

NSW HEALTH POLICY DIRECTIVE

Human Research Ethics Committees (HRECs) - Privacy Addition to HREC Application Form

The *Health Records and Information Privacy Act 2002* (the Act) which commenced operation on 1 September 2004 regulates the collection, use and disclosure of personal health information and requires Human Research Ethics Committees (HRECs) to fulfil certain requirements.

NSW Health has determined the questions that HRECs should include in their application form so as to meet their obligations under the Act and associated Statutory Guidelines. HRECs should incorporate the questions outlined in this policy directive as soon as practicable.

The “office use” section of the questions is to assist HRECs meet annual reporting requirements to the Privacy Commissioner. If any project involves the use of identifying information without consent, the HREC Executive Officer must fill in the “office use” section of the form and retain it for the purposes of reporting to the Privacy Commissioner.

A model information sheet, which HRECs can make available to researchers, is also included.

This policy directive replaces any previous model privacy questions issued by the Department.

The Act and associated Statutory Guidelines can be found on the website of Privacy NSW: www.lawlink.nsw.gov.au/privacynsw

**PRIVACY QUESTIONS TO BE INCLUDED IN APPLICATIONS TO
NSW HEALTH HUMAN RESEARCH ETHICS COMMITTEES**

Q1. Is there a requirement for the researchers to collect, use, or disclose information of a personal nature (*either identifiable or potentially identifiable*) about individuals without their consent:

- from Commonwealth departments or agencies?
- from State departments or agencies?
- from other third parties, such as non-government organisations?

If you ticked one or more of the above boxes, state what information will be sought and how many records will be accessed.

Q2. Is there a requirement for the researchers to collect, use, or disclose personal health information about individuals without their consent which is identifiable or potentially identifiable?

- Yes – go to question 3.
- No – you do not need to complete any more of this privacy section of the application form.

Q3. Indicate the reason(s) why de-identified information cannot be used

- The project involves linkage of data
- Scientific deficiencies would result if de-identified information was used. Please provide details.

- Other. Please provide details

Go to question 4.

Q4. Why is it impracticable to obtain the consent of the individual to the collection, use or disclosure of their health information?

- The size of the population involved in the research.
- The proportion of individuals who are likely to have moved or died since the health information was originally collected.
- The risk of introducing potential bias into the research, thereby affecting the generalisability and validity of the results.
- The risk of creating additional threats to privacy by having to link information in order to locate and contact individuals to seek their consent.
- The risk of inflicting psychological, social or other harm by contacting individuals with particular conditions in certain circumstances.
- The difficulty of contacting individuals directly when there is no existing or continual relationship between the organisation and the individuals.
- The difficulty of contacting individuals indirectly through public means, such as advertisement and notices.
- Other – please give details.

Q5. Explain why the collection, use or disclosure of this information is in the public interest, and why the public interest in the project substantially outweighs the public interest in the protection of privacy.