Research Proposals PHC Guideline

Target Audience	All Clinical Employees
Jurisdiction **Jurisdiction Exclusions**	Primary Health Care Remote CAHS; Primary Health Care Remote TEHS; Correctional Services N/A
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Approval Authority	Chair Clinical Governance Committee PHC CAHS; Primary Health Care Remote Safety and Quality Committee TEHS
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Purpose

To provide Primary Health Care (PHC) remote staff and prospective Researchers with a guideline on the appropriate processes for research proposal applications and approval within PHC.

Guideline

1. General Information

Research of any nature proposed by institutions and researchers is subject to a range of Australian Government and NT legislation and National Health and Medical Research Council (NHMRC) authoritative statements, codes of conduct and guidelines[1]. Where research involves humans, there are relevant ethical guidelines, including specific guidelines for research into Aboriginal and Torres Strait Islander (ATSI) health.

Approval for research involving Primary Health Care (PHC) facilities or resources is subject not only to all of the above, but also to operational considerations. Consequently, PHC utilises an approval process that applies to all research proposals. This process ensures PHC support for each activity, in principle, and also allows PHC to monitor research activities occurring across its' operations. A template to seek approval for research proposals is provided and expected to be utilised by all researchers considering activity involving PHC services and resources.

[1] The principal documents that bind and guide institutions and researchers who wish to conduct health research in PHC facilities are:

- Privacy Act 1988 - NT Information Act, see Schedule 2 for Information Privacy Principles, or 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-DoH researchers who are conducting research involving DoH clients or client information.

To assist PHC manage information relating to current research activities, all relevant approved activities are included on the PHC Master Research Register.

As research is conducted there may be justification to modify the activity from how it has been proposed. PHC 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. The researcher is expected to maintain the integrity of research processes in accordance with submitted proposals and ethical expectations.

2. Definitions

Human Research: systematic investigations for the purpose of adding to generalised knowledge pertaining to human health. Under the Australian Government 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 in 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 For example the National Statement on Ethical Conduct on Research involving Humans.

Clinical Audit Registration: provides for quality assurance audits and grants ethics registration, not ethics approval. See Audit Case Study Ethics Clearance Form.

3. Procedure

3.1 Approval of Research Proposals by Primary Health Care

Prospective researchers must submit a completed proposal, using the Research Proposal Part A Research Application PHC Remote Form provided, which facilitates an appropriate approval process within the structure of PHC. Informal discussion may occur with health centre staff in the preparation of a proposal, but the formal proposal must occur to gain assurance of PHC support.

3.1.1 Submission to NT Clinical Support Advisor

The NT Clinical Support Advisor receives research proposals on behalf of PHC, logs receipt on the Research Spread sheet on the shared network drive and forwards research proposals that include Central Australia Health Service participation to the Quality and Safety Manager PHC CAHS. Researchers must allow a minimum of 8 weeks for approval processes within PHC.

The NT Clinical Support Advisor maintains an ongoing role as the point of contact in relation to all research proposals and initiated activities, including being notified of any changes / extensions to projects. An amended research proposal may need to be submitted for re-approval.

3.1.2 Consideration by Clinical Governance Committee PHC CAHS and/or PHC TEHS Strategic Committee

All research proposals are reviewed by the Clinical Governance Committee PHC CAHS (for research in Central Australia) and PHC TEHS Strategic Committee (for research in Top End), and by both committees if a proposal is for NT wide research.

The Clinical Governance Committee PHC CAHS and/or PHC TEHS Strategic Committee will review and recommend approval / rejection of research proposals with particular regard (as relevant) to:

- how the community / health centre / remote health will benefit from the research
- how the research links to PHC priorities
- how the research will impact on the day to day operation of health centre/s
- how findings will be documented in client health records
- responsibilities for following up and providing treatment of abnormal results

- the extent and type of impact on operational requirements and use of PHC 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 PHC

General Manager (as a member of the Committee) will complete Research Proposal Part B General Manager INITIAL Approval PHC Remote Form to confirm or reject initial apporval for the research and potential use of resources that may be required for the activity and return to the Quality and Safety Manager PHC CAHS and/or NT Clinical Support Advisor PHC TEHS.

3.1.3 Consideration at Health Service Delivery Area (HSDA) level

Relevant District Managers will contribute to the approval process by commenting on the ability of the HSDA to support and host the activity, and providing endorsement / rejection accordingly. District 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, confirming availability and adequacy of required resourcing, with completion of Research Proposal Part C District Manager Approval PHC Remote Form and its return to the Quality and Safety Manager PHC CAHS and/or NT Clinical Support Advisor PHC TEHS.

3.1.4 Consideration at Health Centre level

The PHCM represents the local health centre in commenting on implications of the proposal to the local health service. The PHCM should complete the Research Proposal Part C District Manager Approval PHC Remote Form for the health centre and return to the District Manager.

PHCMs are **not** responsible for obtaining local community approval.

3.1.5 Primary Health Care approval process:

The PHC approval process is outlined in the flowchart on page 6. Final approval is required from the Clinical Governance Committee PHC CAHS and/or PHC TEHS Strategic Committee depending on the location for the research.

Following approval the General Manager signs the Research Proposal Part D General Manager FINAL Approval PHC Remote Form. The NT Clinical Support Advisor forwards approval to the Researcher.

3.2 Other Approvals

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

PHC requires that **ALL** other applicable approvals are obtained and advised to the NT Clinical Support Advisor before research commences. Failure of the researcher to maintain and advise current approvals voids the support of PHC.

Evidence of ethics approval is of critical importance to PHC. An overview of how ethics approval is processed is described below.

When the researcher requires access to DoH data, additional approval is required to facilitate access to the relevant data. The NT Clinical Support Advisor will notify DoH Data Governance Unit when access to DoH data is required and the DoH Data Governance Unit will forward the data release guidelines and forms for the secondary use of DoH data following PHC support and approval of the research proposal.

3.2.1 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 Departmental 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 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.

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 Departmental data or resources the TE and/or CA HRECs must also approve the proposal.

3.2.2 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 - DoH 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 PHC facilities are expected to complete Part D of the DoH 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:
  - ~ Clinical Governance Committee PHC CAHS and/or PHC TEHS Strategic Committee
  - ~ relevant community body / bodies
  - ~ holders of data registries
  - ~ RDH / ASH Executive (only if hospital data is being accessed)
- copies (as relevant) of:
  - ~ consent forms
  - ~ participant information sheets / next of kin/guardian information sheets
  - ~ any other instruments such as questionnaires / surveys / interview guides
  - ~ a Criminal History Check may be required when the research involves access to vulnerable persons or has high level access to information about clients per the NT Health policy
  - ~ a Working With Children Clearance Notice: under the NT Care and Protection of Children Act, required for all who are working with or who will potentially be in contact with children in the Northern Territory (NT)

The Quality Assurance Audit Registration Form is to be completed for studies relating to an audit of clinical activity against related standards. Approval is for grants ethics registration, not ethics approval. An application for ethics approval is not required.

Note: If the researcher plans to use the data obtained from the Quality Assurance audit for further research or publication, it is recommended the researcher obtain prospective HREC approval. HREC approval cannot be gained retrospectively.

3.3 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 PHCM at the local level. Health service activity will always carry priority over research activity.

Health centre staff have a responsibility to ensure that any research activity is compliant with the approvals and they should discuss with the researcher and/or seek advice from PHCM, District Manager or the Quality and Safety Manager if they have concerns.

District Managers must ensure that commencement of research activities is based on final approval having been granted in accordance with PHC requirements and feedback any concerns. Concerns may be addressed and documented by the NT Clinical Support Advisor.

Access to health records will always require specific authorisation and will be part of the negotiated arrangements when approval is granted. Any individual researcher accessing client health records without specific authorisation will be reported to the research agency and disciplinary action will be expected. See Electronic Health Records - User Access.

Informed consent applies to any research being undertaken. Consent by a client (either written or verbal) to participate in research after achieving an understanding of the relevant purpose, importance, benefits and associated risks must be recorded in the EHR. When consent forms are signed by clients for the research activity, the signed forms must be scanned into the client's EHR.

3.4 Master Research Register

PHC maintains a Master Research Register to assist in managing the projects it is associated with. The register is intranet based and is available to PHC 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 NT Clinical Support Advisor is responsible for maintaining the Register for fully supported research proposals.

Quality and Safety Manager PHC CAHS is responsible for maintaining a PHC CAHS Master Research Register for fully supported research proposals for PHC CAHS.

The NT Clinical Support Advisor will provide a monthly Reasearch Report to the Quality and Safety Manager PHC CAHS and Safety and Quality Manager PHC TEHS.

3.5 Feedback by the Researcher

The Researcher must include the timeframe in the Research Proposal for when an interim and final report will be submitted to PHC.

Research Proposals PHC Remote Flowchart

Research Agency / Researcher	- *Researcher prepares proposal and accurate assessment of impact on PHC health facilities and services* - *Allow minimum of 2 months for approval processes in PHC* - *Submit proposal to NT Clinical Support Advisor*
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NT Clinical Support Advisor e-mail: PHCResearch.DoH@nt.gov.au	- *receives Research Proposals from Researcher and logs receipt on the Research Spread sheet on the shared network drive* - *reviews Research Proposal, ethics approval/s and data requirements* - *requests further information from Researcher as required to provide complete information* - *sends Research Proposal to Quality and Safety Manager PHC CAHS providing a list of the communities included in the Research Proposal* - *E-mails the monthly report for the Clinical Governance Committee PHC CAHS and PHC TEHS Strategic Committee to relevant personnel by the last Friday of each month.*
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Quality and Safety Manager PHC CAHS and/or **NT Clinical Support Advisor PHC TEHS**	- *sends Research Proposal to Clinical Governance Committee PHC CAHS for approval* - *sends Research Proposal to PHC TEHS Strategic Committee*
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Clinical Governance Committee PHC CAHS and/or **PHC TEHS Strategic Committee**	- *the proposal is tabled for review and recommendation by the Committee* - *General Manager (as member of Committee) confirms support and completes Research Proposal Part B General Manager INITIAL Approval PHC Remote Form as relevant and returned to the Quality and Safety Manager PHC CAHS and/or NT Clinical Support Advisor PHC TEHS for follow-up:* ~ *supported proposals are sent to District Managers for consideration* ~ *unsupported proposals are returned to the NT Clinical Support Advisor*
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Quality and Safety Manager PHC CAHS and/or **NT Clinical Support Advisor PHC TEHS**	- *sends supported proposals to District Managers for consideration and consultation with health centres*
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District Managers	- *consults with relevant PHCMs re availability and adequacy of required resourcing at the health centre*
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PHC Health Centre Manager/s (PHCM)	- *PHCMs note the proposal and advise the District Manager of any concerns regarding local impact* - *PHCM provides approval on Research Proposal Part C District Manager Approval PHC Remote Form as requested*
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District Managers	- *District Manager(s) confirm availability and adequacy of required resourcing and completes Research Proposal Part C District Manager Approval PHC Remote Form as relevant* - *Concerns are fed back to Clinical Governance Committee PHC CAHS and/or PHC TEHS Strategic Committee*
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Quality and Safety Manager PHC CAHS and/or **NT Clinical Support Advisor PHC TEHS**	- *returns Research Proposal Part B General Manager INITIAL Approval PHC Remote Form and Research Proposal Part D General Manager FINAL Approval PHC Remote Form to the NT Clinical Support Advisor* - *Quality and Safety Manager PHC CAHS maintains a PHC CAHS Master Research Register for fully supported proposals*
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NT Clinical Support Advisor	- *notifies Researcher of approval / non-approval by the completed Research Proposal Part D General Manager FINAL Approval PHC Remote Form* - *notifies DoH Data Governance Unit when access to DoH data is required* - *remains the point of contact and coordination regarding progress of the proposal*
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Research Register	- *Fully supported proposals are entered on the PHC Master Research Register*

Note: the Data Governance Unit sends the researcher the data release guidelines and forms for the secondary use of DoH data when this is required for research.

Document Quality Assurance

	Method	Responsibility
Implementation	Document will be accessible via the Policy Guidelines Centre and Remote Health Atlas	Health Policy Guidelines Program Atlas Development Officer, Primary Health Care CAHS
Review	Document is to be reviewed within three years, or as changes in practice occur	Atlas Development Officer, Primary Health Care CAHS
Evaluation	Evaluation will be ongoing and informal, based on feedback.	Atlas Development Officer, Primary Health Care CAHS

Key Associated Documents

Forms	Research Proposal Form: *Research Proposal Part A Research Application PHC Remote Form* *(Information and Researcher proposal only)* *Research Proposal Part B General Manager INITIAL Approval PHC Remote Form* *(General Manager initial approval only)* *Research Proposal Part C District Manager Approval PHC Remote Form* *(District Manager endorsement only)* *Research Proposal Part D General Manager FINAL Approval PHC Remote Form* *(General Manager final approval only)* Electronic Health Record Application Form - PCIS / EACS HREC Application Form - DoH and MSHR National Ethics Application Form (NEAF) Audit Case Study Ethics Clearance Form
Key Legislation, By-Laws, Standards, Delegations, Aligned & Supporting Documents	Electronic Health Record - User Access Visitors Overview Requests for Access to Medical Information and Records National Health and Medical Research Council Australian Code for the Responsible Conduct of Research Australian Health Ethics Committee Guidelines Under Section 95 of the Privacy Act 1988 National Statement on Ethical Conduct in Research Involving Humans Values and Ethics: Guidelines for Ethical Conduct in ATSI Health Research Human Research Ethics Committee – DoH Human Research Ethics Committee of the Northern Territory Department of Health and Menzies School of Health Research Charles Darwin University - Research (homepage) Guidelines for Research and Evaluation in THS NT Information Act Information Privacy Principles NT Care and Protection of Children Act Privacy Act 1988
References	As Above

Evidence Table

Reference	Method	Evidence level (I-V)	Summary of recommendation from this reference
N/A	N/A	N/A	N/A