



**Northern Territory Government**

Department of Health and Community Services

**Central Australian  
Human Research Ethics  
Committee  
Policy and Procedures  
Manual**



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## 1. Introduction

The Central Australian Human Research Ethics Committee (CAHREC) is a committee of the NT Department of Health and Community Services (DHCS). The Committee's role is to consider the ethical aspects of research involving humans conducted by the organisation, and other organisations in Central Australia, which includes the Alice Springs and Barkly Regions of the Northern Territory, portions of South Australia usually identified as the cross border area, and areas which do not have their own research ethics committee. The Committee also considers research projects being conducted in Central Australia by interstate or overseas research organisations. All research being conducted in Central Australia is considered by the Central Australian Human Research Ethics Committee of the NT Department of Health and Community Services.

The Central Australian Human Research Ethics Committee operates under the guidelines established by the Australian Health Ethics Committee, a sub-committee of the National Health and Medical Research Council.

### Who should apply to the CAHREC?

The CAHREC considers the ethical aspects of research projects involving humans that will be wholly or partially conducted in Central Australia. All research projects being conducted by staff of the DHCS, or by external researchers in health services run by the DHCS, must be approved by the CAHREC. Definitions of what precisely constitutes 'research' are contentious. The NHMRC *'National Statement on the Ethical Conduct of Research Involving Humans'* attempts to provide some guidance on what types of activity should be regarded as research.

The issue of what is research is not so clear for some DHCS projects. DHCS is a health service delivery organisation, and most activities of DHCS are related to organising or delivering health services. The DHCS Research Guidelines state:

*'For the purposes of these guidelines "research" for DHCS includes applied research and evaluation, but not regular or routine monitoring activities. There is an area of overlap between these activities but in general research involves the generation of new information. Thus, while for example initiation and/or development of new audits or monitoring systems would be included within research and development, regular monitoring of the determinants of health, or states of health and illness are not, and neither are monitoring activities that routinely assess service quality.'* Projects done as part of postgraduate training (such as specialist medical training) which are designated as research projects or intended to give trainees research experience require ethics committee approval, even when the project involves minimal or no contact with research participants (such as medical records audits).

People conducting projects which do not fall into the previous categories but which involve:

- the use of questionnaires or survey interviews to obtain any form of personal information;
- access to medical or other personal records (other than audits within a department, with departmental approval);
- investigations of human behaviour;
- routine testing of human subjects;
- administration of drugs, ionising radiation, chemical agents or vaccines;
- any other experimentation on human beings;<sup>1</sup>

should seek the advice of the Secretary of the CAHREC about whether their project is regarded as research and the approval of the CAHREC is required.

Projects which seek funding for research which involves humans from funding agencies such as the

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<sup>1</sup>List taken from University of Sydney categories for ethical approval.

NHMRC, the Desert Knowledge Cooperative Research Centre or the Cooperative Research Centre for Aboriginal<sup>2</sup> Health or which may result in publication of results in the form of a thesis, scientific journals or similar, would in most cases be regarded as research and should be considered by the CAHREC. The CAHREC would expect that most projects conducted by Centre for Remote Health and Menzies School of Health Research staff which involve data collection and analysis to be classified as research projects. All health research projects conducted in Central Australia by students for a tertiary degree (including undergraduate projects that are classified by the teaching institution as a research project) must be considered by the CAHREC.

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<sup>2</sup> Throughout this document the term 'Aboriginal' includes Torres Strait Islander unless otherwise specified

## 2. Establishment of the CAHREC

### Auspecting Institution

The Central Australian Human Research Ethics Committee was established by the CEO of NT Department of Health and Community Services to operate as the Human Research Ethics Committee for the organisation. The Committee operates in accordance with the *'National Statement on Ethical Conduct in Research Involving Humans'*, issued by the National Health and Medical Research Council.

### Terms of Reference

The Committee shall perform the following functions:

1. consider ethical implications of all proposed research projects and determine whether or not they are acceptable on ethical grounds.
2. undertake surveillance of research projects until completion so that the Institutions may be satisfied that they continue to conform with approved ethical standards.
3. maintain a record of all research projects considered by the Committee. The applications for research projects shall be preserved in the form in which they are approved, including any amendments subsequent to approval.
4. maintain communication with the NHMRC's Australian Health Ethics Committee and provide access, upon request, to information in the CAHREC's records.

In carrying out these functions, the CAHREC shall:

1. conform with the NHMRC *'National Statement on Ethical Conduct in Research Involving Humans'* and other guidelines on research in particular fields that may be published from time to time.
2. take account of local circumstances and cultural sensitivities.
3. ensure that procedures relating to participants' consent to be involved in research projects are observed.
4. ensure that no member of the Committee adjudicates on proposals in which s/he may be personally involved (directly or indirectly)

The primary role of an HREC is to protect the welfare and the rights of participants in research and the primary responsibility of each member is to decide, independently, whether, in his or her opinion, the conduct of each research proposal submitted to the HREC will so protect participants.'

*(National Statement on Ethical Conduct in Research Involving Humans 2.5)*

The HREC considers research merit and safety as follows:

- Every research proposal must demonstrate that the research is justifiable in terms of its potential contribution to knowledge and is based on a thorough study of current literature as well as prior observation, approved previous studies, and where relevant, laboratory and animal studies.
- All research proposals must be so designed as to ensure that any risks of discomfort or harm to participants are balanced by the likely benefit to be gained.
- Research must be conducted or supervised only by persons or teams with experience, qualifications and competence appropriate to the research. Research must only be conducted using facilities appropriate for the research and where there are appropriate skills and resources for dealing with any contingencies that may affect participants.

*(National Statement on Ethical Conduct in Research Involving Humans 1.13 – 1.15)*

## NHMRC National Statement on Ethical Conduct of Research Involving Humans

The *'National Statement on Ethical Conduct of Research Involving Humans'* is the authoritative Australian document on ethical principles and standards of practice in health research. It was developed by the Australian Health Ethics Committee, a sub-committee of the National Health and Medical Research Council, and released by the Council in June 1999. The NHMRC's publication *'Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research'* (2003) provides specific advice that is complementary to the National Statement and specific to such research.

The Statement also covers the responsibilities of institutions in which health research is conducted, including the requirements that each institution:

- establish and support a Human Research Ethics Committee to consider the ethical aspects of proposed research
- monitor the conduct of research that has been approved by the HREC
- establish and support a process to receive and consider any complaints about the conduct of research projects.

The NHMRC will not fund research which does not meet these standards, or which is conducted in institutions which do not meet these standards. Several other national bodies have also endorsed or supported this Statement:

- Australian Vice-Chancellors Committee
- Australian Research Council
- Australian Academy of the Humanities
- Australian Academy of Science
- Academy of the Social Sciences in Australia
- Academy of Technological Sciences and Engineering.

The Statement is not 'legislation', and so is not directly enforceable through legal processes, but it would be expected that the courts would regard it as an authoritative statement of 'acceptable practice'<sup>5</sup> in health research.

All researchers submitting applications to the CAHREC are required to have read the National Statement, and other documents such as *Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research*, before submitting an application to the CAHREC.

“Values underpin what we perceive, believe, value and do. In the research context, to ignore the reality of inter-cultural difference is to live with outdated notions of scientific investigation. It is also likely to hamper the conduct of research, and limit the capacity of research to improve human development and wellbeing. Contemporary writing about science recognises this.

To ‘misrecognise or fail to recognise (cultural difference) can inflict harm, can be a form of oppression, imprisoning someone [or a group] in a false, distorted and reduced model of being’... Research cannot be ‘difference-blind’

Research relationships are also influenced by what is not said. ‘Problems [emerge] if we do not recognise that values operate in the everyday world from undeclared evaluations and judgements about other people, their behaviours and practices.’

Within the research process, failing to understand difference in values and culture may be a reckless act that jeopardises both the ethics and quality of research.”

*(Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research, NHMRC, 2003, p3)*

The Statement and Guidelines can be obtained from the NHMRC web-site:  
[www.nhmrc.gov.au](http://www.nhmrc.gov.au)

## Reporting Procedure

The CAHREC reports annually to the Executive Committee of NT Department of Health and Community Services. A summary of the CAHREC annual report is published in the DHCS Annual Report. The CAHREC annual report includes for each reporting period (usually one financial year):

- list of members, including category and period of membership and number of meetings attended
- number of applications received
- number of applications approved, resubmitted, not approved
- monitoring process
- number of projects notified as completed
- number of projects with approved status at the end of the reporting period
- number of above which have submitted an annual report form by the due date
- number of complaints received and outcome.

## Membership

Members of the CAHREC are appointed by the CEO, DHCS, in accordance with the criteria specified in the NHMRC Statement:

- One member appointed as Chair
- At least one laywoman not associated with NT Department of Health and Community Services or a health worker
- At least one layman not associated with NT Department of Health and Community Services or a health worker
- at least one member with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC (eg. health, medical, social, psychological, epidemiological, as appropriate)
- at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people (eg. medical practitioner, clinical psychologist, social worker, nurse, as appropriate)
- a minister of religion, or person who performs a similar role in the community
- a lawyer
- the Chair (or delegate) of the Aboriginal Committee.

Technical experts may be called on from time to time.

The Secretariat function to the Committee is provided by the DHCS. The Secretary is not a member of the Committee.

## Appointment of Members

All vacancies are advertised in organisations/institutions that utilise the CAHREC and the local press as appropriate. Applications for Committee membership are considered by a selection panel consisting of:

- the Chair, CAHREC
- The Chair, Aboriginal Committee
- Two members of CAHREC

The selection panel considers written applications for membership, and may interview potential members if necessary. The selection panel makes a recommendation to the CEO - DHCS, on suitable applicants for appointment.



### **3. Aboriginal Committee**

The CAHREC includes a second committee, the Aboriginal Committee

The Aboriginal Committee's principal role is to protect Aboriginal participants in research and to ensure that Aboriginal people benefit from research being conducted on Aboriginal people or in Aboriginal communities and on Aboriginal health issues.

The Aboriginal Committee exists as a separate committee for Aboriginal people. This is to enable greater confidence to discuss research proposals and consider issues of importance in a separate forum, and to allow freer discussion of Aboriginal cultural issues without domination by technical advice and expert opinion.

#### **Terms of Reference**

The terms of reference of the Aboriginal Committee are:

1. To safeguard the interests of Aboriginal people involved in research, and of the wider Aboriginal community affected by research;
2. to ensure research is conducted in a culturally appropriate manner;
3. to consider ethical issues involved in research proposals from the perspective of Aboriginal people, with particular attention to the specific interests of Aboriginal participants in research projects, recognition of Aboriginal people as researchers and the interests of Aboriginal communities affected by research projects;
4. to advise the CAHREC on ethical issues in relation to each research proposal, and to provide recommendations to improve each proposal, and a decision on whether to approve each proposal, and to
5. ensure research projects involving Aboriginal people will benefit Aboriginal people.

In considering research proposals, members are guided by the National Statement on Ethical Conduct of Research Involving Humans, Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research (2003), and principles and priorities specific to Aboriginal people in Central Australia, including:

- the promotion of education of Aboriginal people in the conduct of research, and
- the promotion of employment opportunities for Aboriginal people in health research.

#### **Reporting**

The Aboriginal Committee reports to CAHREC through the Aboriginal Committee Chair (or delegate) as a member of CAHREC, and through the minutes of the Aboriginal Committee meetings. At least one Aboriginal Committee member attends each CAHREC meeting.

The CAHREC will not over-rule a decision made by the Aboriginal Committee that a research proposal should not be approved. All committee decisions and members will be treated in an appropriately respectful fashion. Where CAHREC disagrees with a decision made by the Aboriginal Committee the Chair of CAHREC will:

- advise the principal investigator of the research proposal of the Committee's decision;
- advise the Aboriginal Committee in writing of the reasons why CAHREC disagrees with the Aboriginal Committee decision, and request that the Aboriginal-committee reconsider their decision;
- convene a meeting with at least two members of each committee (including the two chairpersons) to resolve disagreement, if required.

#### **Quorum**

A minimum of three members must be present at each Aboriginal Committee meeting. If less than three members are present and another meeting cannot be scheduled before the next meeting of CAHREC, the Aboriginal Committee meets informally to provide advice to CAHREC. This advice is taken by CAHREC as final advice on all research proposals considered. In contrast to the

above statement, a decision reached by an informal Aboriginal Committee can be over-ruled by the CAHREC. The size of the quorum will be reviewed if the Aboriginal Committee increases in size (see below).

## **Membership**

The members of the Aboriginal Committee are Aboriginal people including at least one member in each of the following categories:

- a person with experience in health service delivery in government run health services;
- a person with experience in health service delivery in Aboriginal Medical Services;
- a person with experience in health research;
- a community member not engaged in health research or service delivery;
- a male Aboriginal Elder ;
- a female Aboriginal Elder;
- one person with research experience in non-health issues eg linguist, sociologist or anthropologist.

Ideally the Aboriginal Committee should include interested parties from remote communities, and span all major language groups with a balance of male and female members, that is, one male and one female from each language group. It is recognised that this is not immediately possible but should be worked towards over time.

The Aboriginal Committee also has two non-voting members who may not be Aboriginal people:

- a scientific adviser with expertise and broad experience in health service delivery and health research ; and
- a secretary, who should also be the secretary of CAHREC.

The Committee may also invite specialist advisers as appropriate.

***The role of the scientific adviser is to advise the Aboriginal Committee, interpret proposals and assist the Chairperson of the Aboriginal Committee with liaison as necessary. The position description will include health service delivery and research experience. The position will be advertised and the same selection panel as detailed below will be convened.***

## **Selection**

All vacancies for the Aboriginal Committee are advertised throughout the institution, Aboriginal organisations and the local press as appropriate, and by seeking interested people through networks in the Aboriginal community. Applications for Aboriginal Committee membership are considered by a selection panel consisting of:

- the Chair, Aboriginal Committee
- the Chair, CAHREC
- Two members of the Aboriginal Committee

The selection panel may elect to invite a community leader to join the panel as appropriate.

The selection panel considers applications for membership and may interview potential members if necessary. The selection panel makes a recommendation to the Secretary, Department of Health and Community Services (DH&CS –NT), on suitable applicants for appointment.

## **4. Committee Processes**

### **Frequency of Meetings**

The CAHREC usually meets ten times per year on the last Thursday of each month, December and January being the exceptions. The CAHREC Secretary will confirm meeting and closing dates.

The Aboriginal Committee meets one week before the CAHREC, on the 2nd Thursday of the same months.

### **Application Procedures**

*The closing date for applications is three weeks prior to each CAHREC meeting.*

*Researchers must supply the original plus 25 copies of each application.. E-mail applications cannot be accepted. Applications are to be sent to the Secretary, CAHREC, Department of Health and Community Services, PO Box 721, Alice Springs, NT 0871.*

Alternative arrangements may be considered under exceptional circumstances (such as applications from remote communities with only basic postal services and office equipment). Such arrangements must be approved in advance by the Committee Secretary. Late applications will not be accepted.

The CAHREC Secretary peruses each application for errors or deficiencies, and when time allows may bring problems to the attention of the Principal Investigator, but it is the responsibility of the Principal Investigator to ensure that the application form has been completed correctly.

The CAHREC Secretary compiles the agenda for each meeting and distributes applications and other meeting papers to arrive with committee members at least one week before the meeting date of the Aboriginal Committee. The Secretary assigns each application to a member of the CAHREC to prepare a brief summary and introduce each application at the HREC meeting. The Secretary may request external advice on a complex research project from specialists in the relevant field of research or health practice, either in writing or in person at the CAHREC meeting.

The Chair of the CAHREC may invite the Principal Investigator to attend the CAHREC meeting where it is felt that further explanation of a research project may assist the Committee members, but this is not a common practice. The application form should provide all necessary information, in a clear and concise plain English, for the CAHREC to make a decision on the application.

### **Application Form**

The application form must be completed in a manner that is understandable to the 'informed layperson'. The application form should succinctly summarise the research project and the ethical issues involved, rather than be a detailed research protocol containing full technical documentation of the project. Researchers should attempt to complete the application form within the space provided for each section, and the entire application should not be more than two pages longer than the blank application form.

Application forms can be downloaded from the Research/ Ethics section of <http://www.health.nt.gov.au>

### **Approvals Process**

The main function of the CAHREC is to consider the ethical aspects of research proposals as summarised by the Principal Investigator in the Application Form.

All applications will be considered by the Aboriginal Committee and the CAHREC. There is no provision to fast track applications.

### **Aboriginal Committee of CAHREC**

The Aboriginal Committee considers all applications addressing Aboriginal health issues and/or with Aboriginal participants. Approval for a research project requires the approval of both the Aboriginal Committee and the CAHREC.

## **CAHREC**

The CAHREC considers all applications after consideration by the Aboriginal Committee, including the outcome of the Aboriginal Committee's deliberations as summarised in the minutes of the Aboriginal Committee meeting and by the Chair of the Aboriginal Committee.

When a member is unable to attend a meeting, the member can provide written comments on each application to the Secretary prior to the meeting, to be presented during the Committee's discussion of each application. However, while these comments will be presented to the meeting they will not form part of the final decision. Only those members present at the meeting are responsible for the Committee's decision on each application.

## **Decisions**

The CAHREC restricts its decisions to either approve or not approve an application. The Committee does not make decisions to give conditional approval. The Committee may:

- approve an application, without recommendations
- approve an application, with recommendations. In this case, the application is approved unconditionally, the recommendations have the status of informal advice to the researcher, which the researcher is not obliged to take note of
- not approve an application, with advice to the researcher of issues which need to be addressed in a modified application, and authorise the Chair to approve the modified application if the Committee's concerns have been adequately addressed. If the Chair is not satisfied that the issues have been adequately addressed, a revised application would then need to be submitted to the CAHREC
- not approve an application, with advice to the researcher of issues that need to be addressed in a revised application to be submitted to the next CAHREC meeting
- not approve an application, with advice to the researcher of the reasons why the application was not approved.

Where there is inconsistency between the recommendations or comments of the CAHREC and Aboriginal Committee the process described above (p 11 – Reporting).

The Chair will send written notification of the Committee's decision, and reasons for that decision where appropriate, within two weeks of each CAHREC meeting.

Progress reports [every six (6) months] and the final report are required from the principal researchers.

A copy of the application *as finally approved* by the CAHREC and reports are kept on file by the Secretary.

## **Projects approved by another Ethics Committee**

The CAHREC assesses all health research projects conducted within Central Australia. All research projects where the principal institution conducting the research is DHCS must be considered in detail by the CAHREC.

Some research projects involving local participants and/or researchers are primarily conducted by another institution, such as a multi-centre clinical trial including an NT hospital as one of the trial sites, or a national epidemiological study using data from multiple states including the NT. Such projects may have been considered in detail and approved by one or more other Ethics Committees.

In this case, the CAHREC may accept the consideration and approval of another Ethics Committee instead of undertaking detailed consideration of the application itself. However, where there are significant local issues involved which may not have been considered by another Ethics Committee, the CAHREC must consider the project in detail.

The provision for an ethics committee to accept the approval of another committee was introduced by the NHMRC in June 1999.

## **Appeals Process**

Where a Principal Investigator of a research proposal disagrees with a decision of the CAHREC, the Principal Investigator may request in writing to the Chair of the CAHREC that the decision be reconsidered, giving reasons why the researcher feels that the CAHREC decision is incorrect. The reasons why the decision is incorrect must be based on the *National Statement for the Ethical Conduct of Research Involving Humans*.

The CAHREC will reconsider the application, including further information supplied by the Principal Investigator, at the next available meeting (subject to the normal closing dates for applications).

The CAHREC Chair may invite the Principal Investigator to attend a CAHREC meeting to discuss the application.

If after a reconsideration of a research proposal the Principal Investigator remains dissatisfied with the decision, or reasons for a decision of the CAHREC, the Principal Investigator may request in writing to the Chair CAHREC that an independent review of the CAHREC decision be undertaken. The Chair will then notify the CEO, DHCS, of the need for an independent review. The Principal Investigator will have six (6) months from the time of CAHREC reconsideration of the Principal Researcher's objection(s) to the original decision, or reasons for the decision to request an independent review.

The independent review will be conducted by a review committee consisting of people who have previous or current experience as members of a research ethics committee, but are not current members of the CAHREC, the Aboriginal Committee or the Principal Investigator's institution, and with minimum membership as defined in the *National Statement for the Ethical Conduct of Research Involving Humans*. This review should be completed within three months of the receipt of the request for review.

The review committee shall make an independent decision on the research proposal having access to the deliberations of CAHREC, and make recommendations in regard to these considerations. The report with recommendations will be presented to the CEO, DHCS and the Chair CAHREC.



## 5. Monitoring Process

The Secretary maintains a database of all applications considered by the CAHREC, including the expected duration of each project, and the date on which the next progress report is due. Six weeks prior to the date each progress report is due, the Secretary sends a notice (by e-mail only) to the Principal Investigator reminding of the need for a progress or final report and the requirement for the attached progress report form to be returned (the annual/final report form will also be made available during 2006 in electronic format on the DHCS website : <http://www.health.nt.gov.au>)

Failure to provide a progress report by the due date results in expiry of the approval for the project, and the Secretary shall advise the Principal Investigator in writing of the expiry of approval.

Both committees consider Progress Reports for all projects due for review at each meeting. Further information is requested from the Principal Investigator if required.

Where a progress report is considered unsatisfactory, the Chair advises in writing the Principal Investigator and the Head of the Institution in which the research is being conducted that the progress report has not been accepted, and the reasons for this decision.

Recommendations may be:

- to not accept the progress report at this time, temporarily extend approval for the project while seeking further information from the Principal Investigator or other party
- to not accept the progress report, and advise the Principal Investigator and Head of the relevant institution that approval for the project has expired and the reasons for the decision
- in the absence of a progress report, to advise the Principal Investigator and Head of the relevant institution that approval for the project has expired and the reasons for the decision.

The Principal Investigator of each project which has had approval extended is advised by letter by the Secretary after each meeting, including the date when the next progress report is due. The outcome of the review of other projects, and the reason for approval not being extended, and any action required of the investigators, is advised in writing by the Chair within two (2) weeks of each meeting.



## **6. Complaints about Research Projects**

People involved in research projects, or others concerned about the conduct of a research project, may raise their concerns in a variety of ways. The most appropriate way in the first instance would be with one of the senior researchers involved in the project. If this is not appropriate, or does not satisfactorily resolve the issue, a person may express their concerns with the head of the institution that is conducting the research project, with the management of the health service organisation in which the research is being conducted, with the Health Industry Ombudsman, or with the CAHREC.

The CAHREC requires that all researchers inform research participants that they may raise concerns about a research project with the CAHREC, and all participants must be given contact details of the CAHREC Secretary.

For relatively minor issues, the CAHREC Chair or delegated committee member discusses the issue with the complainant and the Principal Investigator and attempts to resolve the issue if possible by correcting a misunderstanding, providing additional information, or similar simple remedy.

The CAHREC does not investigate and resolve complaints about more serious issues. These are the responsibility of the head of the institution in which the research project is being conducted, or external agencies in exceptional circumstances. The CAHREC Chair or delegate will contact the complainant to clarify the issues involved and to advise the complainant of options available, before referring the complaint to the Head of the institution which is conducting the research project. The CAHREC Chair will provide written advice to the complainant of this referral, and to the CEO, DHCS.

Investigation and resolution of the complaint are the responsibility of the institution in which the research is being conducted. For serious issues a member of the CAHREC and Aboriginal Committee should be involved in the complaints handling process. A report to the CAHREC on the outcome of the complaint is required from the institution as soon as possible after the resolution of the issue, or progress reports every three months if resolution takes longer than three months.



## **7 Applying to the CAHREC**

The CAHREC application form is available at [www.health.nt.gov.au](http://www.health.nt.gov.au), or by e-mail from the CAHREC Secretary at the Central Australian Coordination Unit of the Department of Health and Community Services (phone 08 89515294). All applications must be typewritten on the CAHREC form.

### **Issues which the HREC will consider include:**

#### **Scientific validity of the research proposed**

- what is already known about the issue being researched
- why should this research be done in this place at this time
- what are the research questions, and is the study design suitable to answer these questions.

#### **Adequate resources and skills to successfully complete the project**

- experience of the researchers/supervisors
- facilities of the institution
- funding
- support of the organisation whose resources are necessary for the conduct of the project
- support of the institution (signature of the head of the institution).

#### **The balance between potential benefits and risks of the research**

- Potential benefits from this research project (usually to the wider community, not to the research participants)
- Possible harm which may occur to participants (or others), including steps to minimise harm and preparations to deal with any harm.

#### **Maintenance of participants privacy**

- how information will be obtained, stored and reported
- if specimens are being taken, how and for how long they will be stored, how and when they will be destroyed.

#### **Consent of the participants to be involved**

- adequacy of the information provided, appropriate language, need for interpreters
- clear consent form - simple, clearly states what participants are agreeing to, that they can refuse to be involved with no detriment to their health services, and that they can withdraw at any time
- contact for complaints

#### **Support for the project from community representatives (if appropriate)**

- written support from an Aboriginal Organisation; Community Council or one or more Aboriginal community members who are recognised as representing that community on health matters

#### **Aboriginal Involvement**

- what Aboriginal involvement, individual or institutional, there has been or will be in the initiation, implementation, analysis, dissemination and uptake of the research or its findings

### **Participant Information Statement and Documentation of Consent**

#### **Participant Information Statement**

The CAHREC recommends that participant information statements should be in the most appropriate medium for the people being consulted as potential participants in each research project. A clear, concise printed information statement that includes all relevant information about the project is the best format for most participants. For people who are not competent in reading written English, a translation of an English-language statement into their first language would be expected.

Many research projects in the Northern Territory involve Aboriginal people from remote communities, many of whom do not speak English as a first language, if at all, and many of whom are not literate in either English or their Aboriginal language. Written participant information

statements are not appropriate for these people. Thorough oral explanation, possibly supplemented by pictorial or audiovisual material, is required in this situation. An oral participant information statement must be based on a written statement that is delivered by a person competent to translate the information into the appropriate Aboriginal language.

In addition, for research projects that are being conducted in particular Aboriginal communities (including Aboriginal communities located in urban areas) a process of community consultation is required. Community consent is required before the project can proceed within each community. Community consultation is also the initial stage of disseminating information to community members who may be approached to be participants in the project.

Initial consultation should be with community leaders and community organisations such as the community council, health service board, women's group or similar organisation. Staff of the local health service should usually be included in this consultation, but consultation with health professionals alone (including Aboriginal Health Workers) is not usually regarded as adequate community consultation.

All relevant information about the project should be included on a separate participant information statement. The consent form, which would usually be signed by the participant or parent, should be as clear as possible and only include information relevant to documenting participant consent - it should not be used as a substitute for a participant information statement.

The patient information statement should advise that if the participant has any complaints about the research project they may contact the head of the institution conducting the research or the Secretary of the CAHREC, and contact details of both should be provided.

### **Documentation of consent**

The purpose of the consent form is to:

- provide specific information about the conditions of consent
- provide a permanent record that the participant has consented

The consent form should be a plain English document which is short and concise and includes:

- the title of the project
- the name and contact telephone numbers of the principal and local investigators
- the name of the institution conducting the research
- statement that the details of the research project have been explained to the participant, and the participant information statement has been read or otherwise viewed and given to the participant
- who provided this information to the participant
- that the participant is free to decline to be involved without any effect on their health care or other aspects of their lives
- that the participant is free to withdraw at any time during the project without any effect on their health care or other aspects of their lives
- whether the participant consents to data about them or specimens from them being retained and used for future, unspecified research projects
- the signature of the participant
- the signature of the person who witnessed the participant's consent, which may be the person who provided the participant information.

Note that the signature of the research participant on the consent form is not the principal act of consent. The participant should express clearly to the researcher that the participant has

understood the information provided, is confident to make a decision, and what that decision is. The signature on the consent form is an important confirmation of that consent, but is not consent of itself.

For people who are not literate, a written consent form and signature may not be adequate confirmation of consent, indeed a written consent form may be inappropriate confirmation of consent. A person who is not literate cannot read the information on the form - it must be read to him or her. This person also may not be able to sign their name, other than a cross or similar mark. Such a signature provides minimal if any distinctive confirmation that the person has indeed made that mark. In these circumstances an independent witness may be required to confirm that the participant information statement has been provided and the consent form read to the participant, and that the participant has consented to be involved in the research project.

While a written participant information statement and signed consent form are required in most situations, they are not always optimal or appropriate. Particularly with Aboriginal participants who are not fluent or literate in English, alternative means of providing participant information and documenting consent may be required. This does not mean that any lesser standard of information is acceptable, nor that any less clearly and freely given consent is acceptable. Most alternative means of providing information and documenting consent will require more imagination and resources rather than less.



## **8. CAHREC Forms and Instructions**

### **Application Form**

The Application Form is available from the DHCS website:  
[www.health.nt.gov.au](http://www.health.nt.gov.au),  
or on request from the Secretary, Phone: 08 89 515 294.

### **Six (6) Monthly or Final Report Form**

The Progress Report forms is available from the DHCS website:  
[www.health.nt.gov.au](http://www.health.nt.gov.au),  
or on request from the Secretary, Phone: 08 89 515 294.

## **Appendix One : CAHREC Member Selection Criteria**

### **General Criteria**

1. experience of a broad range of community activities
2. able to understand/learn and apply research ethics principles
3. interest in health and social research issues
4. able to read and understand CAHREC application documents
5. able to appreciate the interests of potential research participants and the potential risks and benefits of research proposals, and to assess the balance between the two
6. able to actively participate in and contribute to Committee discussions on research proposals and other research ethics issues
7. able to attend meetings

### **Specific Criteria**

#### **Lay member**

1. interest in and awareness of health consumer issues
2. not involved in health research or health services delivery
3. not directly associated with NT Department of Health and Community Services or
4. not a lawyer or minister of religion (or equivalent)

#### **Member with legal experience**

1. legal qualifications and experience in the practice of law
2. interest in and knowledge of legal issues relevant to health services or health research is desirable

#### **Member with religious/spiritual experience**

1. experience as a minister of religion, spiritual leader or Aboriginal elder
2. interest in and knowledge of religious or spiritual issues relevant to health services or health research is desirable

#### **Members with health services delivery experience**

1. experience in the delivery of health or community services
2. experience in service delivery to Aboriginal people in the NT is desirable

#### **Members with health research experience**

1. experience in the conduct of health research
2. experience in research with Aboriginal people in the NT is desirable.

