



Response to the NHMRC Public Consultation on Proposed revisions to the National Statement on Ethical Conduct in Human Research 2007, Chapters 3.4, 3.6, and 3.2

The Population Health Research Network (PHRN) welcomes the opportunity to comment on the revisions to the National Statement on Ethical Conduct in Human Research 2007. PHRN is pleased to provide the following submission.

Background

The Population Health Research Network (PHRN) is responsible for the creation of a research infrastructure that will enable research using linked non-identifiable data from health data sets across all jurisdictions in Australia. The data linkage infrastructure will support the beneficial use of information held by governments for population based research to improve the health and wellbeing of Australians and enhance the effectiveness and efficiency of health services.

The PHRN was established in 2009 with collaboration between Australian state and territory governments and their academic partners to develop national health data linkage infrastructure. It has received \$30 million from the Australian Government Department of Innovation, Industry, Science and Research (DIISR) through the National Collaborative Research Infrastructure Strategy and the Education Investment Fund. State and territory governments and their academic partners have contributed a further \$32 million in cash and in-kind.

The PHRN is working with states and territories to develop safe and secure infrastructure for the linkage of health and related data contained in statutory and administrative data collections, and for the provision of this data to data users for approved projects. PHRN is also developing the capacity to link data across state and territory boundaries.

The purpose of the PHRN is to support the conduct and quality of population level research which can be conducted without researchers having access to personal information. The protection of privacy is, therefore, central to the rationale and activities of the PHRN.

Response

This response relates to Chapter 3.2.

1. We have proposed some minor changes to the wording of the draft documents as outlined below.

Data Linkage

In Australia information is collected via a range of departments and agencies such as public hospitals, state and territory health and education departments, and registries of Births, Deaths and Marriages. The collection of this information is generally required by law. The information is then used for policy, planning, management, monitoring, evaluation and research purposes. Additionally, governments and other agencies may collect information from time to time for a particular purpose such as a survey of health behaviours or a specific research project. Access to this information by researchers has the potential to provide major improvements in the health and wellbeing of Australians.

Data linkage, in simple terms, is a method of bringing together this information about people, places and events. This can be done in a way that protects individual privacy. Data linkage units link existing information from different data collections. The creation of data links can only be performed using identifying information about the data. Data can then be provided to researchers in a way that enables them to match individuals in different data sets without actually being able to identify the person.

Data linkage in research provides a more accurate picture of the health of a population and can be seen to be in the public interest when used:

- *to develop population based health services and evidence-based policy*
- *to investigate potential projects i.e. testing a hypothesis and pilot studies*
- *as a capture-recapture tool, to improve the quality of datasets*
- *for follow-up and comparison of different treatment regimes*
- *to study the cause, co-morbidities and outcomes of disease*

There are three distinct stages in data linkage that may be subject to ethical review. These are:

- *the establishment of a new data linkage unit;*
- *the linking of new data collections; and*
- *applications for access to linked data for individual research projects*

Data linkage projects should be undertaken in ways that protect individual privacy. A waiver of consent for research using personal information in medical research or personal health information must be approved by an HREC in accordance with paragraph 2.3.5 of this National Statement. In addition, the research exception in privacy legislation states that the use and disclosure of personal information for research without the person's consent must be approved by an HREC in accordance with the relevant ethical guidelines.

2. We believe a thorough review of Chapter 3.2 is warranted for the following reasons:
 - 2.1. The chapter currently deals with databanks specifically, however guidance is required around the use of data more generally. Therefore we recommend that the title of the chapter should be changed to “Data” and that guidance be given on assessing and minimising the risks to privacy including:
 - Ensuring that it is necessary to use identifiable data
 - Minimising the access to identifiable data e.g. through role separation
 - Ensuring that researchers only collect and use the data necessary for the project e.g. year of birth instead of full date of birth
 - Ensuring an adequate plan for the management and security of the data
 - 2.2. The role of the HREC in privacy legislation is not acknowledged or explained;

3. Definitions of Data Identifiability

This section should be revised to ensure that

- 3.1. The definitions of data identifiability are consistent with the definitions in both State and Commonwealth Privacy legislation; and
- 3.2. The definitions of identifiability explain that identifiability relates to a particular holder of the information and is not an intrinsic property of the information

We include a proposed draft for your consideration and would be happy to consult further on this and any of our other comments.

Data identifiability

The risk to individual privacy in the collection, use or disclosure of information depends on the degree to which the identity of a specific individual can be ascertained. The degree of identifiability must be assessed in relation to each person or organisation which holds the information. The identity of individuals may be ascertainable by one person or organisation but not by another. Factors relevant to the degree of identifiability of data include:

- *The type of information held;*
- *The quantity of information held;*
- *Other information known to the person who hold the information:*
- *The skills and technology of the holder*

Data may be;

- **Personal information/individually identifiable information** - where the identity of a specific individual can reasonably be ascertained by the holder. For example, information that includes identifiers such as the individual's name, image, date of birth or address
- **Non-identifiable information** – where the identity of individuals cannot reasonably be ascertained by the holder.

Information may be converted from identifiable to non-identifiable or vice versa by:

- **De-identification** – where information is stripped of identifiers. Commonly this is done to enable the information to be provided to another person/organisation in a non-identifiable form
- **Re-identification** - where the identifiers are restored to the information e.g.by using a code