



HUMAN RESEARCH ETHICS COMMITTEE (HREC)

APPLICATION FOR ETHICS APPROVAL OF A RESEARCH PROJECT WITH HUMAN PARTICIPANTS

Instructions:

1. The HREC's *Guidelines for Researchers* should be used to complete this application form.
2. Research projects requiring the use of the name of Royal District Nursing Service (RDNS), or its equipment, premises, clients, students, or staff is not to be undertaken until written approval from the RDNS Human Research Ethics Committee (HREC) has been granted.
3. Researchers wishing to conduct research are required to complete the RDNS *Application for Ethics Approval of a Research Project with Human Participants* form and submit the form to the HREC for approval at least ten (10) clear working days before a meeting. Please refer to separate Meeting and Submission Dates for Human Research Ethics Committee document for the dates of meetings. All relevant sections of the application must be completed before the HREC will consider the proposal. The original signed form together with twelve (12) photocopies must be forwarded to:

The Secretary
RDNS Human Research Ethics Committee
RDNS Helen Macpherson Smith Institute of Community Health
31 Alma Road
St Kilda Victoria 3182

Ph: 9536 5322
Fax: 9536 5300

4. The following attachments are to be enclosed with the completed application:
 - Plain Language Statement (see Attachment 1)
 - Informed Consent Form (see Attachment 2)
 - Declaration of Confidentiality by Transcribers of Taped Data Form (see Attachment 3)
 - Ethical Issues Checklist
 - Evidence of permission to use public or private places (where applicable)
 - Other Ethics Committee evidence of approval, (e.g. multi-centre research) where applicable
 - Copies of relevant supporting documents (e.g. surveys, questionnaires, introductory letters, etc.); and
 - Supporting documentation from relevant manager/s supporting the research and employees involvement.
 - If project is related to public health or public safety *under Privacy Act 1988* (see Attachment 4)

APPROVAL (Office use only)

Date application submitted to HREC: ____/____/____ Date project commenced: ____/____/____

Date application approved by HREC: ____/____/____ Date project completed: ____/____/____

Application approved/not approved: _____
(Signature of Chair of HREC) (Date)

Conditions of approval (if any):

1. OVERVIEW OF RESEARCH PROJECT

1.1 Title of research project:

1.2 Is another Human Research Ethics Committee involved with this research project?

Yes No

(If 'YES', please give details. Where available, evidence of ethics committee approval should be attached).

1.3 Period of time for which activities requiring HREC approval will be required?

FROM: TO:

2. DECLARATION

I/We, the undersigned, verify that:

- I/We have accessed and become familiar with the NHMRC's *National Statement on Ethical Conduct in Human Research* and the RDNS Human Research Ethics Committee's *Guidelines for Researchers*
- I/We accept responsibility for the accuracy of the information provided in this application, and
- I/We accept responsibility for the conduct of the research as outlined in this application.

APPLICANTS

Name(s) (in block letters)

Signature

Date

3. PROJECT DETAILS

3.1 Details of researcher(s) making submission: (Attach details of additional researchers)

PRINCIPAL RESEARCHER

Full name:	Phone no:
Address:	Email:
Position and employer's name:	
Qualifications:	
Formal research education:	

RESEARCHER 2

Full name:	
Telephone No:	Email:
Position and employer's name:	
Qualifications:	
Formal research education:	

RESEARCHER 3

Full name:	
Telephone no:	Email:
Position and employer's name:	
Qualifications:	
Formal research education:	

RESEARCHER 4

Full name:	
Telephone no:	Email:
Position and employer's name:	
Qualifications:	
Formal research education:	

Further names should be submitted as attachments.

3.5 Auspice of research.
What is the name of the organisation taking responsibility for the project?

Educational Institution:
Title of course:
Supervisor's name:
Supervisor's title:
Address of supervisor:
Phone number:
Email:

a) What steps will be taken by the supervisor to ensure the student is sufficiently competent to undertake the procedures involved in data collection?

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b) How will the supervisor ensure the research project is conducted in accordance with the procedures approved by the RDNS HREC?

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3.6 Is the research being undertaken by an undergraduate or postgraduate student under supervision?

Yes No (If Yes, give details).

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3.7 Is the research project being sponsored or funded by a group or organisation?

Yes No If Yes, give details).

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3.8 Provide clear details of RDNS related costs.

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3.9 What are the potential benefits of the research to:

1) The participants?

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2) To RDNS?

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3) To the community it serves?

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4. PROTECTION OF PARTICIPANTS

4.1 Are there procedures associated with the research project that might leave a participant open to the risks of emotional or physical harm greater than or in addition to the risks they would normally encounter? (Examples of these risks include those associated with disclosing a participant's name or data to another person or a participant recalling a traumatic or distressing event during an interview).

Yes No

If Yes, identify the steps you will take to prevent or minimise them. Identify the steps you will you take if a participant becomes distressed. For example, include below the name, address and phone number of a person who has agreed to offer psychological counselling.

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4.2 Are there any invasive procedures involved with your research project? Will participants come into contact with equipment and/or substances that have the potential to harm them?

Yes No

(If Yes, what safety precautions will you take to protect participants from harm?)

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4.3 What steps will you take to ensure the confidentiality of the data provided by participants? How will the security of data be maintained? How long will data be stored for?

a) During the study?

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b) Following completion of the study?

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4.4 Are there any ethical issues that are inherent in the research that have not been identified above?

Yes No

Please declare and explain how you will address this.

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(Use the Ethics Checklist - to review your research project. If Yes, explain and justify your response and provide details about how you will address these issues).

ETHICAL CHECKLIST

Please tick any of the following ethical issues you believe are relevant to this application. Please provide a response to every question. **If you answer 'YES' to any of the questions listed above, you are required to explain and justify your response in the relevant part of Section 4 of this application (especially Section 4.4). Provide details on how you will address these issues.**

	YES	NO
1. Is deception of any kind to be used?	<input type="checkbox"/>	<input type="checkbox"/>
2. Does the research involve sponsorship and funding?	<input type="checkbox"/>	<input type="checkbox"/>
3. Does the data collection process involve access to confidential records/health information without the prior consent of participants?	<input type="checkbox"/>	<input type="checkbox"/>
4. Will the research involve access to data stores subject to privacy legislation?	<input type="checkbox"/>	<input type="checkbox"/>
5. Will the subjects have pictures or videos taken of them?	<input type="checkbox"/>	<input type="checkbox"/>
6. Will data have a secondary use in another research project?	<input type="checkbox"/>	<input type="checkbox"/>
7. If interviews are to be conducted, will they be tape-recorded or video-taped?	<input type="checkbox"/>	<input type="checkbox"/>
8. Will participants come into contact with any electrical equipment in any form (e.g., audiometer, biofeedback device, electrical stimulator)?	<input type="checkbox"/>	<input type="checkbox"/>
9. Will participants be asked to perform acts or make any statements which might diminish their self-esteem or cause them to experience embarrassment or regret?	<input type="checkbox"/>	<input type="checkbox"/>
10. Will any procedures, substances, tasks, investigations be used with potentially unpleasant, noxious or harmful effects during or after the research?	<input type="checkbox"/>	<input type="checkbox"/>
11. Will the research involve the use of no-treatment or treatment withdrawal or placebo control conditions?	<input type="checkbox"/>	<input type="checkbox"/>
12. Will any samples of body fluids or body tissues be obtained specifically for the research?	<input type="checkbox"/>	<input type="checkbox"/>
13. Is there any special relationship between any recruiter, or any investigator, and the participants?	<input type="checkbox"/>	<input type="checkbox"/>
14. Are there any social, cultural, linguistic, religious or other sensitivities that have to be considered in regard to this project?	<input type="checkbox"/>	<input type="checkbox"/>
15. In your opinion, are there any other ethical issues involved in this research project?	<input type="checkbox"/>	<input type="checkbox"/>

ATTACHMENT 1

PLAIN LANGUAGE STATEMENT

(This is to be attached to every application involving human participants, and accompanied by Informed Consent Form. Use plain language and provide a copy of statement in language of participant)

Title of research project:

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Names of researchers:

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Description of project:

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If you have any questions about this project or would like to participate please contact:

Name of Principal Researcher:

Address:
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Phone:

If you have any concerns or complaints about the conduct of this research project please contact:

Chair
RDNS Human Research Ethics Committee
RDNS Helen Macpherson Smith Institute of Community Health,
31 Alma Road,
St. Kilda, Victoria, 3182

Phone (03) 9536 5382, Fax (03) 9536 5300

Email getinfo@rdns.com.au

* See RDNS Guidelines for researchers regarding special requirements for translation for people of non-English speaking background.

ATTACHMENT 2

EXAMPLE ONLY OF INFORMED CONSENT FORM

- Minimum requirement for informed consent is set out below
- Additional requirements may be included dependent on the research project
- May be adjusted to suit requirements of research project
- Must be accompanied by Plain Language Statement

Consent (participant must fill out below)

Name of research project:

Participant's details:

Name: (in block letters)

Address:

I hereby consent to participate in the above research project.

- The details of this research project have been explained to me verbally, and
- I have received a copy of the Plain Language Statement, and
- Any questions I have asked in regard to this project have been answered to my satisfaction.

I agree to participate in this research project and understand that I may withdraw at any time without my care (or employment) being affected in any way. If I withdraw from the project any data previously collected will be destroyed. I agree that research data provided by me may be used in a report, presented at conferences or published in journals on the condition that neither my name nor any other identifying information is used. I understand that any information I provide will be treated with the strictest confidence.

Signature of participant:
(Print name) (Signature) (Date)

OR

On Participant's behalf:
(Print name) (Signature) (Date)

Relationship to participant:

Witnessed by:
(Print name) (Signature) (Date)

ATTACHMENT 3



DECLARATION OF CONFIDENTIALITY BY TRANSCRIBERS OF TAPED DATA

(If researchers intend to use transcribers in their project, this form must be submitted as soon as the transcribers are employed for the task)*

Research Project Title:

.....
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Transcriber (please print details below)

I (full name)

Of (address)

.....

acknowledge that all information transcribed by me for the research project named above will be treated by me with the strictest confidence.

Further, I will ensure that all tapes while in my possession will be treated with the same level of confidentiality as the transcribed material and, together with the data, will be stored separately and securely, as stated in the research project application.

All material relating to the above project will, while in my possession, be accessible to the researcher(s) only.

Signature:

Date:

Witnessed by: (print name of Principal Researcher)

Name:

Signature:

Date:

ATTACHMENT 4



ADDITIONAL INFORMATION FOR COLLECTION, USE OR DISCLOSURE OF HEALTH INFORMATION IN THE PUBLIC INTEREST UNDER HEALTH RECORDS ACT 2001 (VIC)

Introduction

Under the Health Records Act (HRA) the Victorian Health Services Commissioner has issued *Statutory Guidelines on Research for the purposes of Health Privacy Principles 1.1 (e) (iii) and 2.2 (g) (iii)*, hereafter referred to as 'the Guidelines'. The Guidelines concern the collection, use and disclosure of health information for the purposes of research or the compilation or analysis of statistics, in the public interest where consent to use the information is not obtained, and where the information could identify the individuals concerned.

Intending collectors or users and disclosers of health information under the HRA should familiarise themselves with the requirements of these Guidelines and complete all sections of this form

1. **This proposal relates to** (Please tick appropriate box below):

Health Privacy Principle 1.1 (e)

- Collection of health information

Health Privacy Principle 2.2 (g)

- Use of health information
- Disclosure of health information

2. **Purpose of proposal**

- Research in the public interest
- Compilation or analysis of statistics in the public interest

3. **Has approval to collect health information been obtained from another HREC:**

- Constituted in accordance with the NHMRC's *National Statement on Ethical Conduct in Human Research*. Yes No
- In accordance with the appropriate section of these Guidelines? Yes No

(If yes to both of the above please attach written notification of their decision).

NB: If no to both of the above and this proposal relates **use and/or disclosure** of health information only, this proposal must be **jointly** submitted by the intending collector and the organisation that is being approach or is seeking to use or disclose health information.

4. Please elaborate on the following:

Why the conduct or outcome of the proposed activity would be in the public interest. (The information to be included is set out in Section 2.7 [Collection] and 3.7 [Use and disclosure] in the Guidelines).

Why the public interest in the proposed activity outweighs the public interest in the protection of privacy.

Why de-identified information cannot serve the purpose of the proposed activity.

Why it is impracticable to seek consent from the individual/s.

The specific use to which the health information will be applied during the study

The names of the custodian/s of the health information collected

The names of personnel with access to the health information once it is collected

The level of protection that will apply to protect the health information disclosed to you by RDNS, including:

- i) Terms of any release agreement between RDNS and the researchers that govern limits on the use and disclosure of the health information

- ii) Proposed methods of disposal of health information on completion as required by Health Privacy Principle 4 or the *Public Records Act 1973 (Vic)*

- iii) The level of protection that will be applied to protect the privacy of health information where it is made available to others if that is proposed.

The amount of time you will retain the health information.

The proposed method of publication of the results of the research, including a statement that health information will not be published unless in de-identified form