**COMBINED PROTOCOL & APPLICATION FOR DATA TEMPLATE**

**v.6 September 2019**

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 research protocol template and data request form.

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

1. **PROJECT DETAILS**

|  |
| --- |
| TITLE: |
| REGIS Ref: |
| CHeRel Ref (if applicable): |
| Other (eg Sax Institute or your ref) |

# SHORT TITLE (IF ANY)

|  |
| --- |
|  |

# VERSION CONTROL

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Date | Amendment (brief description) | Amendment date  (as per amendment form) |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

# INVESTIGATORS AND PARTICIPATING INSTITUTIONS

|  |  |
| --- | --- |
| Principal Investigator 1 | |
| Name & title |  |
| Institution |  |
| Division |  |
| Position |  |
| Mailing address |  |
| Email address |  |
| Phone number |  |
| Access to unit  record data (Y/N[[1]](#footnote-1)) | If ‘Y’ name site |
| Is this the contact person? Y / N |  |
| Investigator / Researcher | |
| Name & title |  |
| Institution |  |
| Division |  |
| Position |  |
| Email address |  |
| Phone number |  |
| Access to unit  record data (Y/N1) | If ‘Y’ name site |
| Is this the contact person? Y / N |  |
| Investigator / Researcher | |
| Name & title |  |
| Institution |  |
| Division |  |
| Position |  |
| Email address |  |
| Phone number |  |
| Access to unit  record data (Y/N1) | If ‘Y’ name site |
| Is this the contact person? Y / N |  |

# SUBMISSION CHECKLIST

All forms and further information is available on our website:

|  |  |
| --- | --- |
| Required Documents | Submitted |
| **Cover letter**   * listing all submitted documents with date and version numbers * signed by the Principal Investigator 1 | ☐ |
| **Human Research Ethics Application (HREA) completed in** [**REGIS**](https://regis.health.nsw.gov.au/).  **OR**  **Request for an Amendment to an Approved Research Project form** | ☐ |
| **Research protocol OR Combined Protocol and CHeReL Application for Data\***  Amendment requests will not be accepted without tracked and clean versions of your Protocol or Combined Protocol and Application for Data. | ☐ |
| **Data Linkage Flow Chart** (if applicable) *–* required for all data linkage projects | ☐ |
| **Data Variable list(s) for each data collection** | ☐ |
| **Data Custodian signoff for each data collection** | ☐ |
| [**Centre for Health Record Linkage (CHeReL) Technical Feasibility Letter**](http://www.cherel.org.au/apply-for-linked-data) | ☐ |
| **NSW Privacy Form** | ☐ |
| **Independent Peer Review Report** | ☐ |
| **CVs of all investigators** | ☐ |
| **All documentation relevant to the project**, such as Participant Information and Consent form(s), survey tools, and questionnaires (*where applicable*) | ☐ |
| **Correspondence with other HREC(s) in Australia** (*where applicable*)  *Please note: If your project is an extension or addendum to a project which already has approval from another HREC, ALL documentation reviewed by the original HREC must be provided (including HREC letter of approval).* | ☐ |

**<https://www.cancerinstitute.org.au/data-research/research-ethics/submissions>**

# TABLE OF CONTENTS

[1. Project Title 1](#_Toc496259331)

[2. Short Title (if any) 1](#_Toc496259332)

[3. Version Control 1](#_Toc496259333)

[4. Investigators and Participating Institutions 2](#_Toc496259334)

[5. Submission Checklist 4](#_Toc496259335)

[6. Table of Contents 5](#_Toc496259336)

[7. Background/Rationale 6](#_Toc496259337)

[8. Aims/Objectives 7](#_Toc496259338)

[9. Methods 7](#_Toc496259339)

[10. Analysis Plan 9](#_Toc496259340)

[11. Project funding/Support 10](#_Toc496259341)

[12. References 10](#_Toc496259342)

[13. Data sources 11](#_Toc496259343)

[14. Data linkage 12](#_Toc496259344)

[15. Family Linkage 16](#_Toc496259345)

# BACKGROUND / RATIONALE

|  |
| --- |
| Provide an introduction 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 (where appropriate). The aims/objectives should reflect the datasets and variables requested. **Please do not list variables here – attach a separate data variable list with justifications for individual variables in the context of the statistical analysis plan.** |
|  |

# METHODS

|  |  |  |  |
| --- | --- | --- | --- |
| Study Design | | | |
| Describe the type of study (e.g. retrospective cohort study, case control study). | | | |
|  | | | |
| Cohort/study population | | | |
| Please describe your cohort/study population, specifying any inclusion /exclusion criteria. | | | |
|  | | | |
| DATA 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 a description of the secondary data source(s) below.**  **Please specify the names of the sites or agencies for secondary data collection.**  Please also complete Section 13 below. | | | |
|  | | | |
| **Agency Type for secondary data**  **(tick all that apply)** | State / Territory | Commonwealth | Private Sector |
| Consent | | | |
| Briefly outline the consent process to be used in the study as indicated in the **HREA** and **NSW Privacy Form**. **Select one only:**   1. **Informed consent** 2. **Opt out consent** 3. **Request a waiver of consent – with strong justifications** | | | |
| data governance | | | |
| *Specify the data governance arrangements for the* ***entire data lifecycle*** *for the study. Where applicable, include information regarding:*  **1. Data collection:** specify all site(s) where data will be collected.  **2. Data transfer & security:** specify the processes to be used between sites and methods of encryption.  **3. Data access, use and disclosure:** specify the processes (including the use of a remote access facility).  **4. Data storage:** include all site(s) at which data will be stored.  **5. Data retention:** specify the period of retention of the data following completion of the project.  **6. Data disposal:** specify how the information will be destroyed and the methods to be used. | | | |

# 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 and how these are defined based on the data. 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. Please provide sufficient detail (200 word minimum).* |
|  |

# PROJECT FUNDING / SUPPORT

INDICATE HOW THE PROJECT WILL BE FUNDED?

*[Please note that all fields in any selected funding detail column will need to be completed.]*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **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 |  |
| **By 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 |  |
| **By Researchers Department or Organisation** |  |
| Name of Grant/Sponsor |  |

# REFERENCES

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

# DATA SOURCES

|  |  |  |  |
| --- | --- | --- | --- |
| Is this a data linkage application? | | | |
| No  **Please provide a description of your data sets below, and provide data variable lists for each dataset.**  Yes  **Please skip to Section 14.** | | | |
| Dataset 1 | | | |
| Name and/or brief description of dataset |  | | |
| Number of records |  | Year span of dataset |  |
| Custodian name |  | Email/Phone no. |  |
| **Agency Type**  **(tick one only)** | State / Territory | Commonwealth | Private Sector |
| Dataset 2 | | | |
| Name and/or brief description of dataset |  | | |
| Number of records |  | Year span of dataset |  |
| Custodian name |  | Email/Phone no. |  |
| **Agency Type**  **(tick one only)** | State / Territory | Commonwealth | Private Sector |
| Dataset 3 | | | |
| Name and/or brief description of dataset |  | | |
| Number of records |  | Year span of dataset |  |
| Custodian name |  | Email/Phone no. |  |
| **Agency Type**  **(tick one only)** | State / Territory | Commonwealth | Private Sector |

# DATA LINKAGE

|  |
| --- |
| Who is undertaking the data linkage? |
| Centre for Health Record Linkage (CHeReL)  Other linkage provider (name of provider) |
| Describe the data linkage process. |
| Extract from data collection held in the CHeReL MLK  Other collections to be linked by the CHeReL or other linkage provider (please specify) |
| Are updates required? |
| No  Yes (please specify)       *(e.g. “annually until 2015”, “one further extract in 2012”)* |
| *Does the project involve family linkage?*  (e.g. mother-baby, mother-other parent-baby, mother-baby-sibling links) |
| No - **Please complete Section B only**  Yes - **Please complete Section C only** |
| Provide a concise and simple description of the project (max 400 words) |
|  |

#### (SECTION B) EXTRACT FROM CHEREL MLK COLLECTIONS

|  |  |  |  |
| --- | --- | --- | --- |
| What collections are being used? | | Years | |
| From  (e.g. Jul 2001) | To  (e.g. Dec 2006) |
| NSW Admitted Patient Data Collection (from Jul 2001) [[2]](#footnote-2)  Based on: Admission date **OR** Separation date |  |  |  |
| NSW Perinatal Data Collection (from 1994)3 |  |  |  |
| NSW Central Cancer Registry (from 1972) 3 |  |  |  |
| NSW RBDM Birth Registrations (from 1994) |  |  |  |
| NSW Perinatal Death Review Database (from 2000) |  |  |  |
| NSW Mental Health Ambulatory Data Collection (from 2001) |  |  |  |
| NSW Pap Test Register (from Jul 1996) |  |  |  |
| NSW Ambulance (from 2009) |  |  |  |
| NSW Emergency Department Data Collection (from 2005) |  |  |  |
| The 45 and Up Study |  |  |  |
| NSW RBDM Death Registrations (from 1985) [[3]](#footnote-3) |  |  |  |
| NSW Notifiable Conditions Information Management System  (from 1993) |  |  |  |
| Cause of Death Unit Record File (from 1985) 3 |  |  |  |
| [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) |  |  |  |
| BreastScreen NSW (from Jan 1988) |  |  |  |
| ACT Admitted Patient Collection 2 (from Jul 2004)  Based on:  Admission date **OR**  Separation date |  |  |  |
| ACT Cancer Registry (from 1994) 3 |  |  |  |
| ACT Emergency Department Data Collection (from Jul 2004) |  |  |  |
| ACT Perinatal Data Collection (from 1997) 3 |  |  |  |
| ACT Notifiable Diseases Register (from 2000) |  |  |  |
| ACT BDM Death Registrations (from 1997) |  |  |  |
| ACT BDM Birth Registrations (from 1997) |  |  |  |
| ACT Australian Early Development Census (from 2009) |  |  |  |
| ACT Cervical Screening Registry (from 1994) |  |  |  |
| ACT Kindergarten Health Check (from 2014) |  |  |  |
| ACT ANZDATA (from 1963) |  |  |  |
| Comments: | | | |

#### COHORT AND RESTRICTIONS

|  |
| --- |
| Approximately how many records/individuals are in the cohort? |
|  |
| *How is your cohort to be defined?*  *Please include datasets from which your cohort will be drawn and any inclusion and exclusion criteria* |
|  |
| If your cohort is defined by ICD codes please select: |
| Principal diagnosis/procedure codes only OR  Any of the multiple diagnosis/procedure codes within a record |
| Please describe the ICD codes required (e.g. from the APDC - all separations during 2002 with the following ICD diagnoses) and attach an excel spread sheet (filename – abbreviation\_cohort code list\_date.xlsx) |
|  |
| Do you require: |
| All linked records required for these individuals  Only records relating to the specified condition |
| *Do you require any restrictions/subsets for data collections not in your cohort? (e.g. Hepatitis A records from the NSW Notifiable Conditions Information Management System)* |
|  |

#### OTHER COLLECTIONS (NOT HELD IN CHEREL MLK)

Please include any external datasets and national datasets (e.g. PBS, MBS, NDI or ACD).

|  |  |  |  |
| --- | --- | --- | --- |
| Dataset 1 | | | |
| Name and/or brief description of dataset |  | | |
| Number of records |  | Year span of dataset |  |
| Custodian name |  | Email/Phone no. |  |
| **Agency Type**  **(tick one only)** | State / Territory | Commonwealth | Private Sector |
| 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**  **(tick one only)** | State / Territory | Commonwealth | Private Sector |
| Personal identifiers available for linkage\* |  | | |

\*[Contact the CHeReL](http://www.cherel.org.au/contact-us) for advice on personal identifiers

Please note: variable list(s) and Data Custodian sign off MUST be obtained for each data collection.

* + Variables lists are available [here](http://www.cherel.org.au/data-dictionaries).
  + CHeReL will facilitate data custodian sign off for Ministry of Health datasets.

# SECTION C - FAMILY LINKAGE

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

#### EXTRACT FROM DATA COLLECTION HELD IN THE CHEREL MLK

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Dataset CHeReL MLK datasets listed below.  Please add or remove datasets as required | Years | | Relationship[[4]](#footnote-4) | | | |
| From  (e.g. Jul 2001) | To  (e.g. Dec 2006) | M | B | S | O |
| NSW Admitted Patient Data Collection (from Jul 2001) [[5]](#footnote-5)  Based on: Admission date **OR** Separation date |  |  |  |  |  |  |
| NSW Perinatal Data Collection (from 1994)3 |  |  |  |  |  |  |
| NSW Central Cancer Registry (from 1972) 3 |  |  |  |  |  |  |
| NSW RBDM Birth Registrations (from 1994) |  |  |  |  |  |  |
| NSW Perinatal Death Review Database (from 2000) |  |  |  |  |  |  |
| NSW Mental Health Ambulatory Data Collection (from 2001) |  |  |  |  |  |  |
| NSW Pap Test Register (from Jul 1996) |  |  |  |  |  |  |
| NSW Ambulance (from 2009) |  |  |  |  |  |  |
| NSW Emergency Department Data Collection (from 2005) |  |  |  |  |  |  |
| The 45 and Up Study |  |  |  |  |  |  |
| NSW RBDM Death Registrations (from 1985) [[6]](#footnote-6) |  |  |  |  |  |  |
| NSW Notifiable Conditions Information Management System  (from 1993) |  |  |  |  |  |  |
| Cause of Death Unit Record File (from 1985) 3 |  |  |  |  |  |  |
| [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) |  |  |  |  |  |  |
| BreastScreen NSW (from Jan 1988) |  |  |  |  |  |  |
| ACT Admitted Patient Collection 2 (from Jul 2004)  Based on:  Admission date **OR**  Separation date |  |  |  |  |  |  |
| ACT Cancer Registry (from 1994) 3 |  |  |  |  |  |  |
| ACT Emergency Department Data Collection (from Jul 2004) |  |  |  |  |  |  |
| ACT Perinatal Data Collection (from 1997) 3 |  |  |  |  |  |  |
| ACT Notifiable Diseases Register (from 2000) |  |  |  |  |  |  |
| ACT BDM Death Registrations (from 1997) |  |  |  |  |  |  |
| ACT BDM Birth Registrations (from 1997) |  |  |  |  |  |  |
| ACT Australian Early Development Census (from 2009) |  |  |  |  |  |  |
| ACT Cervical Screening Registry (from 1994) |  |  |  |  |  |  |
| ACT Kindergarten Health Check (from 2014) |  |  |  |  |  |  |
| ACT ANZDATA (from 1963) |  |  |  |  |  |  |

1. Access to tabulated results ONLY = N [↑](#footnote-ref-1)
2. Records in the NSW APDC and ACT APC are based on separations and do not include data for patients who have been admitted but not discharged from hospital. [↑](#footnote-ref-2)
3. For National datasets (e.g. NDI; ACD) please refer to OTHER COLLECTIONS on the following page. [↑](#footnote-ref-3)
4. M - Mother records; B - Baby records; S - Sibling records; O - Other parent records [↑](#footnote-ref-4)
5. Records in the NSW APDC and ACT APC are based on separations and do not include data for patients who have been admitted but not discharged from hospital. [↑](#footnote-ref-5)
6. [↑](#footnote-ref-6)