**COMBINED PROTOCOL & APPLICATION FOR DATA TEMPLATE**

**V 4 – October 2017**

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.**

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| Project Title |
|       |

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| --- |
| Short Title (if any) |
|       |

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| Version Control |
| Version | Date | Amendment (brief description)  | Amendment date (as per amendment form) |
|       |       |       |       |
|       |       |       |       |
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| Investigators and Participating Institutions**The order of the Investigators as listed must be consistent with the order of Investigators in the HREA.** |
| Principal Investigator 1 |
| Name & title |       |
| Institution |       |
| Position |       |
| Mailing address |       |
| Phone number |       |
| Access to unit record data (Y/N[[1]](#footnote-1)) |       If ‘Y’ name site       |
| Contact Person |
| Name & title |       |
| Institution |       |
| Position |       |
| Mailing address |       |
| Phone number |       |
| Access to unit record data (Y/N1) |       If ‘Y’ name site       |
| Investigator / Researcher |
| Name & title |       |
| Institution |       |
| Position |       |
| Mailing address |       |
| Phone number |       |
| Access to unit record data (Y/N1) |       If ‘Y’ name site       |
| Investigator / Researcher |
| Name & title |       |
| Institution |       |
| Position |       |
| Mailing address |       |
| Phone number |       |
| Access to unit record data (Y/N) |       If ‘Y’ name site       |

 **Access to tabulated results ONLY = N**

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| Submission Checklist |
| **Required Documents** | **Submitted** |
| **Cover letter** * listing all submitted documents with date and version numbers and signed by the Principal Investigator (date and version numbers MUST be provided on all documents)
 | ☐ |
| **Human Research Ethics Application (HREA)\* – as submitted at** [www.ethicsform.org/au](http://www.ethicsform.org/au) Signatures from ALL investigators are required. **OR Request for an Amendment to an Approved Research Project** form <http://www.cancerinstitute.org.au/research-grants-and-funding/ethics/research-amendments> *Please note: Unsigned forms will not be accepted* | ☐ |
| **Research protocol\***  including appendices (*OR tracked protocol for an Amendment*)**OR Combined Protocol and CHeReL Application for Data\****Please note: Protocols submitted without track-changes and appropriate version control will not be accepted* | ☐ |
| **Data Linkage Flow Chart** *(where applicable)* | ☐ |
| **Data Variable list(s) for each data collection including Data Custodian signoff** **Centre for Health Record Linkage (CHeReL)**For projects involving data linkage through the CHeReL, please provide the * 1. A signed **CHeReL Technical Feasibility Letter**
	2. **Combined Protocol and CHeReL Application for Data**

 *(Information and forms available from* [*http://www.cherel.org.au*](http://www.cherel.org.au)*)* *Please note: Applications without evidence of support from Data Custodians and/or the linkage provider WILL NOT be put forward to the HREC* | ☐☐ |
| **NSW Privacy Form**\* | ☐ |
| **CVs of all Principal Investigators** (please confirm with the PHSREC Secretariat for researchers who have previously submitted applications to the PHSREC) |  |
| **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 original approved participant information and consent documents and HREC letter of approval).* | ☐ |

***\* Links to these forms can be found on the Cancer Institute NSW website:*** [**https://www.cancerinstitute.org.au/data-research/research-ethics/submissions**](https://www.cancerinstitute.org.au/data-research/research-ethics/submissions)

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| 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). |
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| Aims/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.** |
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| Methods |
| Study Design |
| Describe the type of study (e.g. retrospective cohort study, case control study). |
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| 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. |

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| 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 |   |

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| References |

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| **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 complete from 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 |

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| 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  **Please also complete section (I) below.**[ ]  Other collections to be linked by the CHeReL or other linkage provider (please specify)       **Please also complete section (II) below.** |
| 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)** |
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| **(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 RBDM Death Registrations (from 1985) [[3]](#footnote-3) |[ ]   |  |
| NSW RBDM Birth Registrations (from 1994) |[ ]   |  |
| Cause of Death Unit Record File (from 1985) 3 |[ ]   |  |
| NSW Perinatal Data Collection (formally Midwives Data Collection) (from 1994) 3 |[ ]   |  |
| The 45 and Up Study |[ ]   |  |
| NSW Emergency Department Data Collection (from 2005) |[ ]   |  |
| NSW Central Cancer Registry (from 1972) 3 |[ ]   |  |
| NSW Perinatal Death Review Database (from 2000) |[ ]   |  |
| NSW Notifiable Conditions Information Management System (from 1993) |[ ]   |  |
| NSW Mental Health Ambulatory Data Collection (from 2001) |[ ]   |  |
| NSW Pap Test Register (from Jul 1996) |[ ]   |  |
| NSW Ambulance (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) |[ ]   |  |
| Comments:        |

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| COHORT AND RESTRICTIONS |
| Approximately how many records/individuals are in the cohort? |
|       |
| *How is your cohort to be defined?* |
|       |
| 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 |
| Do you require: |
| [ ]  All linked records required for these individuals[ ]  Only records relating to the specified condition |
| 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 any restrictions/subsets for data collections not in your cohort? (e.g. Hepatitis A records from the NSW Notifiable Conditions Information Management System)* |
|       |

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| other collections (not HELD in CHEREL MLK) |
| 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 for advice on personal identifiers (cherel.mail@moh.health.nsw.gov.au)

Please note: variable list(s) including Data Custodian sign off MUST be provided for each data collection. Available at <http://www.cherel.org.au/data-dictionaries> and <http://www.cherel.org.au/additional-datasets#section7>

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| 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) |
|       |

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| Extract from DATA COLLECTION HELD IN THE cherel mlK |
| DatasetCHeReL 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 RBDM Death Registrations (from 1985) [[6]](#footnote-6) |  |  |  |  |  |  |
| NSW RBDM Birth Registrations (from 1994) |  |  |  |  |  |  |
| Cause of Death Unit Record File (from 1985) 6 |  |  |  |  |  |  |
| NSW Perinatal Data Collection (formally Midwives Data Collection) (from 1994) 6 |  |  |  |  |  |  |
| The 45 and Up Study |  |  |  |  |  |  |
| NSW Emergency Department Data Collection (from 2005) |  |  |  |  |  |  |
| NSW Central Cancer Registry (from 1972) 6 |  |  |  |  |  |  |
| NSW Perinatal Death Review Database (from 2000) |  |  |  |  |  |  |
| NSW Notifiable Conditions Information Management System (from 1993) |  |  |  |  |  |  |
| NSW Mental Health Ambulatory Data Collection (from 2001) |  |  |  |  |  |  |
| NSW Pap Test Register (from Jul 1996) |  |  |  |  |  |  |
| NSW Ambulance (from 2009) |  |  |  |  |  |  |
| BreastScreen NSW (from Jan 1988) |  |  |  |  |  |  |
| ACT Admitted Patient Collection 5 (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  |  |  |  |  |  |  |
| ACT BDM Death Registrations (from 1997)  |  |  |  |  |  |  |
| ACT BDM Birth Registrations (from 1997) |  |  |  |  |  |  |

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| COHORT AND RESTRICTIONS |
| Approximately how many records/individuals are in the cohort?  |
|       |
| 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 |
| Do you require: |
| [ ]  All linked records required for these individuals[ ]  Only records relating to the specified condition |
| Please describe the ICD codes required (e.g. from the APDC - all separations during 2002 with the following ICD diagnoses) |
|       |
| *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)*  |
|       |

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| other collections (not HELD in CHEREL MLK) |
| Dataset 1 |
| Name and/or brief description of dataset |       |
| Group *(e.g. Mother, baby, other parent, sibling)* |       |
| 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 |       |
| Group *(e.g. Mother, baby, other parent, sibling)* |       |
| 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 for advice on personal identifiers (cherel.mail@moh.health.nsw.gov.au)

1. [↑](#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. For National datasets (e.g. NDI; ACD) please refer to OTHER COLLECTIONS on the following page. [↑](#footnote-ref-6)