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Section 1: Introduction

The NSW Population and Health Services Research Ethics Committee (PHSREC) is a joint initiative of the Cancer Institute NSW and NSW Ministry of Health. The NSW PHSREC is accredited in NSW as a lead Human Research Ethics Committee (HREC) for general research. The Committee has been certified under the National Approach to Single Ethical Review in the category of Population health and/or public health.

The NSW PHSREC undertakes scientific and ethical review of population health research utilising and/or linking routinely collected health (and other) data, including:

- data collections owned or managed by NSW Ministry of Health (e.g. NSW Admitted Patient Data Collection; Perinatal Data Collection; NSW Emergency Department Data Collection; and New South Wales Population Health Surveys);

- data collections owned or managed by the Cancer Institute NSW, (e.g. NSW Central Cancer Registry, NSW Pap Test Registry, BreastScreen Registry).

The NSW PHSREC will also review mixed methods research where a component of the research meets the above description (in the case of clinical trials, the Committee will review a data linkage component, but is not accredited to review the trial itself). If such research is multi-centre within the public health sector, the NSW PHSREC can provide single ethical review on behalf of the NSW Public Health Organisations (PHOs) in which the research is to be conducted.

Please note that all research involving access to data collections owned or managed by NSW Health or the Cancer Institute NSW must be reviewed by the NSW PHSREC.

There is no other Ethics Committee with a mandate to approve research proposals requiring access to these collections.

Where the research project may affect the health and wellbeing of Aboriginal people and communities in NSW, approval from the Aboriginal Health and Medical Research Council (AHMRC) Ethics Committee is required. Researchers are referred to http://www.ahmrc.org.au/ethics.php for more information.
Section 2: Research Governance

Site governance

For some research projects, separate governance review at a particular site, or sites, will be required. This process is in addition to, and separate from, the ethical review of the project. For example, research studies which are to be carried out in a Public Health Organisation (PHO) will require separate site authorisation from the Chief Executive or delegate of that organisation. In such cases, a Site Specific Assessment (SSA) application should be made to the Research Governance Officer of each PHO at which it is proposed the research will be conducted.

Data governance for Cancer Institute NSW and NSW Ministry of Health collections

Proposals involving access to data collections owned or managed by NSW Health or the Cancer Institute NSW must be reviewed by the relevant Data Custodian before applying to the PHSREC. Data Custodians for these collections are required to sign off on access to data for each registry or dataset which is part of the current application. The Data Custodian Sign Off form must be submitted to the PHSREC.


The Centre for Health Record Linkage (CHeReL)

For studies requiring linkage of NSW Health datasets, it is recommended that the linkage is performed by the Centre for Health Record Linkage (CHeReL). If the research involves linkage to the NSW Central Cancer Registry, there is a requirement that the linkage must be performed by the CHeReL.

For projects involving linkage by the CHeReL, please follow their application process. The CHeReL will obtain data custodian sign-off on your behalf. You will need to submit your National Ethics Application Form (NEAF) and study protocol to the CHeReL for technical feasibility sign off, prior to submitting to the PHSREC.

For more information about the CHeReL, visit the website at http://www.cherel.org.au/

The Secure Unified Research Environment (SURE) facility

Depending on the nature of the data linkage for which you are applying, it may be a requirement of one or more data custodians that your linked dataset is housed in the Secure Unified Research Environment (SURE) facility. The SURE is a remote-access computing environment that allows researchers to access and analyse linked health-related data files for approved studies in Australia. For more information about the SURE facility, visit the website at https://www.sure.org.au/
Section 3: Submissions to the NSW PHSREC

As of 01 July 2015 for ALL APPLICATIONS, the NSW PHSREC no longer requires paper copies of submissions and subsequent correspondence. Electronic copies of the following documentation should be submitted to Ethics@cancerinstitute.org.au:

- The completed submission checklist

- **Ethics application form:** For most applications to the NSW PHSREC, a National Ethics Application Form (NEAF) will be required. For some proposals a Low & Negligible Risk Research (LNR) form may be appropriate (see section 4). Application forms are available via the Online Forms website www.ethicsform.org.au.

  - **Note on Coordinating / Principal Investigator:** The Coordinating / Principal Investigator is the individual who takes overall responsibility for the research project and submits the project for ethical and scientific review. They are responsible for ongoing communication with the Ethics Committee, and if the project is undertaken at multiple sites, passing this information on to other Principal (site) Investigators as listed on the NEAF.

  - **Note on commissioned research:** In general, the Coordinating / Principal Investigator should be someone from the agency which has commissioned the work, rather than the organisation which has been contracted to undertake the work. Please contact the Executive Officer for more information about this requirement.

  - **Note on Student projects:** It is not the usual practice of the PHSREC to approve a student as the Coordinating / Principal Investigator of a study. Applicants should therefore appoint a Coordinating / Principal Investigator for the application who is not a student.

  - **Note on signatures:** Signatures for ALL Investigators must be provided in Section 10 of the NEAF. Unsigned documentation will not be accepted. Please see below for more information regarding Electronic submission.

  - A detailed **Research Protocol** including objectives, design, methodology, statistical analysis plan, ethical considerations and how the study will be conducted and evaluated.


    Please do not recycle documents used in funding applications. The review of your ethics application will be more efficient if the protocol is written specifically to address PHSREC requirements.

- **Variable list(s)** for each data collection including Data Custodian signoff where applicable. The Committee recognises that some Data Custodians will not provide
sign-off until after ethics approval has been granted. In this case the applicant should seek the advice of the Executive Officer.

- For projects involving data linkage by the CHeReL:
  - A signed letter of support from the CHeReL as evidence that the project is technically feasible.
  - The CHeReL Application for Data

- The NSW Privacy Form

- All documentation relevant to the project, such as Participant Information and Consent form(s), survey tools, and questionnaires where applicable

- Correspondence from other HREC in Australia where applicable (Please note: if your project is an extension or addendum to a current project which has already been approved by another lead HREC in NSW, please see specific requirements in Section 6 below).

- A brief Curriculum vita for the Coordinating / Principal Investigator.

Electronic copies of all documents should be submitted to: Ethics@cancerinstitute.org.au

**Electronic Submission:**

The NSW PHSREC is a paperless Ethics Committee. Please do not submit paper copies of your application. The requirements for electronic submission are outlined below:

- Signatures for ALL Investigators must be provided in Section 10 of the NEAF
- Unsigned documentation will not be accepted
- Electronic signatures can be inserted into a document and saved as a PDF, or individual signed pages can be scanned and saved as a PDF
- Electronic and/or scanned signatures must clearly identify an Investigator and indicate their consent for the submission
- All submissions and correspondence must be sent from a valid email address linked to the contact person’s organisation
- The Coordinating / Principal Investigator must be cc’d on all submissions to the PHSREC (including amendments and reporting).

Section 4: Low and Negligible Risk Research

The National Statement on Ethical Conduct in Human Research 2007 describes research as ‘low risk’ where the only foreseeable risk is one of discomfort to participants.

The Statement describes research as ‘negligible risk’ where there is no foreseeable risk of harm or discomfort and any foreseeable risk is not more than an inconvenience to the participants.

A NSW Health Guidance document gives further information about the type of research which qualifies as low and negligible risk (LNR), and identifies categories of research which are exempt from low and negligible risk review.

Researchers are advised to review these guidelines prior to commencing their application:


The NSW PHSREC will undertake expedited review of certain projects that are considered to be of low or negligible risk to participants. The types of research that the NSW PHSREC will consider to be LNR are those where:

- The level of intrusiveness and disruption to participants is minimal (taking into account who the participants are and whether they constitute a vulnerable population);
- The project does not (or does not have the potential to) involve sensitive information about participants;
- The threat to a participant’s privacy and confidentiality is remote; and
- The project involves the use of data which has been stripped of identifiable information (such as name, address, dates of birth or death) and the potential to re-identify the information is remote. The following examples would not qualify for LNR review, since there is a potential for re-identification of information:
  - projects investigating rare events or outcomes
  - projects requiring the release of full date variables

Researchers are asked to contact the Executive Officer on (02) 8374 3562, to discuss whether their proposed research qualifies as LNR research, prior to application.

The LNR ethics application form can be found on the online forms website at www.ethicsform.org.au.
Section 5: Data repositories/program linkages

This section describes the requirements for submissions involving large-scale data linkages designed to address multiple research questions. The Committee recognises that plans for specific projects, unidentified at the time of the original submission, may arise from these linkages in the future. The Committee refers to applications of this kind as data repositories or program linkages and has specific processes related to these.

- In the first instance the Committee approves the linkage to undertake the program of work and then requires submissions for each new project conducted under the auspices of the original approval.
- The overarching linkage and broad topic of investigation must be submitted to the PHSREC as a full NEAF.
- The Committee also requires a detailed Research Protocol including objectives, design, methodology, statistical analysis plan, ethical considerations and how the study will be conducted and evaluated.
- For program linkages, Investigators must also provide additional information in the protocol regarding data governance including information regarding transfer, access and/or use, storage (include site(s) at which data will be stored), retention and disposal of the data.
- For data repositories, the PHSREC also requires researchers to outline the policies and procedures related to the management and governance of the repository. These policies should address the following points:\[1\]
  - Details of the ongoing management and governance of the data including the roles and responsibilities for the management of the information. The management structure must be independent of movement of personnel.
  - Details of funding demonstrating that funding is available for the management and protection of the data for the approval period (5 years)
  - Details of how the privacy of the individuals is protected and how the impact on privacy is minimised (separation principle)
  - The data access policy including
    - a. The kinds of research for which it can be used
    - b. The access criteria applied to applicants to use data
    - c. The conditions of access
    - d. Who approves access
    - e. Whether the data can be used by researchers from other institutions
  - The procedure for managing participants’ consent and ensuring that future research is within the parameters of the consent obtained (if relevant)
  - The policies for collecting additional information, contacting participants and disclosing information to participants.

\[1\] With thanks to the Department of Health Western Australia Human Research Ethics Committee which developed these guidelines for ongoing data repositories
Details of the security policy including:
   a. Physical and environmental security
   b. Human resources security
   c. Communications and operational security
   d. Access controls
   e. Cryptography
   f. Incident and breach management
   g. Audit program

- Proposals for new projects must be submitted to the Committee as amendments
  accompanied by a Request for an Amendment to an Approved Research Project form
  and project-specific protocol(s). Project-specific protocols should outline key research
  questions, and/or a clearly defined hypothesis (where appropriate), and include
  detailed methods and statistical analysis plans. Where applicable, these must also
  include information regarding transfer, access and/or use, storage (include site(s) at
  which data will be stored), retention and disposal of the data.

- Generally these amendments will be approved by the Executive Committee but the
  Executive retain the right to refer them to the Full Committee for review if deemed
  necessary.
Section 6: Extension or addendum to a project which already has approval from another HREC

Sometimes submissions are made to the NSW PHSREC for an extension or addendum to a current project which has already been approved by another Ethics Committee. For example, a clinical project approved by an Ethics Committee from a PHO, may subsequently require approval from the NSW PHSREC for access to data collections owned or managed by NSW Health or the Cancer Institute NSW.

- For these submissions applicants must clearly outline, in both the NEAF and the protocol, the parts of the project which already have approval from the original Ethics Committee, and those that require subsequent approval from the PHSREC
- Both the NEAF and protocol should explicitly address the scientific and ethical issues related to the record linkage. The protocol may be an amendment to an existing protocol (information relating to data and linkage must be highlighted) or a new standalone data protocol specific to this component of the research.

The following information is also required:

- ALL documentation reviewed by the original HREC including original approved participant information and consent documents (where applicable) and HREC letter of approval
- The scope of original ethics approval; including details of original access to any non-NSW Health or the Cancer Institute NSW datasets and the variables associated with these.
- Where the new application involves the collection, use or disclosure of personal health information which is identified, or from which the identity of the person can be reasonably obtained the following is also required:
  - Specific details of participant consent for the collection, use or disclosure of personal health information OR
  - A detailed plan to re-consent participants for the collection, use or disclosure of personal health information
  - Approval for a waiver of the usual requirement for consent from the original Ethics Committee OR
  - A fully justified request for a waiver of the usual requirement for consent + NSW Privacy form
- Variable list(s) for each data collection to be accessed as part of the new application including Data Custodian signoff.
Contact for all enquiries

Please phone the Ethics Committee Administrative Officer on (02) 8374 5615 or Ethics@cancerinstitute.org.au