

# Justice Health Human Research and Ethics Committee (HREC)

## Application Procedure & Guidelines

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## Introduction

In Australia, all research studies involving human subjects must adhere to the National Statement on Ethical Conduct in Human Research 2007

[www.nhmrc.gov.au/publications/synopses/e72syn.htm](http://www.nhmrc.gov.au/publications/synopses/e72syn.htm)

All health research undertaken with people in the correctional environment is subject to review by the Justice Health Human Research and Ethics Committee (HREC). The role of this committee is to safeguard the welfare and rights of both research subjects and researchers. This committee reviews all research within Justice Health and ensures that all projects are undertaken within the nationally and internationally approved ethical and safety framework.

The Committee has developed specialist expertise in the areas of health and human rights, research on people deprived of their liberty and research involving persons in dependent or unequal relationships.

The Committee's major roles are to:

- Consider the ethical implications of all proposed research projects;
- Advise applicants of approval, rejection or recommendations for changes to research submissions;
- Maintain surveillance of approved research, and
- Maintain a register of projects.

In carrying out its functions the Committee will consider the risks and benefits to subjects on the research and perceived benefits of the research.

The core membership of the Justice Health HREC complies with the National Statement in that it includes a chairperson, a laywoman, a layman, a minister of religion, an Aboriginal person, a lawyer, a medical scientist with research experience and a nurse. The Committee is chaired by Associate Professor Sandra Egger, who is the Head of School, Faculty of Law University of New South Wales.

The Committee meets five times per year, considering between 12 and 15 new protocols per year, as well as reviewing progress and compliance of all currently approved studies. Out of session consideration of new protocols is also undertaken when necessary.

The types of protocols typically reviewed by the committee includes:

- Clinical research (all disciplines)
- Clinical trials
- Mental health research
- Public health and epidemiological research
- Psychological and behavioural research
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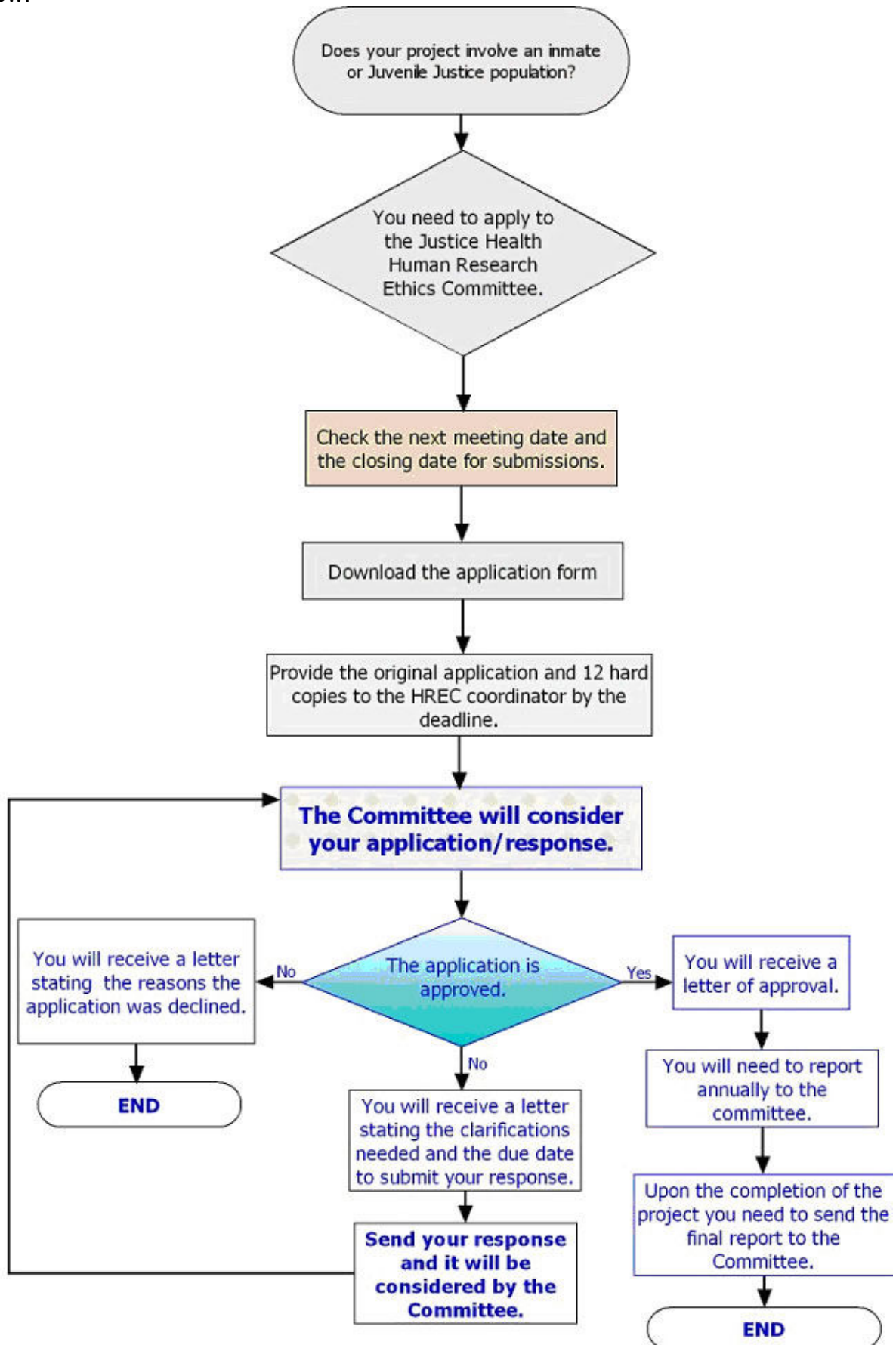
In undertaking an ethical assessment of a proposed project, the Committee considers a number of issues:

- Is the purpose of the study such that it will usefully advance medical/scientific knowledge?
- Has it been designed so that a valid conclusion will be reached?
- What procedures will subjects undergo? Are they unnecessarily painful, arduous, risky or time-consuming?

- Are questionnaires phrased in such a way that they do not cause anxiety or alarm to subjects?
- Is any undue inducement being offered to encourage prospective subjects to participate?
- Have the Subject Information Statement and Consent Form been prepared in clear, concise, plain language giving full details of the procedures, risks and benefits that the subject will face if he/she agrees to participate?
- Have suitable arrangements been made to ensure that subjects of non-English speaking backgrounds also have the opportunity to take part in the study and to give informed consent to their participation?

# Information for Applicants

The standard process for applying to the Justice Health HREC is detailed in the flowchart below.



## **Responsibilities of researchers and Justice Health staff**

Justice Health Staff must ensure that:

- no research is conducted which has not received approval by the Justice Health HREC;
- all relevant information has been provided to the Justice Health HREC;
- all relevant guidelines and legal requirements are complied with;
- monitoring requirements are complied with;
- proposed protocol modifications and amendments are submitted to the Justice Health HREC for approval;
- adverse events are promptly notified.

Researchers are expected to declare:

- sources of funding
- commercial sponsorship or involvement
- relevant personal or competing interests, including consultancies, paid travel, shareholdings, patents or patent applications, etc.
- any payments, inducements, or rewards offered to research participants

It is the applicant's responsibility to:

- Obtain all necessary administrative approvals from relevant administrative sections of Justice Health.
- Obtain any necessary clearances (biosafety, use of ionising radiation, etc)
- Provide information (where relevant) about compensation, indemnity, nature and currency of insurance policies, etc.
- Provide copies of any contracts entered into with commercial sponsors or other third parties.

## **Justice Health administrative approval**

Researchers are required to obtain a letter of Justice Health administrative approval from the relevant clinical stream within Justice Health in order to conduct the research.

Providing this letter of approval at the time of ethics submission to the Justice Health HREC application would be looked favorably upon. If this is unable to be achieved, the letter of approval must be sought and provided to the HREC prior to the research getting underway.

## **Acknowledgement of Justice Health**

If Justice Health administrative or clinical staff made a contribution towards any research being conducted, they must be acknowledged in any report, peer-reviewed publication, conference presentation or any other public dissemination of the findings. An example of this acknowledgement is: 'The authors wish to thank Justice Health for their support in the conduct of this research.'

## **Monitoring**

The conduct of approved studies is monitored by the Justice Health HREC. In most cases, this involves the completion of an annual report form.

## **Complaints**

Any person (including participants, researchers, staff, students, administrators, etc) can make a complaint to the Justice Health HREC about any aspect of a research study. Any other matter of ethical concern can also be brought to the Committee's attention, and will be appropriately investigated. Complaints should be directed to the Secretary of the Committee in the first instance (see contact details below).

## Committee Members

- A/Prof Sandra Egger (Chairperson)
- Ms Rhonda Booby (Lawyer)
- Ms Shiree Smit (Laywoman)
- Mr Richard Gartrell (Layman)
- Ms Julie Babineau, Chief Executive, Justice Health
- Associate Professor Andrew Cashin, Justice Health & University of Technology
- Ms Jenny Graham, Director Adult Clinical & Nursing Operations
- Professor Jo-anne Brien, St Vincent's Hospital & University of Sydney
- Dr Alex Wodak, St Vincent's Hospital & University of New South Wales
- Ms Shireen Malamoo, Justice Health Board
- Dr Bronwen Ross, Medical Director, Justice Health
- Ms Devon Indig, A/Research Manager, Centre for Health Research in Criminal Justice, Justice Health

## Schedule of Meetings for 2008

Closing date for submissions	Meeting date
7th February 2008	21st February 2008
3rd April 2008	17th April 2008
12th June 2008	26th June 2008
7th August 2008	21st August 2008
9th October 2008	23rd October 2008

## Application Forms and Guidelines

The original plus 12 copies of the application and all associated documents (eg: questionnaires, letters of support, Participant Information Statement and Consent Forms) must be submitted by the closing date. Click on the link below to download the application.

- [Application form](#) (signed by all investigators)
- Subject information sheet
- Consent form
- Parental consent form (if appropriate)
- Annual monitoring report form

## Useful Links

National Health and Medical Research Council:

[www.nhmrc.gov.au/ethics](http://www.nhmrc.gov.au/ethics)

National Statement on Ethical Conduct in Human Research (2007):

[www.nhmrc.gov.au/publications/synopses/files/e72.pdf](http://www.nhmrc.gov.au/publications/synopses/files/e72.pdf)

## FAQs

### ***Under what circumstances do I need ethical approval?***

There is sometimes uncertainty whether or not a research project requires ethical approval or whether it can be classified as a 'quality assurance' project. The project is considered to require ethical consideration if:

- it involves a direct approach to patients or staff;
- consent is to be sought;
- medical or electronic records of groups of patients are to be accessed;
- identifying information is to be collected;
- personally or culturally sensitive information is to be collected;
- individuals (or groups) could be disadvantaged as a result of participation;
- information collected could have ethical, legal or commercial implications;
- the results might be submitted for publication.

Examples of projects that do *not* require ethical approval are:

- laboratory QA programs where no identifying information is recorded;
- anonymous patient satisfaction questionnaires;
- statistical summaries of hospital activities.

### ***Who do I contact for getting Justice Health administrative approval?***

Contact the Director, Centre for Health Research in Criminal Justice (Phone (02) 8372 3000, Fax (02) 9344 4151) for advice on the appropriate person within Justice Health to provide a letter of support for the project.

### ***Do I need to also get ethical approval from Department of Corrective Services (DCS) or the Department of Juvenile Justice (DJJ)?***

In most circumstances, if a research project is to take place within the correctional environment, ethical approval will also be required by DCS and DJJ, as appropriate. Please contact them directly (see details below) to clarify their needs.

#### **Department of Corrective Services ethics information:**

Ms Caroline Ritchie  
Research Officer  
Henry Deanne Building  
20 Lee Street  
CHIPPENDALE NSW 2008  
Phone: (02) 8346 1254  
Fax: (02) 8346 1590

#### **Department of Juvenile Justice ethics information:**

Director  
Research, Planning and Evaluation  
Phone: (02) 9219 9441  
[www.djj.nsw.gov.au/research\\_applying\\_conduct.htm](http://www.djj.nsw.gov.au/research_applying_conduct.htm)

### ***Do I need to also get ethical approval from Aboriginal Health & Medical Research Council?***

Ethical approval may be necessary from the Aboriginal Health & Medical Research Council if one of the following factors applies to the research:

- Aboriginality is a key determinant;
- Data collection is explicitly directed at Aboriginal peoples;

- Aboriginal peoples, as a group, are to be examined in the results;
- The information has an impact on one or more Aboriginal communities; and
- Aboriginal health funds are a source of funding.

Therefore, if the research will involve Aboriginality as a demographic variable in the results, it is recommended to submit the study to the AH&MRC for ethical approval. The details are below.

**Aboriginal Health & Medical Research Council:**

PO Box 1565

Strawberry Hills NSW 2012

Phone: (02) 9212 4777

Fax: (02) 9212 7211

Email [ahmrc@ahmrc.org.au](mailto:ahmrc@ahmrc.org.au)

***Can I submit an ethics application that is in a different format to your form (eg. The National Ethics Application Form, NEAF)?***

Yes, the Justice Health HREC will review NEAF ethics applications directly. If you wish to use another ethics application form, please consult with the Chairperson to confirm it will cover all the necessary areas.

***My research takes place both in the correctional setting and in health services out in the community. Do I need to submit my ethics application to Justice Health when it will already be covered by a Lead HREC in the community?***

Yes, you will need to submit the ethics application to Justice Health. For a multi-site research project, a Lead HREC will cover your ethics approval for all health agencies in the community. However, any research that also involves the correctional setting must also be sent to the Justice Health HREC for separate approval. Similarly, if the research also involves Aboriginal persons, it must also be submitted to the Aboriginal Health & Medical Research Council for approval.

***When will I be notified of the outcome of my application?***

Within two weeks of the meeting date.

***How long is my approval valid for?***

Justice Health HREC approvals are valid for 5 years.

***What if I want to make changes/amendments to the protocol?***

During the course of an approved research project, modifications to the study design may be necessary (eg. changes in protocol, addition of researchers, addition of study sites, etc). In this circumstance, the Chief Investigator should detail the modification in a letter to the HREC and attach relevant documents (eg. Updated Participant Information Sheet and Consent Form). If the proposed amendment is substantial, the HREC may decide to treat it as a new project. In this event, a new application will be required.

***What are my responsibilities for annual reporting of HREC-approved projects?***

The Ethics Secretariat will send out an annual monitoring form to all researchers. The data are required for assessment of compliance and for mandatory reporting. Failure to complete annual monitoring forms will result in withdrawal of HREC approval.

A serious adverse event is defined as serious or unexpected harm (physical, psychological, financial, social or cultural) to a researcher or research participant. These must be reported to the HREC within 72 hours.

## Contact Us

**For further advice about Justice Health HREC policies, guidelines, submissions, please contact:**

Galia Guirguis  
Secretary, Justice Health HREC  
PO Box 150  
Matraville NSW 2036  
Phone: (02) 8372 3000  
Fax: (02) 9344 4151  
Email [chrcj@justicehealth.nsw.gov.au](mailto:chrcj@justicehealth.nsw.gov.au)

**Or, if specific ethical advice is sought, please contact:**

A/Professor Sandra Egger  
Chairperson, Justice Health HREC  
PO Box 150  
Matraville NSW 2036  
Phone: (02) 8372 3000  
Fax: (02) 9344 4151  
Email [chrcj@justicehealth.nsw.gov.au](mailto:chrcj@justicehealth.nsw.gov.au)