

Human Research Ethics Committees: National Ethics Application Form - Application within NSW Health

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Functional Sub group Clinical/ Patient Services - Research

Summary This Policy Directive sets out the requirements of Human Research Ethics Committees in accepting applications for research submitted on the National Ethics Application Form.

Replaces Doc. No. Human Research Ethics Committees - Privacy Addition to HREC Application Form [PD2005_582]

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Applies to Area Health Services/Chief Executive Governed Statutory Health Corporation, Board Governed Statutory Health Corporations, Affiliated Health Organisations - Non Declared, Affiliated Health Organisations - Declared, NSW Dept of Health, Public Health Units, Public Hospitals

Audience Human Research Ethics Committees, researchers

Distributed to Public Health System, NSW Ambulance Service, NSW Department of Health, Public Health Units, Public Hospitals

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Status Active

Director-General

This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is **mandatory** for NSW Health and is a condition of subsidy for public health organisations.

HUMAN RESEARCH ETHICS COMMITTEES: NATIONAL ETHICS APPLICATION FORM – APPLICATION TO NSW HEALTH HUMAN RESEARCH ETHICS COMMITTEES

Mandatory policy

This policy directive sets out the requirements for the use of the National Ethics Application Form (NEAF) within the NSW public health system. Human Research Ethics Committees (HRECs) within NSW Health must accept research proposals that are submitted on NEAF.

HRECs may continue to accept research proposals submitted using the HREC's own application form. Lead HRECs must require multi-centre research proposals to be submitted on NEAF.

Application

This policy directive applies to all NSW public health organisations.

The objective of this policy directive is to improve the efficiency and effectiveness of the ethical review process by providing for a nationally consistent HREC application form. The existence of a national standard for the submission of research applications to HRECs will enable HRECs to be confident that they are provided with the information necessary to undertake an ethical review. It will also go some way towards reducing duplication of effort for researchers, by encouraging a consistent approach towards the information HRECs require in research submissions.

This policy directive replaces PD2005_582 *"Human Research Ethics Committees – privacy addition to HREC application form"*.

Background

NEAF is co-sponsored by the National Health and Medical Research Council, the Australian Research Council and the Australian Vice Chancellors' Committee.

Implementation

This policy takes effect immediately.

Enquiries regarding this policy should be directed to the NSW Health Research and Ethics Branch (02) 9391 9427.

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Human Research Ethics Committees: National Ethics Application Form (NEAF) – Application within NSW Health

1. The National Health and Medical Research Council, in conjunction with the Australian Research Council and Australian Vice Chancellors' Committee, has released a National Ethics Application Form (NEAF) for the submission of research proposals to Human Research Ethics Committees (HRECs). NEAF is a web-based application form that is based upon the legislation and guidelines surrounding research ethics, including the NHMRC *National Statement on Ethical Conduct in Research Involving Humans*.
2. All HRECs within the NSW public health system must accept research proposals that are submitted on NEAF. It is a matter for each individual HREC to determine the manner in which it will accept applications submitted on NEAF (whether in electronic or hard copy) and the number of copies required.
3. HRECs may continue to accept research proposals submitted using the HREC's own application form. However, lead HRECs accredited under the NSW Health model for single review of multi-centre research, must require multi-centre research proposals to be submitted on NEAF. If an HREC so wishes, it may make the use of NEAF mandatory.
4. The use of NEAF will enable NSW Health HRECs to:
 - determine whether a research project complies with the Health Records and Information Privacy Act 2002; and
 - complete the annual report required by Privacy NSW (the annual report is found in the Statutory Guidelines issued under HRIPA which can be found at <http://www.lawlink.nsw.gov.au/privacynsw>).

Accordingly, researchers submitting proposals on NEAF are not required to complete the additional NSW Health privacy questions outlined below.

5. Researchers not submitting proposals on NEAF are required to complete the additional NSW Health privacy questions outlined in the "Privacy Addition to HREC Application Form" below. This form has been annotated to show where the corresponding questions appear in NEAF.
6. HREC Executive Officers may complete the "office use only" section of the "Privacy Addition to HREC Application Form" to assist them in reporting to the Privacy NSW. The "office use only" section can be completed in respect of projects submitted using NEAF, and projects submitted using the HREC's own form with the additional privacy questions. The "office use only" section is not part of the prescribed annual report to Privacy NSW, but merely a tool to assist HREC Executive Officers with their reporting obligations.
7. NEAF can be accessed from: <http://www.neaf.gov.au>.

Robyn Kruk
Director-General

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**Privacy Addition to HREC Application Form
(to be completed when using HREC applications forms other than the
National Ethics Application Form (NEAF))**

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 when conducting their ethical review.

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.

These questions do not apply to research proposals submitted on the National Ethics Application Form (NEAF). NEAF includes corresponding questions to those in this form. The corresponding NEAF references are annotated below each question.

The “office use” section of this form is to assist HRECs meet annual reporting requirements to Privacy NSW. If any project (either submitted on NEAF or on the HREC’s own application form with this form annexed) involves the use of identifying information without consent, the HREC Executive Officer may complete the “office use” section of this form and retain it for the purposes of reporting to the Privacy Commissioner.

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

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PRIVACY QUESTIONS TO BE INCLUDED IN APPLICATIONS TO NSW HEALTH HUMAN RESEARCH ETHICS COMMITTEES OTHER THAN THOSE SUBMITTED ON THE NATIONAL ETHICS APPLICATION FORM (NEAF)

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.

NEAF:3.5.1.3.0; 3.5.1.4.0; 3.5.1.4.1.1.4

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 section of the application form. Go to [*insert next section of your standard HREC application form*]

NEAF:3.5.1.4.1.1.5

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

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NEAF: 3.6.2.1.1

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.

NEAF: 3.5.1.4.1.1.5.3.1

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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.

NEAF: 3.12

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Office use only: report to the Privacy Commissioner

- If the project uses identifying health information without consent, mark here and keep a copy of this page for attaching to the annual report required by Privacy NSW or to help you complete their report.
- Insert number of trial protocol.....

In compliance with HRIPA, the HREC found:

1. The purposes of the proposed activity could not be achieved using de-identified information because
 - The proposed project involves linkage of data.
 - Scientific defects in the project would result if de-identified information was used
 - Other. Give brief description.....
2. It was impracticable to obtain consent in this project because
 - 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 –give brief details.....

The outcome of this project was

- Approved including privacy aspects.
- Rejected for reasons including privacy aspects.
- Rejected for other reason.