Research Protocol

**FOR THE ESTABLISHMENT OF A DATABASE/CLINICAL REGISTRY DATABASE
(GREATER THAN LOW RISK ETHICS REVIEW PATHWAY)**

***DELETE all guidance in BLUE. Insert N/A for sections that are not relevant.***

*This template is to prepare a protocol to store data for future research use. We acknowledge It is based upon a NSW Heath Template.*

*Don’t describe specific hypotheses or planned future analyses. Each request to use or analyse the collected data for research should be submitted separately to the HREC using the* [***Protocol template for Retrospective Medical Record Studies***](https://www.slhd.nsw.gov.au/concord/ethics/forms.html)

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| **Protocol Number** | (This will be allocated by the Research Office after submission, i.e., X24-0000 or CH62/6/2024-xxx) |
| **Study Title** | Same as the study title in REGIS and on all other documents |
| **Coordinating Principal Investigator** | Name and affiliation(Not a student on the database/registry) |
| **Signature:** | Date: |
| **Co-investigators** | Names and affiliations**List Principal and Associate Investigators** |
| **Student Investigator(s) (if applicable)** | *List here all the investigators who are students and outline which parts of the Protocol will contribute to the requirements of their degrees.**Insert the statement:* NAME is conducting the study to partially fulfil the requirements of NAME OF DEGREE under the supervision of NAME(s)  |

**Ethics Statement:**

The database/registry will be conducted in accordance with the *National Statement on Ethical Conduct in Human Research* (2023) ([Link to National Statement](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)) , the *CPMP/ICH Note for Guidance on Good Clinical Practice* ([Link to CPMP/ICH](https://www.tga.gov.au/publication/note-guidance-good-clinical-practice-july-2000)) and consistent with the principles that have their origin in the Declaration of Helsinki. Compliance with these standards provides assurance that the rights, safety and well-being of trial participants are respected.

Protocol Version Control box

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| **Protocol** **Version Number** | **Date**  | **Summary of Changes** |
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**CONTEXT FOR THE DATABASE/REGISTRY**

*Describe the purpose, significance and intended uses for the database/registry. Include relevant information that supports its importance, justification and scientific value.* *Don’t include research hypotheses/questions* *or planned future analyses. The projects that use the dataset/registry in future will have their own hypotheses or questions.* **DATABASE/REGISTRY DESIGN**

Only include this section if it is useful to describe the structure of the Registry. For simple databases, it may not be useful. For Example, *‘This is a multi-centre registry, with enrolment of participants with NAME OF CONDITION into a long-term database/registry. Data will be collected on epidemiology, CONDITION history, CONDITION management, clinical course, symptoms, and burden of disease from all participants who are diagnosed with CONDITION.

 Data will be collected (select one and delete two):*

* *Retrospectively*
* *Prospectively*
* *Both Retrospectively and Prospectively*

**DATABASE/REGISTRY SETTING(S)**

*All the sites and locations where recruitment, data collection, storage, sharing and analysis of data will occur.* *Additional sites may be added as new sites come on board. New sites should be added through an ethics amendment post-approval.

Identify here any sites that are in Europe or UK. For registries collecting data from sites in EUROPE then GDPR legislation applies - particularly the right to be “forgotten" or the right of erasure. The ‘technical implementation is possible but must be set-up at planning stage.*

**DATABASE/REGISTRY PARTICIPANTS**

*Describe the people whose data will be used.*

**INCLUSION CRITERIA**

*For example:*

* Disease status
* Sex
* Age range, e.g., adults > 18 years. *If the age range is undefined or broad, indicate whether both children and adult information will be collected.*

**EXCLUSION CRITERIA***If any. List the criteria that define cases that will be excluded e.g. records with missing data.* *Explain why exclusion is appropriate if there is a possibility of direct benefit to participants* *e.g., the condition does not occur in children.*

**SAMPLE SIZE***For example, there is no defined sample size as the database/registry aims to capture incidence of CONDITION.*

**RECRUITMENT AND CONSENT ARRANGEMENTS**

 **RECRUITMENT PROCESS** *Only include this section if there will be contact with participants.

How will eligible people be identified? For example, through medical records or will participants* ***self-identify*** *in response to advertising, e.g., flyers; emails; social media posts?*

*State who will* ***initiate contact*** *with potential participants, e.g., member of treating team. Cultural sensitivities of participants and their communities should be considered and respected during the recruitment process. Will this take place as patients present at each participating centre or outside of the treatment setting? If sending emails, detail where the patient emails will be obtained from and who will send the emails.*

*Will there be arrangements (e.g. interpreters or translated documents) to facilitate the participation of potential participants who do not speak or write English?*

 *Describe all* ***recruitment materials*** *and how these will be received by participants, e.g., emails; flyers in clinics; social media advertising. If using social media, then a* [*social media plan*](https://www.slhd.nsw.gov.au/RPA/research%5Ccontent/pdf/Social_Media_Plan_Template-v4-final.zip) *should be submitted with your application. State the number and timing of any reminder emails.

Submit all* ***advertising materials*** *and* ***recruitment emails*** *(and any reminder emails) with version numbers and dates in the footers. For emails, include a subject line; and indicative signature block.

Describe the amount (and maximum value), timing, and type of any* ***compensation to participants****, e.g., retail vouchers, travel expenses.*

*Outline any education planned to* ***inform the general community*** *about data collection and use, especially if the collection will occur without participant knowledge or consent.*

*Differentiate between* ***research procedures (i.e. data collection) and routine procedures****. State whether there are any out-of-pocket costs to the participant for procedures performed as part of routine care, especially if they are patients recruited or treated in private practices and private hospital settings where healthcare fund excess may be applicable. This information should also be clearly explained to participants and stated in the Participant Information Sheet*

**PROSPECTIVE CONSENT PROCESS***Include this section if consent will be obtained from* ***some or all participants****. State the scope of consent sought, i.e., consent to the use of data in future research, e.g., EXTENDED. See* ***National Statement* *2.2.14*** [***Consent to future use of data and tissue in research****:*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)  *State:*

* *Who will obtain consent and where will the consent process take place?*
* *Arrangements to recruit potential participants who do not speak or write English*
* *Whether consent will be written or electronic, i.e.,* [*eConsent*](https://www.slhd.nsw.gov.au/rpa/research/eConsent.html) *on REDCap*
* *The time between providing information & obtaining consent, e.g., at least 24 hours*
* *Any process for ongoing consent, e.g., children need to be re-consented as adults at 18 years*

Consider ‘opt-out’ consent. Potential participants are informed about the research and their involvement in it. They are automatically “recruited” and included in the database if they do not return the opt-out form within a certain time, e.g., two weeks.See***National Statement****:* [***Chapter 2.2: General requirements for consent***](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#toc__235)***;*** [Chapter 2.3: Qualifying or waiving conditions for consent](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)

**WAIVER OF CONSENT**Include if a waiver of consent will be requested in respect of **some or all participants**.A waiver of consent can be considered if it is impracticable to obtain consent or use an opt out approach, e.g., if the patient does not have capacity to provide consent (e.g. they are unconscious or intubated) or if patients are deceased. Confirm that the research meets the following conditions for a waiver of consent and address each criteria in the protocol**:**

a) involvement in the research carries no more than low risk to participants
b) the benefits from the research justify any risks of harm associated with not seeking consent
c) it is impracticable to obtain consent (e.g., due to the quantity, age or accessibility of records)
d) there is no known or likely reason for thinking that participants would not have consented if they had been asked
e) there is sufficient protection of their privacy
f) there is an adequate plan to protect the confidentiality of data
g) 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)
h) the 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
i) the waiver is not prohibited by State, federal, or international law.

*See National Statement:* [Chapter 2.2: General requirements for consent](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)***;*** [Chapter 2.3: Qualifying or waiving conditions for consent](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023)

A separate **Waiver of Consent Form** to request a waiver of consent is required to be submitted with your application (see Research Webite).

**WITHDRAWAL OF CONSENT**

*Where consent is obtained, describe how participants may withdraw from the database/ registry at any time without penalty and without affecting future medical care. Describe what will happen to data already collected. Participants may wish to have all their data deleted describe how this will be implemented technically. Patients should be made aware of their rights and given options for withdrawal in the consent form.

For registries collecting data from sites in EUROPE or UK then General Data Protection Regulation (GDPR) legislation applies - particularly the right to be “forgotten" or the aright of erasure. The technical implementation is possible but it must be set-up at planning stage.*

**DATA COLLECTION PROCEDURES***If already-existing data will be used, e.g., medical records, PROMS, specify the sources (locations, data collections) of data; how records will be accessed and by whom. Explain why the researchers have legitimate access to the records, e.g., because they are members of the treating team. Provide a list of variables as a separate standalone* [***Data Collection Form***](https://www.slhd.nsw.gov.au/rpa/research/forms.html) *with a version number and date.

Describe information collected directly from participants* ***specifically for the database/registry****, e.g., QoL measures; interviews; diaries; images etc. State how information will be collected, e.g., written, electronic, verbally; when (the data collection schedule); and by whom (provide the position title e.g. registrar). State the time commitment and any extra burdens, e.g., how long do questionnaires take to complete; will extra clinic visits be required?*

*Describe the data’s journey from its collection to its entry into the database. For example: Is the person who collects the data the same person who enters/uploads the data in the database? Identify all the personnel (positions) involved and describe all the steps in this process. Will data entry be performed manually, electronically or a combination of both? When will data be entered? For example, ‘baseline data will be collected after consent is obtained and at least every 6 months thereafter’.

Describe the measures to ensure that data are properly collected, handled, processed, used, and maintained. Measures may include: training at site initiation and a pre-specified Data Dictionary;* *an intuitive interface for data entry; range checking and logical consistency checks during data entry; sites may contact the Data Custodian for technical support and Protocol questions.*

**DATA LINKAGE**

*Only include this section if records in the database/registry will be linked with records in other data collections.*

*For example, linkage may be performed at a local level, between data sources within Dr’s Rooms or Dr’s rooms and Ramsay Facility*

*Linkage may also be performed with records in state-wide and/or federal administrative datasets to ascertain participants’ clinical outcomes; health care utilisation; medication usage; and survival.* *Separate ethics approvals will be required from the appropriate HRECs e.g.* [*Australian Institute of Health and Welfare (AIHW)*](https://www.aihw.gov.au/about-us/committees/aihw-ethics-committee) *HREC if doing data linkage with AIHW datasets.*

**PLANNED ANALYSES, STUDIES OR REPORTS USING THE DATABASE**

*List here any planned analyses or studies or reports. For instance, the investigators may wish to publish/report on demographics or trends regularly or on an ad hoc basis. An Australian ambulance service may establish a cardiac arrest registry to report to the Australian Productivity Commission on rates of survival in patients who have had an out-of-hospital cardiac arrest.*

**GOVERNANCE AND OVERSIGHT**

**DATA CUSTODIAN:** *NAME will be responsible for the oversight and technical management of the database/registry.*

**ACCESS MANAGEMENT AND DATA USE MANAGEMENT***Specify all roles that will have access to the database. Define each role’s access rights, including, view, edit, delete, and export rights. Specify which roles will have access to identified data and the roles with access to coded data only.*

*(If applicable) If the database will be ongoing for a long period e.g. 50 years or indefinitely, describe continuity arrangements and contingencies in the event that the Coordinating Principal Investigator (CPI) leaves the project. For example, training the replacement CPI, updating study documents, informing the HREC and Principal Investigators, transfer of data, re-consenting participants, etc. If data will be transferred externally, consider whether the relevant permissions have been obtained for the transfer and if a Data Transfer Agreement is required.*

**DATA OWNERSHIP***Indicate who owns the data in the database/registry. Note: Ramsay Hospitals cannot transfer ownership of data from the Medical Record. A Data Transfer Agreement will also be required – contact* *researchgovernance@ramsay.com.au* *for further information.*

**ACCESS TO THE DATABASE/REGISTRY FOR RESEARCH PURPOSES**

Any stored data that is used for related or future research, will first be reviewed and approved by an appropriately constituted Ethics Committee. An amendment should also be submitted each time a study will use the database/registry (for tracking purposes)

*(If applicable) Describe a process for data use by external users (e.g. research collaborators) including who can apply to access to the data. For example, the Data Custodian will review requests for data access from the database and ensuring there is separate ethics approval for new projects. Indicate whether research collaborators may be from national or international sites.*

**QUALITY ASSURANCE PLAN:** *Data should be cleaned, checked for errors, inconsistencies and inappropriate duplicates. As a minimum, (clinical quality) registries should:*

* *report as a quality measure the percentage of eligible patients recruited*
* *have a QA plan to monitor the completeness and accuracy of data collected*
* *incorporate in-built data management processes, e.g., data range and validity checks*
* *Perform audits against source documents for a sample of cases sufficient to produce reliable measures of data completeness and accuracy. The frequency of audits needs to be sufficient for data quality.*

**DATABASE/REGISTRY TIMELINE**

*Provide a chronological description of data to be included in the database/registry. For example:* *Data from 2011 will be included as well as ongoing collection. It is intended to collect data for the next 10 years / indefinitely.*

**DATA STORAGE AND RETENTION**

**Storage**: *Describe how and where data will be stored and maintained, e.g., Within REDCap housed at XXX. Entered into REDCap and exported to Excel worksheets password protected at Dr Rooms.*

**Destruction**: *Describe how long the data will be stored for and if, when, and how research documents will be disposed of. It is recommended that researchers comply with the longest applicable data retention standard.*

**PRIVACY AND** **CONFIDENTIALITY**

*A confidentiality breach is a risk associated with chart review research. Please indicate the magnitude of this risk and specify the procedures implemented to minimise this risk. The collection of sensitive information should be limited to the amount necessary to achieve the aims of the database/registry, so that no unneeded sensitive information is being collected.
Describe the steps that will be taken to secure the data (e.g., training, authorisation of access, password protection, encryption, physical controls, and separation of identifiers and non-identifiable health data) for storage, use, and transmission of data. Indicate how you will share any data among research team members, e.g., REDCap ‘Send-it’ function or Accellion file transfer. Ideally, data is never sent by email and never by non-institutional emails e.g. Gmail; Hotmail etc.

To help maintain confidentiality, each participant should be assigned a unique identifying number listed in the Master Code Sheet and stored separately from the content data. Only the treating clinician and their designees should have access to identifying information. A clinician’s access to identifying information will be limited to their own site’s patient(s).

If data will be disclosed to outside persons or entities, list the entities and the method used to code or de-identify the data prior to transfer. A* ***Data Transfer Agreement*** *must be in place if data from the Medical Record will be sent outside the Ramsay Facility, e.g., to Drs Rooms or a university. Under no circumstances should any identifying information be shared with or disclosed to a third party.*

*Refer to the:* [*Management of Data and Information in Research: A guide supporting the Australian Code for the Responsible Conduct of Research*](https://www.nhmrc.gov.au/sites/default/files/documents/attachments/Management-of-Data-and-Information-in-Research.pdf)

*Refer to the* [*Australian Code for the Responsible Conduct of Research (2018)*](http://www.nhmrc.gov.au/guidelines/publications/r39)*, the* [*CPMP/ICH Note for Guidance on Good Clinical Practice*](http://www.tga.gov.au/industry/clinical-trials-note-ich13595.htm)*, the* [*National Statement*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023) *and any other relevant documentation/legislation.*

**SYSTEMS**

*For best practice data storage and management, a secure web-based data management tool designed for research purposes should be used. Preferably, data would not be should be stored in Excel; individual desktops; laptops; USBs; external drives or mobile devices. Data should be stored on a password-protected, networked drive within an institutional secure IT environment.*

**RESEARCH DATA MANAGEMENT PLAN (RDMP)**

*This is a required document and should be completed using the RHC Data Management Plan Template – refer webiste*

**ETHICS AND PROTOCOL AMENDMENTS**

The conduct of this database/registry will commence once the initial approval process has been completed through Ethics and Governance authorisation for each site.

Updated documents will only be implemented once they have been reviewed and approved by an Ethics Committee and if applicable Governance Officer for each site.

**SPONSORSHIP AND FUNDING**

*Indicate who is funding the study, what costs are being covered, and if sufficient funding is available for the duration of the research and archival period. If the data will be stored indefinitely, describe what contingencies will be in place if funding is no longer in place or discontinued.*

*If applicable, indicate the amounts and sources of funding for the research. This may include financial support, in-kind support, or other payments or incentives provided by any organisation supporting the research.*

**DECLARATION OF CONFLICTS OF INTEREST**

*Refer to* [*National Statement Section 5.4*](https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023) *and the* [*NHMRC Disclosure of interests and management of conflicts of interest Guideline Document*](https://www.nhmrc.gov.au/file/14503/download?token=YtUTSjW4)*. For staff members of NSW Health, compliance with the NSW Health Policy Directive PD2015\_045 “Conflicts of Interest and Gifts and Benefits” must be followed. All staff in any permanent, temporary, casual, termed appointment or honorary capacity within NSW Health, including volunteers, patient advocates, contractors, visiting practitioners, students, consultants and researchers performing work within NSW Health facilities are expected to avoid actual or perceived conflicts of interest and must not accept gifts or benefits of a non-token value.*

*It is essential that all conflicts of interest are identified, transparently reported and appropriately managed to reduce the risk of bias. Detail in the below table whether any members of the research team (including persons not listed in this application), have any financial, business or other non-financial interests related to this research.*

*Explain the nature and extent of the interests and to which member of the team they apply. \*\**

*Explain how you intend to manage these interests and any potential conflicts that may arise*

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| *Research or Non-research member name* | *Type of Interest (please specify and provide details including monetary value ($$)\*\**1. *Employment or voluntary involvement*
2. *Grants or scholarships to the author or organization*
3. *Personal fees (eg, honoraria, consulting fees, lecture or speaking fees)*
4. *Intellectual property (eg, patents, copyrights, royalties)*
5. *Stock or share ownership*
6. *On the board*
7. *Benefits related to the development of products as a result of the research*
8. *Royalties*
9. *Operational/ Infrastructure support*
 | *Management of the Potential Conflicts of Interest^* | *If applicable;* *Have the relevant details been disclosed in the Participant Information Statement?* | *Comments* |
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*\*\* When disclosing financial interests, researchers and institutions should consider the significance of the financial interest, including:*

*• the monetary value of the payment, gift, or interest*

*• the significance that a reasonable, independent observer would attach to the payment,*

*gift or interest*

*• the circumstances under which a gift or payment is made, for example, if the gift or*

*payment is a regular payment or a single instance.*

*Non-financial interests that require disclosure include, but are not limited to:*

*• board membership (even if unpaid) or other affiliation with an organisation that could stand to benefit from or be affected by the research*

*• personal or social relationships and current and past professional relationships, where relevant*

*• recent employment with, or role in, organisations with financial links or affiliations with industry groups that could stand to benefit from or be affected by the research.*

*^ If a conflict of interest is identified, the appropriate decision maker must determine what measures, if any, are most appropriate to manage that conflict of interest. These measures should be tailored to the individual circumstances and could include one or more of the following:*

*• requiring the public disclosure of the interests, for example when presenting or publishing the research*

*• involving an appropriate individual to oversee some or all of the research activity*

*• requiring the researcher to absent themselves from any deliberative decision making regarding the research*

*• requiring the researcher to play a different or reduced role in some or all of the research*

*• requiring the researcher to relinquish financial or other interests.*

*• Registering the conflict of interest in the COI register at your institution*

*• Developing a detailed COI plan (template available upon request)*

**PUBLICATION POLICY**

*The publication and authorship policies should be established and clearly outlined in this section. Authorship should be determined in line with the* [*NHMRC Authorship Guide*](https://www.nhmrc.gov.au/file/14358/download?token=jrA-2qrR)*.*

**REFERENCES**

*List all the references used in the background section at the end of the protocol.*

**APPENDICES**

*List appendices here. All appendices to be submitted as standalone documents with version numbers and dates (for version control purposes).*