**PHSREC PROTOCOL TEMPLATE**

**v.4 February 2022**

This template has been designed for population health research utilising routinely collected health data held by the NSW Ministry of Health or the Cancer Institute NSW.

**Please do not use this template for data linkage projects** – instead, refer to the PHSREC\_CHeReL Combined Protocol and Application for Data at the PHSREC website.

**This research protocol template must be used in conjunction with, and complement, the HREA.**

All forms and further information for submission to the NSW Population and Health Services Research Ethics Committee (PHSREC) can be found at:

**https://www.cancer.nsw.gov.au/research-and-data/nsw-population-health-services-research-ethics-com/how-to-apply**

# PROJECT DETAILS

|  |
| --- |
| Title:       |
| Short Title:       |
| NSW PHSREC REGIS Ref:       |
| Other (e.g., Sax Institute, SURE workspace name, AIHW, ACT Health and/or your ref):       |
| Project Contact Person:      Email and Phone no.:        |
| Is this a data linkage Project: ☐ Yes (Please speak to PHSREC before proceeding) ☐ No  |
| Is this a cross or multi-jurisdictional Project☐ Yes Please provide PHRN number (if applicable)        List jurisdictions (if applicable)       ☐ No  |
| Are you seeking PHSREC approval under the National Mutual Acceptance (NMA) Scheme?☐ Yes☐ No  |

# VERSION CONTROL (MAKE CONSISTENT WITH FOOTER)

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Date | Amendment (brief description)  | Amendment date (as per amendment form) |
|       |       |       |       |
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# INVESTIGATORS AND PARTICIPATING INSTITUTIONS

|  |
| --- |
| 2BPrincipal Investigator 1 |
| Name & Title |       |
| Institution |       |
| Division |       |
| Position |       |
| Mailing address |       |
| Email address |       |
| Phone number |       |
| Access to unit record data containing personal and/or health information (Y/N[[1]](#footnote-2)) |       If ‘Y’ name site       |
|  INVESTIGATOR / RESEARCHER |
| Name & Title |       |
| Institution |       |
| Division |       |
| Position |       |
| Email address |       |
| Phone number |       |
| Access to unit record data (Y/N) |       If ‘Y’ name site       |
| 4BInvestigator / Researcher |
| Name & title |       |
| Institution |       |
| Division |       |
| Position |       |
| Email address |       |
| Phone number |       |
| Access to unit record data (Y/N) |       If ‘Y’ name site       |
| 4BInvestigator / Researcher |
| Name & title |       |
| Institution |       |
| Division |       |
| Position |       |
| Email address |       |
| Phone number |       |
| Access to unit record data (Y/N) |       If ‘Y’ name site       |

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# BACKGROUND / RATIONALE

|  |
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| *Provide an abstract/summary of your project (max 100 words)*  |
|  |

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| Provide a background to the study including a brief literature review, outline of knowledge gaps, how the study will address these, and the intended contribution to the field (750 - 1000 words) |
|  |

# AIMS AND OBJECTIVES

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| Provide a statement of primary and secondary aims/objectives, key research questions, and/or a clearly defined hypothesis. |
|  |

# METHODS

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| --- |
| 5BStudy Design |
| Describe the type of study (e.g., retrospective cohort study, case control study). |
|  |
| 6BCohort/study population |
| Please describe your cohort/study population, specifying any inclusion /exclusion criteria. |
|  |

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| 7BDATA COLLECTION |
| Please identify the nature of the data to be collected (multiple options may be selected).  |
| [ ]  Primary data collection (e.g., original data from surveys, interviews, and/or focus groups etc.) **Please provide a description of primary data sources below.**  **Please specify the names of the sites for primary data collection.** |
|  |
| [ ]  Secondary data collection (e.g., routinely collected data)  Please provide details for all datasets including those not to be linked by CHeReL  |
| **Dataset Name**(e.g., NSW Admitted Patient Data Collection, Medicare Benefits Schedule, Victorian Admitted Episodes Dataset) | **Data Collection Site/Agency**(e.g., NSW Dept. Education) | **To be Linked By** (e.g., CHeReL/AIHW/DVL) | **Agency type for secondary data** |
|  |  |  | [ ]  State / Territory [ ]  Commonwealth [ ]  Private Sector |
|  |  |  | [ ]  State / Territory [ ]  Commonwealth [ ]  Private Sector |
|  |  |  | [ ]  State / Territory [ ]  Commonwealth [ ]  Private Sector |
|  |  |  | [ ]  State / Territory [ ]  Commonwealth [ ]  Private Sector |
| 8BConsent |
| Outline the consent process(es) to be used e.g. 1. **Informed consent**
2. **Opt-out consent**
3. **Request a waiver of consent – with strong justifications**
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|  |

# DATA GOVERNANCE

|  |
| --- |
| **1. Data Flow:** Please outline the movement of data within and between sites including the methods of transfer used. This section should correspond with the flow diagram. |
|  |
| **2. Data Storage, Access and Security:** Where will the data be stored? (e.g., SURE, Local Server, etc).Provide details of the security measures and access governance in place at each site.  |
|  |

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| --- |
| **3. Use and Disclosure**How and in what format will the data outputs be disseminated and used. How is confidentiality upheld.  |
|  |
| **4. Data Retention:** Specify the method and duration of data retention following completion of the project. |
|  |
| **5. Data Disposal:** Specify the method the information will be destroyed. |
|  |

# ANALYSIS PLAN

|  |
| --- |
| Outcomes/exposures and covariates |
| *Describe the study outcome measures (primary and secondary) and include information on study exposure/s, covariates, and other factors. How are these defined based on the data and how do they reflect the aims? Please provide sufficient detail (200 word minimum).* |
|  |
| statistical analysis |
| *Provide a statistical analysis plan outlining how the aims/objectives will be met, the statistical methods to be used, and who will be carrying out the analysis. Provide sufficient detail (200 word minimum).* |
|  |

#  PROJECT FUNDING / SUPPORT

|  |  |  |
| --- | --- | --- |
| **Funding** | **Confirmed or Sought?** | **Amount of funding $**  |
| **External Competitive Grant** | Confirmed [ ]  | Sought [ ]  | Not Sought [ ]   |  |
| **Internal competitive grant** | Confirmed [ ]  | Sought [ ]  | Not Sought [ ]  |  |
| **Sponsor** | Confirmed [ ]  | Sought [ ]  | Not Sought [ ]  |  |
| **Researchers’ department or organisation** | Confirmed [ ]  | Sought [ ]  | Not Sought [ ]  |  |

|  |  |
| --- | --- |
| **External Competitive** |   |
| Name of Grant/Sponsor |   |
| **Internal Competitive** |   |
| Name of Grant/Sponsor |   |
| **Sponsor** |   |
| Name of Grant/Sponsor |   |
| **Researchers Department or Organisation** |   |
| Name of Grant/Sponsor |   |

# REFERENCES

1. Access to tabulated/aggregated results ONLY = N [↑](#footnote-ref-2)