

HREC ALERT No 2, 18 April 2007

ADVICE FOR HRECS ON USE OF:

- **GUIDELINES UNDER SECTION 95 OF THE *PRIVACY ACT 1988* (NHMRC, MARCH 2000); AND**
- **GUIDELINES APPROVED UNDER SECTION 95A OF THE *PRIVACY ACT 1988* (NHMRC, DECEMBER 2001)**

1. PURPOSE

This ALERT is designed to assist HRECs to decide when they need to use – and when they do not need to use

- the Guidelines under Section 95 of the *Privacy Act 1988* (section 95 guidelines); and
- the Guidelines approved under Section 95A of the *Privacy Act 1988* (section 95A guidelines).

2. BACKGROUND

Status of the section 95 and section 95A guidelines

Revisions to both the section 95 and the section 95A guidelines are overdue.

On 31 January 2006, the Australian Law Reform Commission (ALRC) commenced its Inquiry into the *Privacy Act 1988*. The Inquiry report is due in March 2008.

There is a possibility that the Inquiry report could recommend changes that affect the need for, or have implications regarding, the section 95 guidelines and/or the section 95A guidelines.

Therefore, the NHMRC has decided to postpone reviews of these guidelines until more is known about the direction of the Inquiry. In March 2007, the Chief Executive Officer of NHMRC advised the Deputy Privacy Commissioner of NHMRC's decision to defer the revision of the guidelines pending more information about the direction of the Inquiry. .

Use of the section 95 and section 95A guidelines

Analysis of HREC annual reports shows that only a very small number of the research projects reviewed by HRECs require consideration of the section 95 guidelines or section 95A guidelines.

However, the Australian Health Ethics Committee (AHEC) is aware that many HRECs and researchers have found it difficult to determine when it is necessary to use either the section 95 guidelines or the section 95A guidelines, in their consideration of research that proposes to collect, use or disclose personal health information.

To address this, new guidance has been prepared to assist HRECs to more readily determine whether they do or do not need to use either the section 95 guidelines or the section 95A guidelines, in their consideration of research proposals. The guidance comprises a set of **threshold** questions the answers to which will identify proposals for which the section 95 guidelines or the section 95A guidelines are – or are not – needed .

Where a HREC determines that it needs to use either of the guidelines, full details of the consideration of the proposal must be reported in that HREC's annual report to NHMRC.

3. NEW GUIDANCE ON USE OF SECTION 95 AND SECTION 95A GUIDELINES: THRESHOLD QUESTIONS

PART 1 DO YOU NEED TO USE THE S95 OR S95A GUIDELINES?

1. Does the research proposal involve the collection, use or disclosure of personal information?
 - If the answer is **no**, you do not need to use either the section 95 guidelines or the section 95A guidelines in the ethical review of the proposal.

YOU NEED ANSWER NO FURTHER QUESTIONS

- If the answer is **yes**, go to Question 2.

2. Does the research proposal involve the collection, use or disclosure of personal information **without the consent** of the people to whom the information relates?
 - If the answer is **no**, you do not need to use either the section 95 guidelines or the section 95A guidelines in the ethical review of the proposal.

YOU NEED ANSWER NO FURTHER QUESTIONS

- If the answer is **yes**, go to Part 2.

PART 2 DO YOU NEED TO USE THE S95 GUIDELINES?

3. Is the personal information to be collected from an *agency*?
 - If the answer is **no**, go to Part 3.
 - If the answer is **yes**, go to Question 4.
4. Is the personal information to be used for medical research?
 - If the answer is **yes**, you will need to use the section 95 guidelines.
 - If the answer is **no**, you do not need to use the s95 guidelines.

YOU NEED ANSWER NO FURTHER QUESTIONS

If you need to use the section 95 guidelines, record :

- The details required by paragraph 3.4 of the *Guidelines Under Section 95 of the Privacy Act 1988*.
- Any complaints received in relation to any of the proposals to which you applied the section 95 guidelines.

and

- Include all this information in your annual report to NHMRC.

PART 3 DO YOU NEED TO USE THE S95A GUIDELINES?

OR

DO YOU NEED TO REFER TO STATE LEGISLATION?

5. Is the personal information to be collected from a *State or Territory authority*?
- If the answer is **no**, go to Question 6.
 - If the answer is **yes**, you may need to refer to State or Territory legislation that governs the use of personal information by public authorities.

6. Is the information health information?
- If the answer is **no**, you do not need to use the section 95A guidelines.

YOU NEED ANSWER NO FURTHER QUESTIONS

- If the answer is **yes**, go to Question 7.

7. Is the health information to be collected from a *State or Territory authority*?
- If the answer is **no**, go to Question 8.
 - If the answer is **yes**, you may need to refer to State or Territory legislation that governs the collection, use or disclosure of health information by either State or Territory public authorities.

8. Is the health information to be collected from an *organisation* in the private sector?
If the answer is **no**, you will not need to use the s95A guidelines.

YOU NEED ANSWER NO FURTHER QUESTIONS

- If the answer is **yes**, and if the answer to any of the sub-questions listed below is also **yes**, then you will need to use the section 95A guidelines:

Is the information to be collected to be used for:

- research relevant to public health or to public safety; and/or
- the compilation or analysis of statistics; and/or
- the conduct of the management, funding or monitoring of a health service?

If you need to use the section 95A guidelines, record:

- The details required by paragraph D.6 of the *Guidelines approved under Section 95A of the Privacy Act 1988*.
- Any complaints received in relation to any of the proposals to which you applied the section 95 guidelines.

and

- Include all this information in your annual report to NHMRC.

PART 4 DEFINITIONS

The following definitions are either as they appear in the *Privacy Act 1988* or, where those are complex, a summary of their effect, indicated by using the expression “refers”.

agency refers to a Minister, a Department or a body established or appointed for a public purpose by or under a Commonwealth enactment, by the Governor-General, or by a Minister, or a person holding or performing the duties of an office established by or under, or an appointment made under a Commonwealth enactment, or a person holding or performing the duties of an appointment under an Act or by the Governor-General.

"health information" means:

(a) information or an opinion about:

- (i) the health or a disability (at any time) of an individual; or
- (ii) an individual's expressed wishes about the future provision of health services to him or her; or
- (iii) a health service provided, or to be provided, to an individual;

that is also personal information; or

(b) other personal information collected to provide, or in providing, a health service; or

(c) other personal information about an individual collected in connection with the donation, or intended donation, by the individual of his or her body parts, organs or body substances; or

(d) genetic information about an individual in a form that is, or could be, predictive of the health of the individual or a genetic relative of the individual.

health service means:

(a) an activity performed in relation to an individual that is intended or claimed (expressly or otherwise) by the individual or the person performing it:

- (i) to assess, record, maintain or improve the individual's health; or
- (ii) to diagnose the individual's illness or disability; or
- (iii) to treat the individual's illness or disability or suspected illness or disability; or

(b) the dispensing on prescription of a drug or medicinal preparation by a pharmacist.

organisation refers to an individual, a body corporate, a partnership any other unincorporated association or a trust that is not a small business operator, a registered political party, an agency, a State or Territory authority.

personal information means information or an opinion (including information or an opinion forming part of a database), whether true or not, and whether recorded in a material form or

not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion.

small business refers to an organisation whose annual turnover for the previous financial year is \$3,000,000 or less.

small business operator refers to an individual, body corporate, partnership, unincorporated association or trust that only carries on one or more small businesses. However, an individual, body corporate, partnership, unincorporated association or trust is not a ***small business operator*** if he, she or it provides a health service to another individual and holds any health information except in an employee record or collects or discloses personal information about another individual to anyone else for a benefit, service or advantage.

Note: The practical effects of the definitions of organisation, small business and small business operator are:

- (a) where personal information and not health information is involved, the Act applies only to organisations with an annual turnover of more than \$3million;
- (b) where health information is involved, the Act applies to organisations that are small businesses or small business operators with health information.

State or Territory authority refers to a State or Territory Minister or a Department or a body established or appointed for a public purpose under a law of a State or Territory or by a Governor of State or Executive authority of a Territory or a person holding or performing the duties of an office established under a law of a State or Territory or by an appointment made by a Governor of a State or Executive Authority of a Territory and includes a State or Territory court.