**COMBINED PROTOCOL & APPLICATION FOR DATA TEMPLATE**

**v.8 December 2021**

This template has been designed for population health research utilising and/or linking routinely collected health data held by the NSW Ministry of Health or the Cancer Institute NSW. This template combines the NSW PHSREC research protocol template and CHeReL data request form.

**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**

All forms and further information for submission to the NSW Centre for Health Record Linkage (CHeReL) can be found at: [**https://www.cherel.org.au/apply-for-linked-data**](https://www.cherel.org.au/apply-for-linked-data)

# PROJECT DETAILS

|  |
| --- |
| Title:       |
| Short Title:       |
| CHeReL Ref:       |
| NSW PHSREC REGIS Ref:       |
| Other (e.g., Sax Institute, SURE workspace name, AIHW, ACT Health and/or your ref):       |
| Contact Person:      Email and Phone no.:        |
| Is this a data linkage Project: ☐ Yes ☐ No (Please speak to PHSREC before proceeding)  |
| 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 |       |
|  INVESTIGATOR / RESEARCHER |
| Name & Title |       |
| Institution |       |
| Division |       |
| Position |       |
| Email address |       |
| Phone number |       |
| 4BInvestigator / Researcher |
| Name & title |       |
| Institution |       |
| Division |       |
| Position |       |
| Email address |       |
| Phone number |       |
| 4BInvestigator / Researcher |
| Name & title |       |
| Institution |       |
| Division |       |
| Position |       |
| Email address |       |
| Phone number |       |

|  |
| --- |
| 4BInvestigator / Researcher Accessing Linked Unit-record DataPlease list all the project personnel, including students who will have access to linked data.  |
| Researcher Name | Email address | Site of data access (e.g., *Institution* via *the SURE, Institution* on *secure file server*) | Accessing NSW Linked Data | Accessing Linked Data (other Jurisdiction(s)) |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |
|  |  |  | [ ]  | [ ]  |

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# BACKGROUND / RATIONALE

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

|  |
| --- |
| 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

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

# METHODS

|  |
| --- |
| 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. |
|  |

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

# DATA GOVERNANCE

|  |
| --- |
| **1A. Data Flow Diagram** |
|  e.g.**External Linkage Facility** e.g., AIHW**Cohort Definition**Describe the cohort **Data Storage Facility**Name**External Dataset****External Dataset****External Dataset****External Dataset****MLK Dataset****MLK Dataset****MLK Dataset****MLK Dataset****NSW/ACT Linkage**CHeReL |

|  |
| --- |
| **1B. 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.  |
|  |
| **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

|  |
| --- |
| **DATA REQUEST SECTION** |

#  DATA LINKAGE

TYPE OF PROJECT

|  |
| --- |
| *Does this project involve datasets not within* [*CHeReL’s Master Linkage Key (MLK)*](https://www.cherel.org.au/master-linkage-key)*?* |
| ☐ No - Please complete Section A & B.1☐ Yes - Please complete Section A & B.1 & B.2 |

|  |
| --- |
| *Does the project involve family linkage (e.g., mother-baby,* *mother-baby-sibling)?*  |
| ☐ No - Please complete Section A & B (B.1 & B.2 as required) ☐ Yes - Please complete Section A & C (C.1 & C.2 as required)  |

|  |
| --- |
| *During which calendar year do you require your first data linkage?* |
|  |

|  |
| --- |
| *Will updates to your Linkage be required?* |
| [ ]  No[ ]  Yes (please specify how/when *e.g., “annual extracts until 2028, one further extract in 2025”)* |
|  |

#### (SECTION A) COHORT AND RESTRICTIONS FOR LINKAGE

|  |
| --- |
| *Approximately how many individuals are in the cohort(s)?* |
|       |
| *List all datasets to be used to define your cohort(s) for linkage* |
| ***Dataset*** | ***Start Date*** | ***End Date*** | ***Any additional information*** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
| *If your cohort is defined by diagnosis/procedure codes (e.g., ICD, ACHI, SNOMED) please select:* |
| [ ]  Principal diagnosis/procedure codes only OR [ ]  Any of the multiple diagnosis/procedure codes within a record |
| *Please describe codes required and attach a list in excel format (filename – abbreviation\_cohort\_code\_list\_date.xlsx)* |
| *(e.g., from the APDC - all separations during 2002 with the following ICD diagnoses)* |

#### (SECTION B) What data collections are being linked to your cohort?

|  |
| --- |
| *Do you require:* |
| [ ]  All linked records required for these individuals (e.g., all APDC records relating to all morbidity)[ ]  Only records relating to the specified condition (e.g., APDC records relating only to CVD). Please specify:  |

(SECTION B.1) EXTRACT FROM CHEREL MLK COLLECTIONS

|  |  |
| --- | --- |
| **MLK Data Collections** | Dates |
| From (e.g., Jul 2001) | To (e.g., Dec 2020 / Latest Available) |
| [ ]  | NSW Admitted Patient Data Collection (from Jul 2001)Based on: [ ]  Admission date **OR** [ ]  Separation date |  |  |
| [ ]   | NSW Emergency Department Data Collection (from 2005) |  |  |
| [ ]  | NSW Non-Admitted Patient Data Collection (from Jul 2015)  |  |  |
| [ ]   | NSW Perinatal Data Collection (from 1994) |  |  |
| [ ]   | NSW Perinatal Death Review Database (from 2000) |  |  |
| [ ]   | NSW RBDM Birth Registrations (from 1994) |  |  |
| [ ]   | NSW RBDM Death Registrations (from 1985) |  |  |
| [ ]   | NSW Cause of Death Unit Record File (from 1985) |  |  |
| [ ]   | NSW Mental Health Ambulatory Data Collection (from 2001) |  |  |
| [ ]   | NSW Central Cancer Registry (from 1972) |  |  |
| [ ]   | NSW Pap Test Register (from Jul 1996) |  |  |
| [ ]   | BreastScreen NSW (from Jan 1988) |  |  |
| [ ]   | NSW Ambulance (from 2009) |  |  |
| [ ]   | The 45 and Up Study  | [ ]  Baseline (2006-09)[ ] SEEF (2010)[ ] Follow-up (2012‑15) [ ] Follow-up (2018‑20) |
| [ ]   | NSW Notifiable Conditions Information Management System(from 1993) |  |  |
| [ ]   | NSW Notifiable Conditions Information Management System – COVID-19 Case (from 2020) |  |  |
| [ ]   | [NSW ANZDATA](http://www.anzdata.org.au/documents/pdf/ANZDATA-data-dictionary-2016_v0.4_20170626.pdf) (from 1963) |  |  |
| [ ]   | NSW Australian Early Development Census (from 2009) |  |  |
| [ ]   | NSW Bureau of Crime Statistics and Research Reoffending Data Collection (BOCSAR) (from 1994) |  |  |
| [ ]  | NSW Controlled Drugs Data Collection (CoDDaC) (from 1985) |  |  |
| [ ]   | ACT Admitted Patient Collection (from Jul 2004)Based on: [ ]  Admission date **OR** [ ]  Separation date |  |  |
| [ ]   | ACT Cancer Registry (from 1994) |  |  |
| [ ]   | ACT Emergency Department Data Collection (from Jul 2005) |  |  |
| [ ]   | ACT Perinatal Data Collection (from 1997) |  |  |
| [ ]   | ACT Notifiable Diseases Register (from 2000) |  |  |
| [ ]   | ACT BDM Death Registrations (from 1997)  |  |  |
| [ ]   | ACT Cause of Death Unit Record File (from 2006) |  |  |
| [ ]   | ACT BDM Birth Registrations (from 1997) |  |  |
| [ ]   | ACT Australian Early Development Census (from 2009) |  |  |
| [ ]   | ACT Kindergarten Health Check (from 2014) |  |  |
| [ ]   | ACT ANZDATA (from 1963) |  |  |
| [ ]   | ACT Ambulance (from 2011) |  |  |

(SECTION B.2) OTHER COLLECTIONS (NOT HELD IN CHEREL MLK)

Please include any non-MLK datasets that **will be linked by CHeReL** (e.g., your own cohort dataset etc). Please list all other non-MLK datasets at Section 7- METHODS – Secondary Data.

|  |
| --- |
| Dataset 1 |
| Name and/or brief description of dataset |       |
| Number of records |       | Year span of dataset |       |
| Custodian name |       | Email/Phone no. |       |
| Agency Type | [ ] …State / Territory | [ ] …Commonwealth | [ ] …Private Sector |
| Who should CHeReL contact to source data? | Name        | Email       |
| Please list personal identifiers available for linkage |       |
| Dataset 2 |
| Name and/or brief description of dataset |       |
| Number of records |       | Year span of dataset |       |
| Custodian name |       | Email/Phone no. |       |
| Agency Type | [ ] …State / Territory | [ ] …Commonwealth | [ ] …Private Sector |
| Who should CHeReL contact to source data? | Name        | Email       |
| Please list personal identifiers available for linkage |       |
| Dataset 3 |
| Name and/or brief description of dataset |       |
| Number of records |       | Year span of dataset |       |
| Custodian name |       | Email/Phone no. |       |
| Agency Type | [ ] …State / Territory | [ ] …Commonwealth | [ ] …Private Sector |
| Who should CHeReL contact to source data? | Name        | Email       |
| Please list personal identifiers available for linkage |       |

#  SECTION C - FAMILY LINKAGE

|  |
| --- |
| Please provide a description of family relationships required (e.g., mother-baby, mother-other parent-baby, mother-baby-sibling links)  |
|       |
| *Are restrictions on family relationships required? (e.g., only full and not half siblings required)* |
|       |
| Additional requirements for your family linkage |
|       |

(SECTION C.1) EXTRACT FROM DATA COLLECTION HELD IN THE CHEREL MLK

|  |  |  |
| --- | --- | --- |
| **MLK Data Collections**Using the relationship columns, indicate which cohort(s) you require linked data for | Years | Relationship0F[[1]](#footnote-2) |
| From (e.g., Jul 2001) | To (e.g., Dec 2020 / Latest Available) | M | B | S | O |
| NSW Admitted Patient Data Collection (from Jul 2001) Based on: [ ]  Admission date **OR** [ ]  Separation date |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| NSW Emergency Department Data Collection (from 2005) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| NSW Non-Admitted Patient Data Collection (from Jul 2015) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| NSW Perinatal Data Collection (from 1994) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| NSW Perinatal Death Review Database (from 2000) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| NSW RBDM Birth Registrations (from 1994) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| NSW RBDM Death Registrations (from 1985) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| NSW Cause of Death Unit Record File (from 1985) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| NSW Mental Health Ambulatory Data Collection (from 2001) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| NSW Central Cancer Registry (from 1972) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| NSW Pap Test Register (from Jul 1996) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| BreastScreen NSW (from Jan 1988) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| NSW Ambulance (from 2009) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| The 45 and Up Study | [ ]  Baseline (2006-09)[ ] SEEF (2010)[ ] Follow-up (2012‑15) [ ] Follow-up (2018‑20) | [ ]  | [ ]  | [ ]  | [ ]  |
| NSW Notifiable Conditions Information Management System(from 1993) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| NSW Notifiable Conditions Information Management System – COVID-19 Case (from 2020) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| [NSW ANZDATA](http://www.anzdata.org.au/documents/pdf/ANZDATA-data-dictionary-2016_v0.4_20170626.pdf) (from 1963) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| NSW Australian Early Development Census (from 2009) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| NSW Bureau of Crime Statistics and Research Reoffending Data Collection (BOCSAR) (from 1994) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| NSW Controlled Drugs Data Collection (CoDDaC) (from 1985) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| [ ] CT Admitted Patient Collection (from Jul 2004) Based on: [ ]  Admission date **OR** [ ]  Separation date |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| ACT Cancer Registry (from 1994) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| ACT Emergency Department Data Collection (from Jul 2005) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| ACT Perinatal Data Collection (from 1997) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| ACT Notifiable Diseases Register (from 2000) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| ACT BDM Death Registrations (from 1997)  |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| ACT Cause of Death Unit Record File (from 2006) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| ACT BDM Birth Registrations (from 1997) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| ACT Australian Early Development Census (from 2009) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| ACT Kindergarten Health Check (from 2014) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| ACT ANZDATA (from 1963) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |
| ACT Ambulance (from 2011) |  |  | [ ]  | [ ]  | [ ]  | [ ]  |

(SECTION C.2) OTHER COLLECTIONS (NOT HELD IN CHEREL MLK)

Please include any non-MLK datasets that **will be linked by CHeReL** (e.g., Your own cohort dataset etc). Please list all other non-MLK datasets at Section 7- METHODS – Secondary Data.

|  |
| --- |
| Dataset 1 |
| Name and/or brief description of dataset |       |
| Number of records |       | Year span of dataset |       |
| Custodian name |       | Email/Phone no. |       |
| Agency Type | [ ] …State / Territory | [ ] …Commonwealth | [ ] …Private Sector |
| Who should CHeReL contact to source data? | Name        | Email       |
| Please list personal identifiers available for linkage |       |
| Please indicate which cohort(s) (M,B,S,O) this dataset links to |  |
| Dataset 2 |
| Name and/or brief description of dataset |       |
| Number of records |       | Year span of dataset |       |
| Custodian name |       | Email/Phone no. |       |
| Agency Type | [ ] …State / Territory | [ ] …Commonwealth | [ ] …Private Sector |
| Who should CHeReL contact to source data? | Name       | Email       |
| Please list personal identifiers available for linkage |       |
| Please indicate which cohort(s) (M,B,S,O) this dataset links to |  |

1. M - Mother records; B - Baby records; S - Sibling records; O - Other parent records [↑](#footnote-ref-2)