- Aims and Background

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

|  |
| --- |
| 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)](about:blank#toc__95) to demonstrate that the research has merit.

|  |
| --- |
| 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 2. Use of Existing Biobank Samples 3. Surveys 4. Questionnaires 5. Interviews 6. Focus Groups 7. Observations 8. Secondary Use of Existing Datasets 9. Workshops 10. Activities   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]   **Biospecimens**  Biospecimens will be obtained from [insert biobank name]. Once the sample arrives it will then be [explain fate of sample]. Data obtained from the sample will be collected by:   * [insert inclusion criteria for biosamples] * [insert list of datapoints that need to be obtained from the biobank] * [insert list of analysis you will undertake once you have received the biosamples]   **Survey**  Data will be collected using an [survey/questionnaire etc…] administered through the [person at site reviewing /Redcap Survey Platform] [insert location for in person]. The following versions of the survey will be administered to the following participant groups:   * [insert survey document title] for [Insert participant group] * [insert survey document title] for [Insert participant group] * [insert survey document title] for [Insert participant group]   The survey questions have been developed based on [insert literature references or explain how the questions were developed]. The survey will take approximately [insert the time that it will take to complete] to complete.  Participants will be asked to complete the survey on [x] occasions. [An initial reminder and two follow up reminders to complete the survey will be sent before being considered lost to follow up. Each reminder will include instructions for participants to withdraw their consent to participate in future rounds of surveys or from further contact]  **Focus Groups**  Data will be collected during focus group sessions conducted at [insert location]. The following versions of the focus group guides will be administered to the following participant groups:   * [insert focus group guide document title] for [Insert participant group] * [insert focus group guide document title] for [Insert participant group]   The focus group discussion themes have been developed based on [insert literature references or explain how the questions were developed]. Each focus group will take approximately [insert the time that it will take to complete] to complete.  Participants will be asked to complete the focus groups on [x] occasions. [An initial reminder and two follow up reminders to complete the follow-up focus group will be sent before being considered lost to follow up. Each reminder will include instructions for participants to withdraw their consent to participate in future rounds of focus groups or from further contact]  **Interviews**  Data will be collected during [face to face], [telephone], [online/teams/zoom] interviews the following versions of the interview guides will be administered to the following participant groups:   * [insert interview guide document title] for [Insert participant group] * [insert interview guide document title] for [Insert participant group]   The interview guide questions have been developed based on [insert literature references or explain how the questions were developed]. Each focus group will take approximately [insert the time that it will take to complete] to complete.  Participants will be asked to complete the interview on [x] occasions. [An initial reminder and two follow up reminders to complete the follow-up interview will be sent before being considered lost to follow up. Each reminder will include instructions for participants to withdraw their consent to participate in future rounds of interviews or from further contact]  **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].

|  |
| --- |
|  |

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)](about:blank#toc__95) [3.1.12](about:blank#toc__438) and [3.1.14](about:blank#toc__438).

|  |
| --- |
| **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.   **Exclusion criteria include:**  E.g. Under the age of 18 years |

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](about:blank#toc__417).

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Medical Records**  The research team will access patient records at [Insert site].  **Biospecimens**  The research team will collect [type of biospecimen] from [biobank name and location]. The biobank has been contacted and made aware that their specimens wish to be accessed. A letter of support is included in this application. Once used the biospecimens will be [returned to the biobank or destroyed].  **Survey**  The research team will recruit participants to take part in the survey by posting a [study advertisement] on [website, social media account, newsletter] and/or sending a [letter or email invitation] using their organisation mailing list and/or introducing themselves at a scheduled standard of care appointment for [insert appointment details]. Potential participants will then be sent a participant information consent form which will include further instructions on how to consent to this study.  **Focus Group**  The research team will recruit participants to take part in the focus group by posting a [study advertisement] on [website, social media account, newsletter] and/or sending a [letter or email invitation] using their organisation mailing list and/or introducing themselves at a scheduled standard of care appointment for [insert appointment details]. Potential participants will then be sent a participant information consent form which will include further instructions on how to consent to this study.  **Interview**  The research team will recruit participants to take part in the interview by posting a [study advertisement] on [website, social media account, newsletter] and/or sending a [letter or email invitation] using their organisation mailing list and/or introducing themselves at a scheduled standard of care appointment for [insert appointment details]. Potential participants will then be sent a participant information consent form which will include further instructions on how to consent to this study.  **Social Media**  As described above social media will be used to recruit participants. Social media is going to be used because [e.g it will allow for recruitment of a wider audience that we are unable to recruitment from the hospital alone]. We intend to use [Twitter, LinkedIn, Facebook, Instagram, Google Ads etc] to advertise to [insert target audience e.g. adults 18 years and older]. Advertising is expected to last for [insert duration e.g. 6 months] and begin [specific date or as soon as all necessary approvals have been provided].  Please see below for an outline of the planned advertisements.   |  |  | | --- | --- | | Link | Insert URL to recruitment page | | Key Message | What is the one thing people need to know about this clinical trial? | | Headline | 25 characters max | | Description including any images | 100 characters max |   **Reminders**  In the absence of a response to the initial contact, reminder/follow-up contact with potential participants will/will not be undertaken by [Sending reminder emails or letters on no more than two occasions and providing the recipients with a method of opting out of receiving further reminders].  Conducting a follow-up phone call or sending a follow-up text or social media message with a method of opting out of receiving further reminders |

3.3- Consent

|  |
| --- |
| **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 and/or Biospecimens**  We are requesting to access retrospective records/samples from the electronic medical records. We plan to access records/samples from 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 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.  **Biospecimens**  At the time of collection consent was obtained from the participant. Please find attached evidence of original consent from participants.  **Screening**  To determine whether a participant is eligible to participate in the study, the research team will conduct a screening process. This will occur (e.g. once a participant indicates their interest in taking part in the project by contacting the research team; e.g. after the consent process), and will involve [OUTLINE THE SCREENING PROCESS]  OR  No screening process is required because [e.g. a purposive sampling process has been used that specifically targeted suitable participants; e.g. all members of the public are eligible to participate; e.g. the inclusion and exclusion are such that participants can determine their own eligibility to participate]  **Focus Groups, Interviews or Study Visits in Person**  Participants will be provided with the PICF (e.g. via email, in person) when (e.g. they contact the research team about taking part; they receive the recruitment invitation email as the PICF will be attached to this email (recommended)). Participants will be asked to read the PISCF and will have sufficient time to consider their participation because [describe a time gap in times between provision of the PICF and data collection; explain whether/how the time between provision of the PICF and data collection is sufficient]. Participants will be advised to contact the researcher(s) if they have any questions, and once they are comfortable providing their consent to participate, will be asked [describe how the consent will be indicated e.g. email, online, verbally or a signature on a paper version ] and return it to the researcher(s) prior to data collection by [e.g. emailing it to the researcher(s); bringing it to the research site on the day of data collection (for an interview study)].  **Telephone Interviews or Activities that require Verbal Consent.**  Participants will be provided with the PICF (e.g. via email, in person) when (e.g. they contact the research team about taking part; they receive the recruitment invitation email as the PICF will be attached to this email (recommended)).  Participants will be asked to read the PICF and will have sufficient time to consider their participation because [describe a time gap in times between provision of the PICF and data collection; explain whether/how the time between provision of the PISCF and data collection is sufficient].  At the time of data collection, participants will be read the verbal consent script by the researcher(s) before the data collection commences. Participants will be asked to advise the researcher(s) if they have any questions.  If the participant verbally provides their consent for the researcher(s) to proceed with the data collection, their consent to participate will be recorded by [e.g., audio recording the consent declaration component of the verbal consent script].  **Survey**  Participants will be provided with the PICF at the start of the data collection instrument (e.g. survey) and will be required to read through it before proceeding to the data collection instrument. If they choose to complete the data collection and submit it to the researcher(s) for analysis, this will be evidence of their implied consent to participate in the study. A copy of the PICF will also [e.g. be attached to the recruitment invitation email; be downloadable using the link included in the online PICF] for participants’ reference.  Participants will have sufficient time to consider their participation because [describe a time gap in times between provision of the PICF and data collection; whether explain how the time between provision of the Participant Information Statement and data collection is sufficient].  This written/verbal/implied consent process is appropriate for the data collection method and participant group because [e.g. the survey is anonymous and consent can be implied by return of the survey; e.g. the interview will be conducted via telephone so verbal consent can be recorded prior to the start of the data collection; e.g. participants will be completing the data collection in person, so written consent can be obtained at the time of data collection].  Participants will not be reimbursed for their participation, nor will their participation incur any expenses.  OR  Participants will be reimbursed for their participation by means of [specify the reimbursement, including the form the reimbursement will take (e.g. gift voucher), the dollar value of the reimbursement]. The reimbursement/reward will be provided to participants at [e.g. the conclusion of the data collection process] by [e.g. handing them the reimbursement in person at the conclusion of the data collection; e.g. posting the gift card to their office]. |

* 1. – Risks

This is to address [National Statement 2.2.1 – 2.1.8](about:blank#toc__155). 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.

|  |
| --- |
| **Risk Management to access Medical Records/Databases**  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.  **Risk Management to access stored Biospecimens**  The use of stored biospecimens will not pose any risk because biospecimens will be provided to the research site without information such as hospital number and date of birth will not be passed on. This means the biospecimen samples will be collected received in a [de-identified or re-identified] format.  **Risk Management when recruiting participants**  The researchers anticipate the following discomforts/harms to participants [explain each discomfort/harm, in what context the discomfort/harm may occur, and how likely the discomfort/harm is to occur based on the nature of the participant group/recruitment method/data collection method].  To minimise the risk of these discomforts/harms, the researchers will adopt the following processes [explain how each risk of discomfort/harm will be minimised or mitigated by the research team].  The benefits outweigh these potential risks of discomfort/harm because [explain how the overall purpose/aims/outcomes of the study justify the risk of discomfort/harm]. |

* 1. – Data & Confidentiality Management

|  |
| --- |
| Data will be stored at: [Insert Institution and Department or online database]  As per section 1.2 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)](about:blank#toc__111).

|  |
| --- |
| **Publication & Dissemination of Results for Medical Record Review and/or Secondary Analysis of Biospecimens**  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].  **Publication & Dissemination of Results for Participants**  Participants will be provided with a summary of the findings at the conclusion of the project by (e.g. email) [This should align with the information in the PICF. Note that if you are collecting non-identifiable data (e.g. using an anonymous questionnaire) participants should be instructed at Section 8 to access the results by contacting the research team or by using a link to a designated website (to be provided on the Consent Form) where a summary of the results will be published)]. |

* 1. – Declaration

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

|  |  |
| --- | --- |
| (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. |