

**PUBLIC CONSULTATION ON SECTION 3 (CHAPTERS 3.1  
& 3.5), GLOSSARY AND REVISIONS TO SECTION 5  
NATIONAL STATEMENT ON ETHICAL CONDUCT IN  
HUMAN RESEARCH, 2007**

**Submission to the National Health and Medical Research  
Council**

**from the Population Health Research Network**

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**NCRIS**  
National Research  
Infrastructure for Australia  

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An Australian Government Initiative

## **1 INTRODUCTION**

### **1.1 Population Health Research Network**

The Population Health Research Network<sup>1</sup> (PHRN) is a national data linkage infrastructure network. PHRN commenced in 2009 and is funded by the Australian Government's National Collaborative Research Infrastructure Strategy (NCRIS), with support from state and territory government agencies and academic partners. The University of Western Australia is lead agent for the PHRN. The PHRN's primary purpose is to build and support the operation of collaborative, nationwide data linkage infrastructure capable of securely and safely linking data collections from a wide range of sources including within and between jurisdictions and across sectors and providing access to linked data to enable world class research and analysis.

The ethical linkage and use of data for human research is of high importance to the PHRN. The PHRN supports the NHMRC's review of Chapters 3.1 & 3.5 of the National Statement and hopes that the updated document will clarify the ethical issues and provide additional guidance to researchers and human research ethics committees (HRECs) on the collection, use and disclosure of data for research purposes.

## **2 SUBMISSION**

### **2.1 Element 4: Data Collection and Management**

#### **Data identifiability**

It is noted in the consultation paper that there is a lack of consistency between the definitions of identifiability in the National Statement and the definitions used in privacy legislation. The PHRN has raised this issue in previous submissions to reviews of the National Statement. Given the important role that human research ethics committees (HRECs) play in the implementation of privacy legislation it is essential that the definitions are consistent. It may also be helpful for the role of HRECs in privacy legislation to be acknowledged and explained in the National Statement.

The definitions of identifiability in the proposed National Statement may lead to the assumption that there are three distinct categories of identifiability. In fact, identifiability is a spectrum and the risks of harm related to the identifiability of the data will depend on:

- the type of data;
- the quantity of data;
- the other data held by the person who receives it AND
- the skills and technology available to the person who receives it.

We recommend that the National Statement should include guidance on how to assess the level of identifiability of data, identify the associated risks and how to choose appropriate risk minimisation and management strategies. If sufficient guidance is provided in the National Statement it may be feasible to remove reference to the three categories of identifiability.

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<sup>1</sup> The Population Health Research Network. Perth WA (Aus). 2016 [cited 27/06/2016]. Available from <http://www.phrn.org.au>

## **2.2 Processes for Ethical Review**

An amendment to Chapter 5.1.6 is required to add research where HREC review is required by privacy legislation to the types of research that require review by an HREC. In our experience many HRECs find the fact that this is not listed as one of the types of research which require review by an HREC to be confusing. For example, projects requesting access to data without consent may be low risk but privacy legislation requires review by an HREC. There can be an assumption that all research that is determined to be low risk can be reviewed by an alternative pathway.

It may also be helpful, for clarity, to repeat clause 2.3.5 which states that “Only an HREC may grant a waiver of consent.....” in the list of research where review by an HREC is required.