



Australian Government

National Health and Medical Research Council

Explanatory Statement

Guidelines under section 95 of the Privacy Act 1988

12 March 2014

1. PURPOSE AND AUTHORITY

Section 95 of the Privacy Act 1988 (Cth) (the Privacy Act) allows the National Health and Medical Research Council (NHMRC) to issue guidelines, with the approval of the Commissioner, for the protection of privacy by agencies in the conduct of medical research.

Authority for making the guidelines

Section 95(1) and (2) of the Privacy Act set out the authority to approve the making of the guidelines. They state:

95 Medical research guidelines

- (1) The CEO of the National Health and Medical Research Council may, with the approval of the Commissioner, issue guidelines for the protection of privacy in the conduct of medical research.
- (2) The Commissioner shall not approve the issue of guidelines unless he or she is satisfied that the public interest in the promotion of research of the kind to which the guidelines relate outweighs to a substantial degree the public interest in maintaining adherence to the Information Privacy Principles.

2. REASONS FOR MAKING THESE GUIDELINES

Background to the s95 Guidelines

The s95 guidelines have been issued to reflect amendments to the Privacy Act which take effect on 12 March 2014. They replace the previous version dated March 2000.

In response to the Australian Law Reform Commission's report in relation to Australian privacy law and practice, the *Privacy Amendment (Enhancing Privacy Protection) Act 2012* amended the Privacy Act 1988 to replace the Information Privacy Principles (IPPs) for the public and private sectors respectively with a single set of privacy principles (the Australian Privacy Principles (APPs)). The s95 guidelines were updated in accordance with the amended Act, to replace references to the IPPs with the APPs.

In addition, references to the *National Statement on Research Involving Humans, 1999* was updated with references to the *National Statement on Ethical Conduct in Human Research, 2007*. This human research guideline promotes ethically good human research by providing ethical guidance for researchers, ethical review bodies, those involved in research governance and research participants.

The *Joint NHMRC/AVCC Statement and Guidelines on Research Practice* has been replaced by the *Australian Code for the Responsible Conduct of Research, 2007* and these references have also been updated. This document is a guide to institutions and researchers in responsible research practices.

Information regulated by the s95 guidelines

The s95 guidelines apply where medical research involves the use of personal information held by an agency, the processes that are set out in the s95 guidelines must be followed, in order for the information to be lawfully used or disclosed.

3. CONSULTATION

Public consultation was not undertaken due to the minor/ machinery nature of the changes which give effect to a legislative change, which has been debated in Parliament.

The NHMRC worked closely with the Office of the Australian Information Commissioner in making the updates to the guideline.

4. LEGAL STATUS OF THE GUIDELINES

The s95 guidelines form part of the legal requirements for compliance with federal legislation, namely the Privacy Act.

The s95 guidelines apply where medical research involves the use of personal information held by an agency, the processes that are set out in the s95 guidelines must be followed, in order for the information to be lawfully used or disclosed.

A breach of the s95 guidelines constitutes an interference with privacy under section 13A of the Privacy Act.

An individual may complain to the Privacy Commissioner about an act or practice they believe has not been done in accordance with the s95 guidelines.

The s95 guidelines take effect from 12 March 2014.