NSW Population & Health Services Research Ethics Committee (PHSREC)

Notification of Change in Personnel

* The purpose of this document is to add new investigators to an approved study.
* It is to be attached to an [Amendment Form](https://regis.health.nsw.gov.au/media/1723/qrg-resapp-ethics-amendment-completing-and-submitting.pdf) in REGIS. Please use the REGIS Amendment type “ Change to CPI/PI/Administration amendment” for changes to the CPI only; other changes to personnel can be attached to a “General Amendment”.
* This form can be used to request multiple changes in personnel. Please repeat section 3.2 for each individual investigator.
* Before you begin, it is recommended that you have the most recent approved version of the study Protocol, CVs of new investigators and information on what study data they will access & how they will access it.
* Please note that data custodian reapproval may be required when adding a new site. Please contact the data custodian or relevant data linkage unit (e.g. the Centre for Health Record Linkage, CHeReL) to facilitate this.

1. **Study Details:**

NSW PHSREC REGIS Reference Number (e.g. 2019/ETHXXXXX):

Other Study Reference Numbers (e.g. CHeReL number):

Study Title:

1. **Current Coordinating Principal Investigator (CPI)**

|  |  |
| --- | --- |
| Name & Title |  |
| Institution |  |
| Email address |  |
| Phone number |  |

1. **Details of Change in Personnel** 
   1. **Change to Coordinating Principal Investigator (CPI)**

Is this notification to replace the current Coordinating Principal Investigator?  Yes  No

If **YES**, please Complete section **3.2** below, ensuring the declaration at the end of this form is signed by both the incoming and outgoing\* Coordinating Principal Investigators.

Please also attach the following documents to a new Amendment Form in REGIS selecting [Change to CPI / PI / Administration amendment](https://regis.health.nsw.gov.au/media/1723/qrg-resapp-ethics-amendment-completing-and-submitting.pdf) type:

**Updated Protocol** - *Please update the Protocol to include the details of the New CPI, as well as updating the Protocol document’s version control table & footer. Submit tracked and clean versions of the updated Protocol.*

**Detailed CV** - *Please attach a detailed CV for the new CPI.*

**3.2 Addition of Researcher / Investigator**

Is this notification to add a researcher / investigator?  Yes  No

If YES, please provide the following details:

|  |  |
| --- | --- |
| **NEW INVESTIGATOR / RESEARCHER** | |
| Name & Title |  |
| Institution, Australian State or Territory |  |
| Division |  |
| Position |  |
| Email address |  |
| Phone number |  |

|  |
| --- |
| Please specify the site where this researcher will be located when conducting the work:  Has this site or Institution been previously approved by the PHSREC? *(Please confirm using the most recent version of the Protocol)*.  Yes  No  Please note: if a person is accessing NSW Health data at a **new site**, the NSW Health Data Custodians may need to provide re-approval of the updated Protocol. For unlinked data, please contact the data custodian; for linked data please contact the CHeReL on [MOH-CHeReL@health.nsw.gov.au](mailto:MOH-CHeReL@health.nsw.gov.au) to confirm whether this is needed before submitting this form. |

**Researcher/Investigator Role:**

|  |
| --- |
| Describe the role of the researcher /investigator in this project e.g. collection of data, data analysis, subject matter expertise, administration only: |
| Summary of qualifications and relevant expertise: |
| Please declare any general competing interests e.g. if the investigator is employed by an institution that has a financial interest in the results: |
| Is the new researcher/investigator a student on this project?  Yes  No  If YES, please provide the following details:  Degree/Course:  Faculty & Institution:  Supervisor (Title, Name):  Is the Supervisor already an approved Investigator?  Yes  No |

**Data Governance:**

|  |
| --- |
| Is the person accessing unit record data?  Yes  No  *(Unit record data is person-level data which may contain personal health information; if the new investigator is accessing only aggregated data such as results only, then select “No”)*   * If **YES**, a CV must be supplied and protocol must be updated.   Site of data access (e.g., *Institution* via *the SURE, Institution* on *secure file server*):  CV attached  Protocol updated (please update List of Investigators and the Data Governance section if necessary) |
| Is the person accessing **linked** unit record data?  Yes  No  *(Linked unit record data is person-level data from two or more sources that have been linked together; if the new investigator is accessing only unlinked or aggregated data, then select “No”)*   * If **YES**, a CV must be supplied and protocol must be updated. * If no, please move on to the next question.   Site of data access (e.g., *Institution* via *the SURE, Institution* on *secure file server*):  Accessing NSW Linked Data:  Yes  No  Accessing Linked Data (other Jurisdiction(s):  Yes  No  CV attached  Protocol updated (please update List of Investigators and the Data Governance section if necessary) |

**REGIS Access**

Would you like this researcher/investigator to have access to the study in REGIS? Yes No

*We recommend that only those persons involved in preparing amendments and annual reports have access in REGIS. Please note Coordinating Principal Investigators MUST have access to the study in REGIS.*

If YES, please ask the new investigator [to register an account in REGIS](https://regis.health.nsw.gov.au/media/1712/qrg-all-users-regis-user-account-and-system-symbols.pdf) and complete the following:

Email address associated with REGIS Account:

Level of access required (select all that apply):

|  |  |
| --- | --- |
| Owner/ Coordinating Principal Investigator | Yes  No |
| Submitter (Investigator delegated by CPI to submit ethics documents such as amendments and annual reports) | Yes  No |
| Administration Contact | Yes  No |
| Editor (Investigator on project who can prepare documents but not submit them) | Yes  No |
| Viewer | Yes  No |

**3.3 Deletion of Researcher/Investigator**

Is this notification to delete a researcher / investigator?  Yes  No

If **YES**, please provide name(s)

|  |
| --- |
| Name: |

*Please submit an updated Protocol for deletion of a researcher/investigator.*

1. **Declaration by the Coordinating Principal Investigator**

*Electronic signatures are acceptable*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: Coordinating Principal Investigator Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\*Signature: Outgoing Coordinating Principal Investigator Date

**Please contact the PHSREC Secretariat on** [**cinsw-ethics@health.nsw.gov.au**](mailto:cinsw-ethics@health.nsw.gov.au) **if you have any questions regarding this form.**