1. General Information

In recent decades there has been increasing recognition of the health disadvantage suffered by Aboriginal people, which has resulted in increased interest from academic institutions and researchers in defining Aboriginal Health problems and finding solutions to these. Research of any nature proposed by these institutions and researchers is subject to a range of Commonwealth and NT legislation and NHMRC authoritative statements, codes of conduct and guidelines. Where research involves humans, there are relevant ethical guidelines, including specific guidelines for research into Aboriginal and Torres Strait Islander health.

Approval for research involving Remote Health facilities or resources is subject not only to all of the above, but also to operational considerations. Consequently, Remote Health utilises an approval process that applies to all research proposals. This process ensures Executive level support for each activity, in principle, and also allows Remote Health to monitor research activities occurring across its operations. The process also allows management at area service and health centre levels, be aware of, and comment on, proposals that will affect their activities. A template to seek approval for research proposals is provided and expected to be utilised by all researchers considering activity involving Remote Health services and resources. (If a researcher is uncertain whether a formal proposal is warranted for a given piece of work, this can be discussed with the Quality & Safety Manager on 0427 189 998.)

To assist Remote Health manage information relating to current research activities, all relevant approved activities are included on the Remote Health Master Research Register (DHF intranet access only).

As research is conducted there may be justification to modify the activity from how it has been proposed. Remote Health expects that any significant changes (in particular changes to either the model of the research or the constituents) will be notified by the researcher. This includes extensions to research activities beyond the duration initially proposed.

2. Definitions

Human Research: systematic investigations for the purpose of adding to generalised knowledge pertaining to human health. Under the Commonwealth Privacy Act 1988, this includes epidemiological research.

Human Research Ethics Committee (HREC): a body which reviews a research proposal and ensures that a successful application meets the requirements of the National Statement on Ethical Conduct on Research Involving Humans and is ethically acceptable.

Authoritative Statement: a statement that is not legislation and not directly enforceable through legal processes but is expected to be regarded by the court as a statement of acceptable practice. Example: National Statement on Ethical Conduct on Research Involving Humans.

The principal documents that bind and guide institutions and researchers who wish to conduct health research in RHB facilities are:
- Privacy Act 1988
- NT Information Act
- Information Privacy Principles
- Guidelines Under Section 95 of the Privacy Act 1988
- Australian Code for the Responsible Conduct of Research
- National Statement on Ethical Conduct in Research Involving Humans
- Values and Ethics: Guidelines for Ethical Conduct in ATSI Health Research

The Information Privacy Principles and Information Act apply equally to non-DHF researchers who are conducting research involving DHF clients or client information.

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3. Responsibilities

3.1 External and Internal Researchers

- Independently obtain all other community and human ethics approvals
- Using the [template](#) form, complete and submit a proposal for each research activity
- Maintain integrity of research processes in accordance with submitted proposals and ethical expectations
- Advise Remote Health of relevant changes to research activities
- Provide Remote Health with a final report of each research activity on completion

3.2 Quality and Safety Manager

- Receive research proposals on behalf of the Branch
- Coordinate awareness of proposal and arrange for endorsement by relevant Remote Health management
- Maintain currency of information in the [Remote Health Master Research Register](#)
- Act as the official point of contact between researchers and Remote Health (excepting routine interactions that occur with the research activity at health centre level)

3.3 Remote Health Branch Executive

- Review all research proposals submitted by institutions or researchers for operational approval

3.4 Area Service Manager

- Consult with relevant Primary Health Care Manager/s regarding the capacity of the health centre to participate in or facilitate the proposed research
- Ensure that commencement of research activities are based on final approval having been granted in accordance with RHB requirements

3.5 Primary Health Care Manager (PHCM)

- Contribute to approval of proposals by commenting on likely local implications
- Allow access to health facilities and/or data by researchers according to approvals granted
- Ensure that effective communication with researchers is maintained
- Ensure that health service activities take priority over research activity

4 Procedure

4.1 Approval of Research Proposals by Remote Health

Prospective researchers must submit a completed proposal, using the [template](#) provided, which facilitates an appropriate approval process within the structure of Remote Health. Informal discussion may occur with health centre staff in the work up of a proposal, but the formal proposal must occur to gain assurance of Remote Health support.

4.1.1 Submission to Quality and Safety Manager

The Quality and Safety Manager receives research proposals on behalf of Remote Health and coordinates the awareness of, and approval by, relevant Remote Health management.

Remote Health’s Quality and Safety Manager maintains an ongoing role as the point of contact in relation to all current research proposals and initiated activities. It is particularly important that any future changes / extensions to projects are advised through this channel.

4.1.2 Consideration by Remote Health Executive

Remote Executive Leadership Group (RELG) must be involved in reviewing all research proposals affecting Remote Health. This review is for the purpose of agreeing to the research in principle and to provide senior approval for the use of resources that may be required for the activity.
RELG will review and approve / disapprove proposals with particular regard (as relevant) to:
- how the community / health centre / remote health will benefit from the research
- how the research links to RHB priorities
- how the research will impact on the day to day operation of health centre/s
- how findings will be documented in client medical records
- responsibilities for following up and providing treatment of abnormal results
- the extent and type of impact on operational requirements and use of RHB resources, including overall load of research activities on the health service
- client consent arrangements for access to personal health records and security of that information
- information on what resources the researcher will bring to the project
- how the results of the research will be informed to Remote Health.

4.1.3 Consideration at Regional and Health Service Delivery Area (HSDA) level

Following in principle approval by RELG, the proposal is tabled with the regional Management teams. Relevant Area Service Managers within the regional team will contribute to the approval process by commenting on the ability of the HSDA to support and host the activity, and providing endorsement accordingly. Area Service Managers are to engage all PHCMs of health centres affected by the proposal, to ensure they are collectively aware of and either support, or flag concerns regarding, the proposal. Opinion should be canvassed in a timely manner with completion of the relevant section of the proposal form and it’s return to the Quality and Safety Manager.

4.1.4 Consideration at Health Centre level

Primary Health Care Managers (PHCM) represent the local health centre in commenting on implications of the proposal to the local health service.

PHCMs are not responsible for obtaining local community approval. See 4.2.

Usual Remote Health approval process:

- Researcher prepares proposal with accurate assessment of impact on Remote Health facilities and services
- Allow minimum of 1 month for approval process within Remote Health
- Submit proposal to Quality & Safety Manager.
- The proposal is tabled at RELG and is supported / not supported in principle
- Supported proposals are passed on to the relevant Area Service Manager(s)
- Unsupported proposals are returned to the researcher
- Area Service Manager(s) confirm availability and adequacy of required resourcing and complete Section 3 Part B as relevant
- Concerns are fed back to RELG
- Fully supported proposals are entered on the RHB Master Research Register
- Researcher advises and assists the Area Service Manager of any concerns regarding local impact
- PHC Managers note the proposal and advise the Area Service Manager of any concerns regarding local impact
- The Quality & Safety Coordinator remains the point of contact and coordination regarding progress of the proposal
- Fully supported proposals are entered on the RHB Master Research Register

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4.2 Other Approvals

The researcher is responsible for obtaining all other approvals that are required, which will include Human Research Ethics approval, and where relevant, may include individual community / council approvals, approvals by other health services, etc.

Remote Health requires that all other applicable approvals are obtained and advised to the Quality and Safety Manager before research commences. Failure of the researcher to maintain and advise current approvals voids the support of Remote Health Branch.

Evidence of ethics approval is of critical importance to Remote Health. An overview of how ethics approval is processed, is elaborated on here:

4.2.1 Role of Northern Territory Human Research Ethics Committees

The primary role of NT HRECs is to decide whether the conduct of proposed research will protect the rights and welfare of the participants. They operate under the guidelines established by the Australian Health Ethics Committee (AHEC), a sub committee of the NHMRC. They consider the ethical aspects of research, not clinical practice.

All institutions and researchers who propose to conduct human research in DHF facilities must obtain ethical approval from one or both of the following, depending on location of the research:

- the Human Research Ethics Committee of the Northern Territory Department of Health & Families and Menzies School of Health Research, which includes the Aboriginal Ethics Sub Committee (AESC)
- the Central Australian Human Research Ethics Committee, which also includes an Aboriginal Ethics Sub Committee.

This usually applies even where ethics approval has already been obtained nationally or in other states or the Australian Capital Territory (ACT).

There is a third ethics committee in the NT, namely, the Charles Darwin University (CDU) Human Research Ethics Committee (see CDU - Research - Homepage). However, if a student or researcher at CDU proposes research involving any DHF data or resources the TE and/or CA HRECs must also approve the proposal.

4.2.2 Specific Requirements of NT Human Research Ethics Committees

The National Ethics Application Form (NEAF) is the preferred application form as it takes into account that researchers may have to make multiple HREC submissions. All Australian HRECs will accept this form.

The HREC Application Form - DHF and MSHR may be used if the research is taking place in the Top End only.

If the NEAF is used, those wishing to conduct research in RHB remote health centres are expected to complete Part D of the DHF and MSHR form in addition to the primary application form. Part D relates specifically to Aboriginal and Torres Strait Islander health research and applicants are expected to fully address the values of Reciprocity, Respect, Equality, Responsibility, Survival and Protection, and Spirit and Integrity.

An ethics application to NT HRECs must also include:

- the research proposal signed by the head of the organisation accepting responsibility for the research
- the signatures of all investigators, including the principal investigator
- scientific protocol and insurance certificate (for clinical trials)
- documented support (as relevant) from:
  - RHB Executive
  - relevant community body / bodies
  - holders of data registries
4.3 Research Activity

Researchers may engage directly with health centres according to the terms that have been approved. Researchers should at all times ensure that health centre staff are aware of their activity in relation to the health centre, and must follow the direction of the Primary Health Care Manager at the local level. Health service activity will always carry priority over research activity.

Health Centre staff may rightfully challenge researchers who they believe are not acting according to the terms of approved activity, with arbitration by the Primary Health Care Manager, Area Service Manager or the Quality and Safety Manager as required.

Formal concerns are to be addressed between the Quality and Safety Manager and the research agency.

Access to medical records will always require specific authorisation and will be part of the negotiated arrangements when approval is granted. Any individual researcher accessing RHB client medical records without specific authorisation will be reported to the research agency and disciplinary action will be expected. See also PCIS User Access.

4.4 Master Research Register

Remote Health maintains a Master Research Register to assist in managing the projects it is associated with. The register is intranet based and is available to Remote Health staff to:

- provide an overview of all projects, in particular to ensure that research activities are not burdensome or unbalanced against particular communities
- inform (assure) of the official status of current research proposals or activities
- assist with auditing functions related to monitoring of research activity

The Quality and Safety Manager is responsible for maintaining the Register.

5. Forms

Research Proposal – form :
- Sections 1 & 2 (Information and Researcher proposal only)
- Section 3, Part A (RELG approval only)
- Section 3, Part B (ASM endorsement only)
- Complete form

PCIS Application for User Access
HREC Application Form - DHF and MSHR
National Ethics Application Form (NEAF)

6. References and Supporting Documents

Related Atlas Items:
- PCIS User Access
- Requests for Access to Medical Information & Records
- Requests for Remote Health Data
- Visitors Overview
- Australian Code for the Responsible Conduct of Research
- Australian Health Ethics Committee AHEC
- Human Research Ethics Committee – DHF site
Guidelines Under Section 95 of the Privacy Act 1988
Human Research Ethics Committee of the Northern Territory Department of Health and Families and Menzies School of Health Research
National Health and Medical Research Council
National Statement on Ethical Conduct in Research Involving Humans
NT Information Act
Information Privacy Principles
Privacy Act 1988
Values and Ethics: Guidelines for Ethical Conduct in ATSI Health Research