

Territory Health Services
and
Menzies School of Health Research

Top End
Human Research Ethics Committee
Policy and Procedures Manual

First Edition
July 2000

John Condon, Liz Stubbs
for the
Top End Human Research Ethics Committee
and Aboriginal Sub-Committee

CONTENTS

1. Introduction	3
WHO SHOULD APPLY TO THE TEHREC?	3
2. Establishment of the TEHREC.....	5
AUSPICING INSTITUTIONS	5
TERMS OF REFERENCE.....	5
NHMRC NATIONAL STATEMENT ON ETHICAL CONDUCT OF RESEARCH INVOLVING HUMANS	5
REPORTING PROCEDURE	6
MEMBERSHIP	7
APPOINTMENT OF MEMBERS.....	7
3. Committee Structure and Function	9
ABORIGINAL SUB-COMMITTEE	9
FAST TRACK COMMITTEE	11
4. Committee Processes	12
FREQUENCY OF MEETINGS.....	12
APPLICATION PROCEDURES.....	12
APPROVALS PROCESS	13
APPEALS PROCESS.....	16
5. Monitoring Process	17
6. Complaints about Research Projects.....	18
7. Applying to the TEHREC	19
ISSUES WHICH THE HREC MUST CONSIDER.....	19
PARTICIPANT INFORMATION STATEMENT AND DOCUMENTATION OF CONSENT	20
8. TEHREC Forms and Instructions.....	23
APPLICATION FORM	23
ANNUAL PROGRESS REPORT FORM.....	23
Appendix One : Member Selection Criteria.....	24

1. Introduction

The Top End Human Research Ethics Committee (TEHREC) is a joint committee of Territory Health Services (THS) and the Menzies School of Health Research (MSHR). The Committee's role is to consider the ethical aspects of health research conducted by these two organisations, and other organisations in the Top End of the Northern Territory which do not have their own research ethics committee. The Committee also considers research projects being conducted in the Top End by interstate or overseas research organisations. The only other organisation in the Top End that has a research ethics committee is the Northern Territory University. Research being conducted in Central Australia is considered by the Central Australian Human Research Ethics Committee of Territory Health Services.

The Top End 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 TEHREC?

The TEHREC considers the ethical aspects of research projects, but not of clinical practice. Royal Darwin Hospital has a committee specifically to consider ethical aspects of clinical practice. All research projects being conducted by staff of Territory Health Services or the Menzies School of Health Research, or by external researchers in health services run by Territory Health Services, must be approved by the TEHREC. It is impossible to define precisely which constitutes 'research'. 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, but this is still ambiguous.

Projects which seek funding from research funding agencies such as the NHMRC or Cooperative Research Centre for Aboriginal¹ and Tropical 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 TEHREC. The TEHREC would expect that most projects conducted by MSHR staff which involve data collection and analysis to be classified as research projects. All research projects conducted 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 TEHREC.

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

'For the purposes of these guidelines "research" for THS 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

¹ Throughout this document the term 'Aboriginal' includes Torres Strait Islander unless otherwise specified

Section One: THS & MSHR Policy on Ethical Review of Research

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 categories above 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;²

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

² List taken from University of Sydney categories for ethical approval.

2. Establishment of the TEHREC

Auspecting Institutions

The Top End Human Research Ethics Committee is established by the Governing Board of the Menzies School of Health Research and the Secretary of Territory Health Services to operate as the Human Research Ethics Committee for each institution. 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 for each auspecting Institution:

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 TEHREC's records.

In carrying out these functions, the TEHREC:

1. conforms 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. takes account of local circumstances and cultural sensitivities.
3. ensures that procedures relating to participants' consent to be involved in research projects are observed.
4. ensures that no member of the Committee adjudicate on proposals in which they 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)

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. This

Section One: THS & MSHR Policy on Ethical Review of Research

Statement replaces most other guidelines issued by the NHMRC, although several sections have not yet been revised and previous guidelines remain in effect. In particular, the guidelines on Aboriginal health research will not be revised until the year 2000 or later. The *NHMRC Guidelines on Ethical Matters in Aboriginal and Torres Strait Islander Health Research (Interim, 1991)* remain in effect.

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.

This 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' in health research.

All researchers submitting applications to the TEHREC are required to have read the National Statement, and other documents such as the interim guidelines on Aboriginal health research, before submitting an application to the TEHREC. The Statement can be obtained from the NHMRC web-site:

www.health.gov.au/nhmrc/publicat/e-home.htm

Reporting Procedure

The TEHREC reports annually to the Governing Board of the Menzies School of Health Research and the Executive Committee of Territory Health Services. A summary of the TEHREC annual report is published in the Annual Report of each institution. The TEHREC 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.

Section One: THS & MSHR Policy on Ethical Review of Research

Membership

Members of the TEHREC are jointly appointed by the Director, MSHR and the Secretary, THS, in accordance with the criteria specified in the NHMRC Statement:

- One member appointed as Chair
- At least one laywoman not associated with either Territory Health Services or Menzies School of Health Research
- At least one layman not associated with either Territory Health Services or Menzies School of Health Research
- a minister of religion, or person who performs a similar role in the community
- a lawyer
- one member with experience of clinical service delivery in a hospital setting
- one member with experience of clinical service delivery in an Aboriginal community setting
- one member with experience in clinical research
- one member with experience in social science research
- one member with experience in epidemiological research
- one member with experience in laboratory research
- the Chair (or substitute) of the Aboriginal Sub-Committee.

One member with clinical experience is nominated as the 'clinical adviser', and one with research experience as the 'research adviser', to consider in more detail technical aspects of complex projects when necessary. The Secretary to the Committee is the Administration Officer (or delegate) of the Menzies School of Health Research. The Secretary is not a member of the Committee.

Appointment of Members

All vacancies are advertised throughout both institutions and the local press as appropriate. Applications for Committee membership are considered by a selection panel consisting of

- the Chair
- one member with experience in health research or service delivery
- one member without research or service delivery experience
- one member of the Aboriginal Sub-Committee.

The selection panel considers written applications for membership, and may interview potential members if necessary. The selection panel makes a recommendation to the Director of MSHR and the Secretary, THS, on suitable applicants for appointment.

Members are appointed for a two-year term commencing 1 July in the relevant year or such other time as a vacancy occurs. Members may be re-appointed at the end of each two-year term, to a maximum of three terms. At the expiry of each member's term, the Chair will advise the Director, MSHR and the Secretary, THS, on whether to re-appoint the retiring member or advertise the vacancy based on:

- the interest of the retiring member in re-nominating for membership
- the attendance of the retiring member at meetings

Section One: THS & MSHR Policy on Ethical Review of Research

- the performance of the duties of members as specified in the relevant duty statement
- the balance of the experience required on the Committee.

3. Committee Structure and Function

There are two sub-committees of the TEHREC:

- the Aboriginal Sub-Committee and
- the Fast Track Committee.

Aboriginal Sub-Committee

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

The Aboriginal Sub-Committee exists as a separate committee because Aboriginal people have greater confidence to discuss research proposals and consider issues important to them in a separate forum, which allows freer discussion of Aboriginal cultural issues without domination by technical advice and expert opinion.

Terms of Reference

The terms of reference of the Aboriginal Sub-Committee are:

1. protect the interests of Aboriginal people involved in health research, and of the wider Aboriginal community affected by health research.
2. ensure research is conducted in a culturally appropriate manner.
3. to consider the ethical issues involved in research proposals (see Section 7) from the perspective of Aboriginal people, with particular attention to the specific interests of Aboriginal participants in research projects and the interests of Aboriginal communities affected by research projects.
4. to advise the TEHREC on ethics issues in relation to each research proposal, recommendations to improve each proposal, and the decision of the Sub-Committee on whether to approve each proposal.
5. to ensure research projects involving Aboriginal people will benefit Aboriginal people.

In considering health research proposals, members are guided by the *National Statement on Ethical Conduct of Research Involving Humans*, the *NHMRC Guidelines for Ethical Matters in Aboriginal and Torres Strait Islander Research (Interim 1991)*, and principles and priorities specific to Aboriginal people in the Northern Territory, including:

- promoting the education of Aboriginal people in the conduct of research
- promoting the employment opportunities for Aboriginal people in health research.

Reporting

The Aboriginal Sub-Committee reports to the TEHREC through the Sub-Committee Chair (or delegate) as a member of the TEHREC, and through the minutes of the Sub-Committee.

The TEHREC will not over-rule a decision of the Aboriginal Sub-Committee that a research proposal should not be approved (ie, the Sub-Committee has the right of veto over applications that involve or possibly impact on Aboriginal people). Where the TEHREC disagrees with such a decision the Chair of the TEHREC will:

- advise the Principal Investigator of the research proposal of the Sub-Committee's decision and reasons for it

Section Two: Committee Procedures

- advise the Sub-Committee in writing of the reasons why the TEHREC disagrees with the Sub-Committee decision, and request that the Sub-Committee reconsider their decision.

A minimum of three members must be present at each Sub-Committee meeting. If less than three members are present and another meeting cannot be scheduled before the next meeting of the TEHREC, the Sub-Committee meets informally to provide advice to the TEHREC. This advice is taken by the TEHREC as final advice on all research proposals considered. An informal Sub-Committee meeting does not have the right of veto described above.

Membership

The members of the Sub-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.

The Sub-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.

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

- the Chair
- one member with experience in health research or service delivery
- one member without research or service delivery experience.

The selection panel considers applications for membership and may interview potential members if necessary. The selection panel makes a recommendation to the Director of MSHR and the Secretary, THS, on suitable applicants for appointment.

Members are appointed for a two-year term commencing 1 July in the relevant year or such other time as a vacancy occurs. Members may be re-appointed at the end of each two-year term, to a maximum of three terms. At the expiry of each members term, the Chair will advise the Director, MSHR and the Secretary, THS, on whether to re-appoint the retiring member or advertise the vacancy based on:

- the interest of the retiring member in re-nominating for membership
- the attendance of the retiring member at meetings
- the performance of the duties of members as specified in the relevant duty statement
- the balance of the experience required on the committee.

Section Two: Committee Procedures

Fast Track Committee

The Fast Track Committee is responsible for considering applications for research projects with relatively minor ethical implications where approval is required before the next meeting of the TEHREC.

The Fast Track Committee membership will rotate through the members of the main committee and the Aboriginal Sub-Committee. It will consist of:

- one lay person, lawyer or minister of religion
- one member of the Aboriginal Sub-Committee
- one member with research experience
- one member with health service delivery experience.

One of these members will be appointed by the main committee as Chair of the Fast Track Committee for a period of 12 months commencing with the first meeting in each financial year. Other members will be appointed for the period between each meeting of the TEHREC.

The Chair of the Fast Track Committee provides a written report to each meeting of the TEHREC summarising decisions made by the Fast Track Committee since the previous TEHREC meeting.

4. Committee Processes

Frequency of Meetings

The TEHREC usually meets six times per year on the 3rd Thursday of February, April, June, August, October, and December. The closing date for applications is usually three weeks prior to the meeting date. Please contact the TEHREC Secretary to confirm meeting and closing dates. (Submission deadlines and meeting dates are also available on the Menzies School of Health Research website : <http://www.menzies.edu.au>)

The Aboriginal Sub-Committee meets one week before the TEHREC, on the 2nd Wednesday of the same months. The Fast Track Committee meets by circulation as required.

Application Procedures

The closing date for applications is three weeks prior to each TEHREC meeting. Researchers must supply the original plus 25 copies of each application (for 14 members of the TEHREC and 12 members of the Aboriginal Sub-Committee). Only four copies of each application are required for the Fast Track Committee. E-mail applications cannot be accepted. Applications are sent to the Secretary, TEHREC, at Menzies School of Health Research.

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 TEHREC 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 TEHREC 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 Sub-Committee. The Secretary assigns each application to a member of the TEHREC 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 TEHREC meeting.

The Chair of the TEHREC may invite the Principal Investigator to attend the TEHREC 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 form, for the TEHREC 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.

Section Two: Committee Procedures

The Application should summarise:

- the background to the project - a brief summary of the existing state of knowledge in the area and why this project is being proposed at this particular point in time
- a brief summary of the research protocol
- the potential benefits of the research, for participants (if any) and for society more generally
- the potential harm to participants, how this is being minimised and monitored, and what measures will be put in place to deal with any harm that occurs
- who the research participants will be, and how they will be selected
- what information or specimens will be collected from research participants
- the information that will be provided to people invited to participate (including a copy of the participant information sheet)
- the procedure to obtain consent from participants (including a copy of the consent form)
- how participants information will be kept private, and if tissue specimens are to be used, how these will be securely stored, and how and when they will be disposed of
- if the research will be conducted in specific communities, what discussions have been conducted with the communities, what support there is in the communities, and copies of written expressions of support from representatives of those communities.

Application forms can be downloaded from <http://www.menzies.edu.au>.

Approvals Process

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

Most applications will be considered by the Aboriginal Sub-Committee and the TEHREC. Where there is a reason for an application to be considered before the next TEHREC meeting, a researcher may request that the application be considered by the Fast Track Committee.

Aboriginal Sub-Committee

The Aboriginal Sub-Committee considers all applications considered by the TEHREC, not only those specifically addressing Aboriginal health issues (with the exception of research to be conducted with the Tiwi people). Approval for a research project requires the approval of both the Aboriginal Sub-Committee and the TEHREC: if the Aboriginal Sub-Committee does not approve a project, the TEHREC will not approve the project.

Research with the Tiwi people

Proposals to conduct research with the Tiwi people are not considered by the Aboriginal Sub-Committee. The process for ethical approval of research projects with the Tiwi people, as stipulated in the agreement between the Tiwi Health Board and the Menzies School of Health Research (the Tiwi Legal Agreement) is:

1. Researchers present a very brief summary of the research proposal to the Tiwi Health Board.
2. The Tiwi Health Board considers the brief summary, and provides a written response to the researcher indicating whether or not the Board would be willing to consider the proposal in greater detail. If the Board is willing to consider the

Section Two: Committee Procedures

proposal further, the researcher must obtain Ethics Committee approval for the proposal before submitting a detailed proposal to the Board.

3. The TEHREC will only consider applications for research projects with the Tiwi people that include this written initial support from the Tiwi Health Board.
4. In deference to the local expertise of the Tiwi Health Board in considering matters to do with the Tiwi people, the Aboriginal Sub-Committee does not consider proposals for research with the Tiwi people.
5. Once approved by the TEHREC, the detailed proposal, including written TEHREC approval, is submitted to the Tiwi Health Board.
6. There is no change to the normal monitoring requirements of the TEHREC for research projects with the Tiwi people.

Fast Track approval

The Fast Track Committee (FTC) does not meet face to face. As the Secretary receives proposals they are forwarded to the Chair of the FTC for a decision as to whether the application is considered suitable for fast tracking.

The Chair may accept applications for consideration by the FTC where the following criteria are satisfied:

- there is a degree of urgency - there are substantial reasons why the project needs to commence before the next TEHREC meeting, and
- the ethical issues involved in the project are relatively minor - issues which have been frequently discussed and agreed by the TEHREC

If accepted by the Fast Track Chair for consideration by the FTC, the Secretary sends a copy of the application, together with the 'Recommendation' form, to the other three rostered FTC members for consideration. Approval from all four members of the FTC is required before an application is approved. If any member considers that the application should not be approved by the FTC, the application is referred to the next meetings of the Aboriginal Sub-Committee and TEHREC.

FTC members are expected to return their recommendation to the Secretary within one week of receiving each application. If after one week not all FTC members have returned their recommendation, the Secretary attempts to contact members who have not responded. If no response is received within a further two working days the recommendations of three of the four members are deemed sufficient for a FTC decision.

The Secretary then drafts a response for the Fast Track Chair's signature. The only possible decisions are 'approved' or 'referred to main committee for decision'. If the latter, reasons for the decision are forwarded to the Principal Investigator. The decision of the Fast Track Committee should be forwarded to the Principal Investigator within three weeks of receipt of the application.

HREC

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

Section Two: Committee Procedures

When a member is unable to attend a meeting, the member provides 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.

Discussion of each application commences with one member of the Committee briefly summarising each application. The Secretary allocates each application to one Committee member to prepare a brief summary when sending out the papers for each meeting. All Committee members are included in the preparation of summaries except the scientific and clinical advisers, as they have a considerable workload in providing technical advice on several applications at each meeting.

Decisions

The HREC 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 needs to be re-submitted to the TEHREC
- not approve an application, with advice to the researcher of issues that need to be addressed in a revised application to be re-submitted to the next TEHREC 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 TEHREC and Aboriginal Sub-Committee the Chairs of each Committee, and one other member of each Committee, meet as soon as possible after the TEHREC meeting to resolve the inconsistency. The revised recommendation and comment, and reason for the revision, are reported to the next meeting of each committee.

The Chair should send written notification of the Committee's decision, and reasons for that decision where appropriate, within one week of each TEHREC meeting.

HREC approval is for a period of 12 months from the date of the TEHREC meeting, or until the end of the research project if less than 12 months duration. Approval for subsequent periods of 12 months will be granted on acceptance by the TEHREC of an adequate annual progress report from the principle researchers.

A copy of the application *as finally approved* by the TEHREC is kept on file by the Secretary.

Section Two: Committee Procedures

Projects approved by another Ethics Committee

The TEHREC assesses all research projects conducted within THS and MSHR. All research projects where the principal institution conducting the research is THS or MSHR must be considered in detail by the TEHREC.

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 TEHREC 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 TEHREC 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. As of November 1999 the TEHREC has not received a request to accept the approval of another Ethics Committee. Exact procedures for this situation have not yet been developed.

Appeals Process

Where a Principal Investigator of a research proposal disagrees with a decision of the TEHREC, the Principal Investigator may request in writing to the Chair of the TEHREC that the decision be reconsidered, giving reasons why the researcher feels that the TEHREC 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 TEHREC must reconsider the application, including further information supplied by the Principal Investigator, at the next available meeting (subject to the normal closing dates for applications).

If after a reconsideration of a research proposal the Principal Investigator remains dissatisfied with the decision, or reasons for a decision of the TEHREC, the Principal Investigator may request in writing to the Director, MSHR, or the Secretary, THS, that an independent review of the TEHREC decision be undertaken. This 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 TEHREC or Aboriginal Sub-Committee, 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 and, where requested by the Principal Investigator or the relevant institutional head, shall consider whether the reasons for the original TEHREC were reasonable and whether there were any errors in the process undertaken by the TEHREC, and make recommendations in regard to these considerations.

5. Monitoring Process

The Secretary maintains a database of all applications considered by the TEHREC, including the expected duration of each project, the date on which approval expires, and the date on which the next progress report is due (which would normally be the approval expiry date). 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 approval expiry date and requirement for the attached progress report form to be returned (the annual/final report form is also available in electronic format on the Menzies website : <http://www.menzies.edu.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.

The Secretary and one member of the Committee review Progress Reports for all projects due for review at each meeting. Further information is requested from the Principal Investigator if required.

Any progress report considered unsatisfactory will be reviewed by the Chairs of the TEHREC and Aboriginal Sub-Committee, together with the Secretary and Committee member who initially considered the progress report. This group may request further information from the Principal Investigator, or discuss their concerns with the Principal Investigator and/or other investigators, before making a recommendation to the next meeting of the TEHREC. Where a progress report is considered unsatisfactory and approval is not extended, 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 approval not extended, and the reasons for this decision.

A summary, including recommendation, of all progress reports reviewed, is presented to the TEHREC meeting for endorsement by the Committee. Recommendations may be:

- to extend approval for a further period of 12 months
- to extend approval for a period of less than 12 months
- 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 one week 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 TEHREC.

The TEHREC requires that all researchers inform research participants that they may raise concerns about a research project with the TEHREC, and all participants must be given contact details of the TEHREC Secretary. For relatively minor issues, the TEHREC 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 TEHREC does not have the resources to 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 TEHREC Chair 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 TEHREC Chair will provide written advice to the complainant of this referral, and to the Director, MSHR, and the Secretary, THS.

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 TEHREC and Aboriginal Sub-Committee should be involved in the complaints handling process. A report to the TEHREC 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 TEHREC

The TEHREC application form is available from the MSHR and THS websites, or by e-mail from the TEHREC Secretary at MSHR (phone 08 8922 8196). All applications must be typewritten on the TEHREC form.

Staff and students of the Northern Territory University (NTU) undertaking health research projects are required to apply to the HREC of both NTU and THS/MSHR. For these projects, the THS/MSHR Committee will accept an application on the NTU Committee's application form.

Issues which the HREC Must Consider

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

Section Three: Application Instructions and Forms

Support for the project from community representatives (if appropriate)

- written support from one or more Aboriginal community members who are recognised as representing that community on health matters

Participant Information Statement and Documentation of Consent

Participant information statement

The TEHREC 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 well, if at all, and many of whom are not literate in either English or their Aboriginal language. This is not restricted to older people – many younger adults who have recently completed schooling are not functionally literate either. 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

Section Three: Application Instructions and Forms

conducting the research or the Secretary of the TEHREC, 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

Section Three: Application Instructions and Forms

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. TEHREC Forms and Instructions

Application Form

The Application Form is available on the MSHR Website:
www.menzies.edu.au

Annual Progress Report Form

The Annual Progress Report form is available on the MSHR Website:
www.menzies.edu.au

Appendix One : 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 health research issues
4. able to read and understand TEHREC 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 and participate in the Fast Track Committee roster, including to respond to Fast Track Committee applications within required deadlines

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 Territory Health Services or the Menzies School of Health Research
4. not a lawyer or minister of religion (or equivalent)
5. at least one of the three lay members should be an Aboriginal person

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
3. particular experience of service delivery in a hospital setting or in an Aboriginal community setting, depending on the vacancy being filled

Members with health research experience

1. experience in the conduct of health research
2. experience in research with Aboriginal people in the NT
3. experience in clinical, social science, epidemiological or laboratory research, depending on the vacancy being filled