healthylivingNT

Research Participation and Assessment Framework

Policy and Procedures

Policy Statement

Healthy Living NT recognises the value of all levels and aspects of research related to people with chronic disease. Healthy Living NT will actively consider proposals to support research applications and consumer participation in research activities in which the core ethical values of merit and integrity, respect, justice and beneficence are met and full compliance with Australian Privacy laws and Healthy Living NT's Privacy Policy is demonstrated.

Healthy Living NT will also take the following factors into account when assessing research proposals:

1. Relevance to NT population and ability of NT residents to fully and equally participate in the study
2. Operational impact on HLNT
3. Protection of, and respect for, consumer rights and information

Healthy Living NT:

- will not release personal details to researchers without the express permission of the individual and will at all times ensure compliance with our Privacy Policy.
- will generally not directly recruit participants to an external research study.

Once a research proposal has received support from Healthy Living NT, potential participants will be provided with the researcher's contact details via methods deemed appropriate by Healthy Living NT and asked to contact the researcher directly.

Procedure

Healthy Living NT will manage all requests for research participation and research support openly and fairly through a clear process as outlined in HLNT's Research Participation Policy (appended).

This process is outlined in the attached flow charts which indicate HLNT's responses to Scenarios 1-8 identified later in this paper.

Healthy Living NT will maintain a register of all research activities seeking its support. This register will be reviewed annually by the Board.

Policy

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Definitions

APPs	Mean the Australian Privacy Principles adopted in 2014
Consumer	Means any person that Healthy Living NT: • holds personal and/or sensitive information about or • has access to personal and/or sensitive information through service provision. This includes, but is not limited to, members, education service clients and program participants.
Evaluation (program level)	Program evaluation activities are not considered research when: • Their intent is only to provide information for and about the session or program in which the consumer is involved • They are conducted as part of the standard operating procedures of the program or session • They provide information to support organisational decision-making on specific programs • They are conducted within settings of changing consumers, priorities, resources and timelines
Ethical Research	Refers to, as a minimum, research that meets the following standards: • ***Australian Code for the Responsible Conduct of Research*** • ***National Statement of Ethical Conduct in Human Research*** • ***Statement on Consumer and Community Involvement in Health and Medical Research*** • ***Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research***
External Funder	Means contracted services that HLNT holds with a variety of funders including (but not limited to) the OHS Agreement with the PHN, Service Agreements with NT DoH and the NDSS Agency Agreement with DAL.
HLNT Data	Refers to personal and/or sensitive information about consumers that HLNT directly collects and manages in HLNT databases
HLNT Data Access	Refers to personal and/or sensitive information about consumers that HLNT staff have access to in delivering services to external clinics and services. Examples include the Outreach Health Services and NDSS programs. Whilst HLNT may input data into these databases, they are external to HLNT and ownership vests in the fund-holder.
Identifiable Data:	Means data, whether recorded in a material form or not, that will enable a person to establish the identity of a person. (also known as Personal and Sensitive Information)
Personal and Sensitive Information	Refers to any information of a personal and/or sensitive nature, for example contact details and a medical diagnosis that identifies or could identify a person. This is confidential information. (also known as Identifiable Data)
Privacy	Refers to how personal and sensitive information is handled
Privacy Act	Means the Privacy Act 1988 as amended
Research	As defined by the ***Australian Code for the Responsible Conduct of Research***. This includes health, medical, social and behavioural research. From Healthy Living NT's perspective, research can be additionally defined as a situation where consumer data (identified or de-identified) held by (or can be accessed by) HLNT is sought for purposes other than the reason for which it was collected or provided.

Re-identifiable Data:	Means when Unidentifiable Data is ascertained and used in various combinations, it may reveal sufficient details and characteristics of a person to the extent it will enable the identification of a person to be made. An example of potentially re-identifiable data would be data that holds date of birth and an area code – in an area consisting of 200 – 300 residents. The following factors should be considered when determining whether research involves potentially re-identifiable data: • Presence of rare characteristics in a Statistical Local Area (SLA); • Accuracy of the data; • Age of the data; • Coverage of the data (completeness); • Presence of other information that can assist in identification, including: o publicly available information; o restricted access data holdings that a data user may have access to; and o personal knowledge that a user may have.
Service Reviews	Service reviews conducted by external funders which may seek the release of consumer personal and sensitive information to assist in service appraisal. Service reviews are not considered research in the context of this Framework but will require consideration under HLNT's Privacy Policy.
Unidentifiable Data:	Means data, whether recorded in a material from or not, that do not contain any identifiers such as names, street and postal address of a person. (also known as De-identified or Non-identified data)

Background

Healthy Living NT (HLNT) receives requests from external bodies, researchers and HLNT staff who are seeking support from Healthy Living NT under the following general scenarios:

Scenario 1:	HLNT support in recruiting consumer participation in research projects involving release of personal data to researchers or HLNT communicating directly to consumers on behalf of researchers
Scenario 2:	Access to personal and sensitive consumer data held internally by HLNT to undertake research
Scenario 3:	HLNT participation in research activities, based on HLNT's role as a major service provider to people with chronic conditions
Scenario 4:	HLNT support in general promotion of research projects to consumers
Scenario 5:	HLNT involvement in the recruitment of consumers in the assessment of management devices or therapies owned or manufactured by a third party, with results written up by HLNT in de-identified case studies.
Scenario 6	HLNT participation (organisationally or at an individual practitioner level) in service benchmarking activities based on personal and sensitive consumer data held by HLNT or can be accessed by HLNT staff.
Scenario 7:	HLNT co-participation in research and innovation activities that may be of benefit to consumers; no requirement to access consumer data
Scenario 8	HLNT support for research funding applications

Healthy Living NT is governed by the Privacy Act 1988 ('the Privacy Act'), as amended by the Privacy Amendment (Private Sector) Act 2000, the *Privacy Amendment (Enhancing Privacy Protection) Act 2012 and* the *Privacy Amendment Notifiable Data Breaches (NDB) Act 2017*.

Healthy Living NT is committed to maintaining client, member and customer privacy and confidentiality in accordance with HLNT's Privacy Policy, in compliance with the above Acts and HLNT's ethos as a consumer advocate. Healthy Living NT only collects (with consent) consumer personal and sensitive information that is reasonably necessary for the delivery of one or more of our services or activities. In obtaining consumer consent for the collection of personal and sensitive information HLNT broadly specifies the use of the information to be:

- Provision of education and information and services
- Reporting back to health professionals (where required)
- Use in non-identifiable statistics for reporting to funders and for internal service/program evaluation (internal and externally contracted services)

The use and/or provision of consumer personal and sensitive information for the purpose of research are not permitted under HLNT's Privacy Policy.

Additionally, Healthy Living NT has access to a range of consumer personal and sensitive information contained in non-HLNT databases through external funding agreements covering, for example, provision of services to external clinics and services or the NDSS. This data access is strictly for the purpose of provision of defined services and cannot be accessed or used for any other purpose.

Healthy Living NT recognises the value of research in improving knowledge about the prevention and management of chronic health conditions. However, HLNT's involvement in recruiting consumers for research studies or as a co-participant or participant in research activities requires careful consideration. HLNT support for research activities should be guided by the core ethical values of merit and integrity, respect, justice and beneficence (appended). Additionally, issues of personal privacy, informed consent and risk of coercion or incentivisation are major concerns. HLNT must also be acutely aware of risks arising from notifiable data breaches and reputational damage associated either with a breach or a poorly administered research study.

This framework seeks to outline the parameters under which Healthy Living NT will support the conduct of research activities and the processes to be followed.

Ethical issues associated with research participant recruitment

Whilst all research studies generally require Ethics Committee Approval, this does not automatically confer *ethical status* on the research activity. Compliance with Australian Privacy law and respect of consumer rights and information are additional matters which must be considered as shown in the examples below. Healthy Living NT, as a consumer representative and advocate, cannot rely on Ethics Committee approval alone, when considering its support for, or involvement in, research activities. HLNT must satisfy itself of the bonafides of each application.

Potential ethical issues involved in recruitment of participants to research studies are outlined below.

Recruitment strategies associated with common study designs in primary care research and ethical issues associated with these strategies

Type of study/study design	Possible recruiting strategy	Examples of ethical implications
Audit of clinical records for quality assurance (eg searching own/clinic electronic database)	Not applicable	**Minimal**. This type of study is unlikely to require review by an ethics committee, so long as consumers are not identifiable in any subsequent outputs. However, because of variable editorial policy, it is advisable to get ethics approval if publication in a journal is planned.

Type of study/study design	Possible recruiting strategy	Examples of ethical implications
Audit of clinical records for research	Searching clinical databases	**Moderate**. This study would require review by an ethics committee. Major issues: • Consent needed from HLNT • Consumer consent may be needed even if provided data accessed is de-identified • Who has access to record data • Using records for a purpose they were not originally collected for • Safe storage of data • Privacy protection with publication (especially small sample and towns)

Qualitative study (eg interviews with consumers or their carers of older consumers attitudes)	• Notice, flyer or information pack in clinic, with information to contact external researcher or let HLNT staff know of interest
	• Searching HLNT databases by HLNT staff, followed by invitation to participate face to face or by mail
		Minimal–moderate. This study would require review by an ethics committee. Major issues:
		• Identifying participants
		  • Are consumers' clinical records needed to identify likely participants?
		  • Who has access to this clinical information?
		  • Will HLNT staff know if participants have taken part in the research?
		• Contacting participants
		  • How will information about the study be given? Who will give this and is there risk of coercion?
		• Management of data
		  • Consent to record interviews
		  • Access to data (eg for transcription and analysis) and safe storage of data
		• Dissemination of results
		• Privacy protection with presentations and publication. Is there a possibility the participants could be identified by the characteristics or location of the sample?

Survey of consumers (eg a quality-of-life survey of primary care consumers with chronic illness)	• Notice in clinic
	• Searching clinic databases by HLNT staff, followed by invitation to clients to participate face to face or by mail
		Moderate. This study would require review by an ethics committee. Major issues:
		• Identifying eligible participants
		• Role of HLNT staff in informing consumers about the study, or recruiting consumers to the study
		  • Will HLNT staff know which consumer participates and who does not?
		  • Will participation or non-participation impact on clinical care?
		• Completion of survey may constitute consent. However, if survey addresses issues or topics that may lead to distress, separate written consent may be required
		• Access to data (eg for data entry and statistical analysis); safe storage of data
		• Privacy protection with publication (especially small sample

Type of study/study design	Possible recruiting strategy	Examples of ethical implications
Experimental study – lifestyle or other non-invasive intervention (eg a trial of chronic disease self-management support)	• Notice in clinic • Searching clinic databases by HLNT staff, followed by invitation to consumers to participate face to face or by mail	**Moderate–high**. This study would require review by an ethics committee. Major issues: • Identifying eligible consumers • Role of HLNT staff in informing consumers about the study • Randomisation to control and intervention groups† • Consumer aware of risks, likely benefits or potential harms • Access to data (eg for data entry and analysis); safe storage of data • Privacy protection with publication (especially small sample and towns).
Experimental study – drug trial, medical device or other invasive procedure	• Notice in clinic • Searching clinic databases by HLNT staff, followed by invitation to patients to participate face to face or by mail	**High**. This study would require review by an ethics committee. Major issues: • Identifying eligible consumers • Randomisation to control and intervention groups; • Role of HLNT staff in informing consumers about the study • Consumer awareness of risks, likely benefits or potential harms • Access to data (eg for data entry and analysis); safe storage of data • Privacy protection with publication (especially small sample and towns)

Key Issues for Consideration:

1) Consumer Privacy

Prior to recruiting participants to a research study, there is a need to identify consumers who meet the study selection criteria and inform them about the study. How researchers go about identifying consumers for inclusion and how they gain access to the detail needed to contact potential participants (through Healthy Living NT) is critical.

The key privacy principle is that personal information about an individual that was collected for a particular purpose (the primary purpose) must not be used or disclosed for another purpose (the secondary purpose) unless the individual has consented to it. However, the *Privacy Act 1988* does allow for use and disclosure for a secondary purpose that is *directly related* to the primary purpose.

Policy Position:

Healthy Living NT's Privacy Policy explicitly requires consumer consent for use of personal and sensitive data held by HLNT for additional (or secondary) purposes. Unless research has been nominated as a primary purpose for data collection, the data cannot be used for research unless further specific informed client consent has been given.

The Board of Healthy Living NT must approve any consumer consent form that specifies research as a primary or secondary data collection purpose.

It is not permissible for HLNT or its staff to access or use consumer personal and sensitive data held by third party clinics or in external databases for a reason other than service provision.

2) Informed Consent

A common, acceptable practice among primary care researchers is, following agreement from the participating organisation, to provide the selection criteria to practice staff who will then identify consumers at their clinic from information held in each consumer's clinical record. The participating organisation will then make these consumers aware of the research and invite them to take part. These consumers will then need to contact the researchers to register their interest or otherwise enroll in the study directly.

Consideration of privacy and confidentiality should also be made in the reporting of results from studies of small samples, or samples drawn from small towns, such that individual confidentiality can be protected. It is important to note that ethics do not apply just to the individual, but also to the community or population.

Once potential participants have been identified, they need to be informed about the study and given the necessary information to make an informed decision about participation. Good, informed consent is guided by the principle that *a person's decision to take part in research is to be voluntary, and based on sufficient information and adequate understanding of both the proposed research and implications of participation in it*.

3) Power Relationships

Healthy Living NT must be acutely aware of the potential power imbalance between:

- Consumers and their HLNT health professional(s), and
- Consumers and Healthy Living NT.

In some cases this potential power imbalance is a reflection of the potentially dependent nature of their relationship. Good research design should determine whether a consumer is likely to experience coercion or pressure to agree to take part in the research, or receive (or alter) treatment that they would not otherwise consent to.

Policy Position:

For reasons related to informed consent and power relationships, it is generally inappropriate for Healthy Living NT or its staff to directly recruit participants to a research study. Exceptions must be approved by Board.

4) Incentivisation

A further issue is the use of incentives as part of the recruitment strategy. There is good evidence that incentives (both financial and non-financial) increase response rates to surveys. While incentivisation increases response/participation rates, there is also an overriding need to protect vulnerable individuals.

The use of incentives remains contentious in research. Some consider that any inducement that influences decision-making is a form of coercion – that participation in research should be voluntary and/or for altruistic reasons, and that incentives compromise voluntariness. Others consider that 'payment is never coercive', as it is an offer rather than threat. Pragmatically, reimbursement of costs for out-of-pocket expenses related to research (eg travel, accommodation and parking) is not usually considered unethical in the Australian research context.

From an NT perspective, noting that the majority of Australian research activities are conducted from a southern base, Healthy Living NT believes it is reasonable that a consumer should not be out-of-pocket as a result of participation in a research activity.

Policy Position:

Healthy Living NT does not support incentivised research recruitment practices.

Healthy Living NT does support reimbursement of reasonable costs related to a consumer's participation in research.

5) Project Creep

In the context of research studies, project creep occurs when a study evolves beyond the scope of the original Ethics Approval. Such evolution or project creep in research studies is often perceived as a normal response to mitigating issues or barriers occurring in the implementation phase. This occurs particularly in the area of participant recruitment as studies are dependent on reaching a critical mass in order to achieve a valid sample.

A clear example of this type of project creep occurred in the NT DiP research project – under the Ethics Approval, HLNT's role was clearly defined as service provision and provision of information about the study to potential participants; when the study failed to recruit sufficient participants, it was assumed that HLNT would take a formal role as a recruitment agent for the study. (Whilst HLNT rejected this, the primary researchers perceived no need for a new Ethics Approval and no conflict of interest for HLNT as both a service provider and a research participant recruiter.)

A secondary issue associated with project creep relates to re-use of research data for purposes not specified in the original Ethics Approval. Major research studies such as the NT DiP study obtain a wealth of consumer data which is attractive to other non-related research activities. Research project Steering Committees are often attracted to the idea of consumer data from their specific study being utilised for broader research purposes. In this context, research project Steering Committees falsely assume a level of ownership of consumer data and a role in approving its use in additional research projects not contemplated in the original Ethics Approval and consumer consent documentation.

Policy Position:

Where the conduct of a research study is likely to (or seeks to) vary from the parameters of its original Ethics Approval, a new Ethics Approval must be sought.

Use of consumer data is only permissible for the purposes of the original Ethics Approval. Applications for re-use of consumer data for purposes other than the approved purpose in the original Ethics Approval should form a new Ethics Committee application.

6) HLNT as a researcher

This framework does not preclude Healthy Living NT or its staff undertaking primary research activities involving use of personal and confidential data. However, noting issues related to informed consent and power relationships, HLNT must strive to ensure avoidance of a conflict of interest (research vs best interests of consumers) and potential reputational damage.

Policy Position:

HLNT-initiated research proposals must comply with the policies described in this Framework and adhere to the standards expected of external research applicants.

HLNT-initiated research proposals must be approved by the Board.

7) Requests for support for research funding applications

From time to time, Healthy Living NT receives requests from researchers to provide a letter of support for their research funding application based on HLNT's credentials as a consumer-based advocacy organisation and/or service provider to people with chronic disease(s).

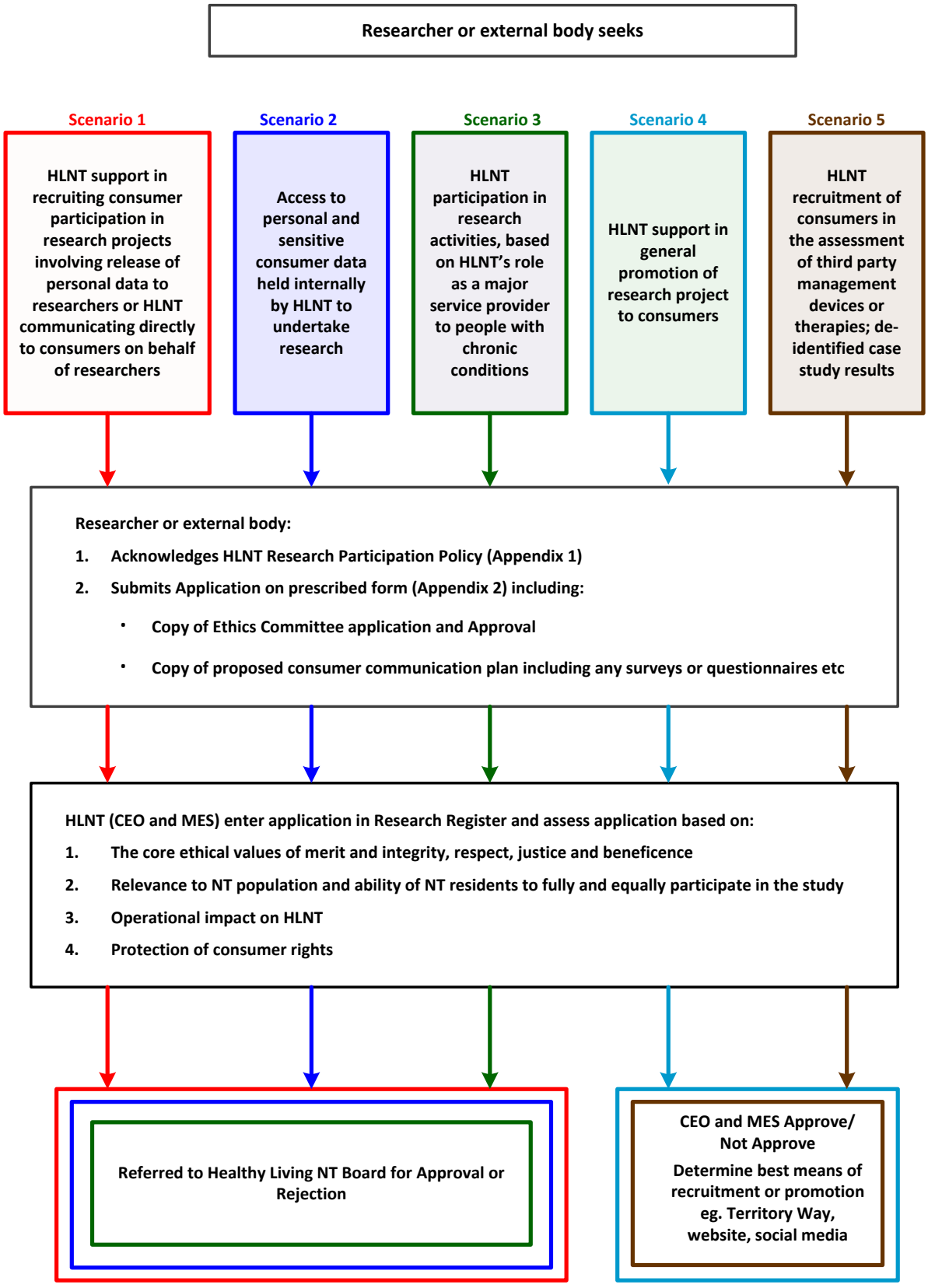
Requests for support for research funding applications may occur prior to Ethics Committee approval, even though the study may ultimately need access to consumer personal and sensitive data. There may or may not be an associated request for HLNT participation.

Policy Position:

HLNT may provide general letters of support for research funding proposals with or without Ethics Committee approval where they are relevant to the NT population, provided no commitment is given in relation to access to consumer data.

Requests for letters of support for research funding proposals that also seek HLNT commitment to research participation require assessment under Scenarios 1-5 as appropriate.

Research Participation and Assessment Framework – Scenarios 1 - 5



Research Participation and Assessment Framework – Scenarios 6-8

Researcher or external body seeks

Scenario 6

HLNT (organisationally or at individual practitioner level) participation in service benchmarking activities based on personal and sensitive consumer data held by HLNT or external clinic; de-identified data only

Notwithstanding use of de-identified data only:

- **this is not a permissible use of consumer personal and sensitive consumer information held by HLNT as it exceeds the level of original consumer consent.**
- **HLNT has no right to access or use personal and sensitive consumer information held by external clinics or databases for reasons other than service provision.**

HLNT (CEO and MES) enter application into Research Register and assess request/opportunity based on:

1. **The core ethical values of merit and integrity, respect, justice and beneficence**
2. **Relevance of benchmarking to NT population and HLNT services**
3. **Relevance to and operational impact on HLNT**
4. **Protection of consumer rights, including measures to obtain voluntary, informed consumer consent for the use of de-identified personal and sensitive data**

CEO and MES Approve/ Not Approve

Scenario 7

HLNT/health professional staff co-participation in research and innovation activities that may be of benefit to consumers; no requirement to access consumer data

HLNT (CEO and MES) enter application into Research Register and assess request/ opportunity based on:

1. **The core ethical values of merit and integrity, respect, justice and beneficence**
2. **Relevance of opportunity to NT population and HLNT services**
3. **Relevance to and operational impact on HLNT**
4. **Benefit to HLNT and health professional staff**

Operational Impact = LOW
CEO and MES Approve/Not Approve
Operational Impact = HIGH
Board Approve/Not Approve

Scenario 8

HLNT support for research funding applications
(Pre- and Post- Ethics Approval)

HLNT (CEO and MES) enter request into Research Register and assess request/opportunity based on:

1. **The core ethical values of merit and integrity, respect, justice and beneficence**
2. **Relevance of study to NT population and HLNT services**
3. **Relevance to and operational impact on HLNT**
4. **Protection of consumer rights.**

- **CEO & MES Approve/Not Approve General Letter of Support for pre- and post-Ethics Approval requests where no involvement is required by HLNT**
- **CEO & MES assess post-Ethics Approval requests where involvement is required by HLNT as per scenarios 1-5**

Researcher:

1. **Acknowledges HLNT Research Participation Policy (Appendix 1)**
2. **Submits Application on prescribed form (Appendix 2)**

Responsibility for Policy

The Board of Healthy Living NT is responsible for ensuring this policy is up to date and complied with.

Approval

Submission Date: Board Meeting 6/18 of 8 December 2018

Approval Date: Board Meeting 6/18 of 8 December 2018

Circulation: All HLNT Board Members and staff.

Sign off by: Chair of the Board

Signature: Ron O'Brien

Related Documents, References and Resources

- HLNT Privacy Policy
- HLNT Privacy Operational Guidelines
- HLNT Ethical Relations Guide
- NDSS Privacy Policy
- NDSS Privacy Breach Complaints Policy and Procedure
- HLNT Service Agreements with external funders
- Privacy Act 1988
- Australian Privacy Principles
- My Health Records Act
- Office of the Australian Information Commissioner, *Data breach notification guide: A guide to handling personal information security breaches*, August 2014.
- Privacy Amendment (Notifiable Data Breaches) Act 2017 (Cth)
- HLNT Privacy Breach Policy and Procedure
- ***Australian Code for the Responsible Conduct of Research***
- ***National Statement of Ethical Conduct in Human Research***
- ***Statement on Consumer and Community Involvement in Health and Medical Research***
- ***Values and Ethics: Guidelines for Ethical Conduct in Aboriginal and Torres Strait Islander Health Research***
- https://www.racgp.org.au/afp/2016/march/ethical-considerations-in-recruiting-primary-care-patients-to-research-studies/

Definition of core ethical values of merit and integrity, respect, justice and beneficence

GUIDELINES

Research merit and integrity

1.1 Research that has merit is:

(a) justifiable by its potential benefit, which may include its contribution to knowledge and understanding, to improved social welfare and individual wellbeing, and to the skill and expertise of researchers. What constitutes potential benefit and whether it justifies research may sometimes require consultation with the relevant communities;

(b) designed or developed using methods appropriate for achieving the aims of the proposal;

(c) based on a thorough study of the current literature, as well as previous studies. This does not exclude the possibility of novel research for which there is little or no literature available, or research requiring a quick response to an unforeseen situation;

(d) designed to ensure that respect for the participants is not compromised by the aims of the research, by the way it is carried out, or by the results;

(e) conducted or supervised by persons or teams with experience, qualifications and competence that are appropriate for the research; and

(f) conducted using facilities and resources appropriate for the research.

1.2 Where prior peer review has judged that a project has research merit, the question of its research merit is no longer subject to the judgement of those ethically reviewing the research.

1.3 Research that is conducted with integrity is carried out by researchers with a commitment to:

(a) searching for knowledge and understanding;

(b) following recognised principles of research conduct;

(c) conducting research honestly; and

(d) disseminating and communicating results, whether favourable or unfavourable, in ways that permit scrutiny and contribute to public knowledge and understanding.

Justice

1.4 In research that is just:

(a) taking into account the scope and objectives of the proposed research, the selection, exclusion and inclusion of categories of research participants is fair, and is accurately described in the results of the research;

(b) the process of recruiting participants is fair;

(c) there is no unfair burden of participation in research on particular groups;

(d) there is fair distribution of the benefits of participation in research;

(e) there is no exploitation of participants in the conduct of research; and

(f) there is fair access to the benefits of research.

1.5 Research outcomes should be made accessible to research participants in a way that is timely and clear.

Beneficence

1.6 The likely benefit of the research must justify any risks of harm or discomfort to participants. The likely benefit may be to the participants, to the wider community, or to both.

1.7 Researchers are responsible for:

(a) designing the research to minimise the risks of harm or discomfort to participants;

(b) clarifying for participants the potential benefits and risks of the research; and

(c) the welfare of the participants in the research context.

1.8 Where there are no likely benefits to participants, the risk to participants should be lower than would be ethically acceptable where there are such likely benefits.

1.9 Where the risks to participants are no longer justified by the potential benefits of the research, the research must be suspended to allow time to consider whether it should be discontinued or at least modified. This decision may require consultation between researchers, participants, the relevant ethical review body, and the institution. The review body must be notified promptly of such suspension, and of any decisions following it (see paragraphs 5.5.7 to 5.5.10).

Respect

1.10 Respect for human beings is a recognition of their intrinsic value. In human research, this recognition includes abiding by the values of research merit and integrity, justice and beneficence. Respect also requires having due regard for the welfare, beliefs, perceptions, customs and cultural heritage, both individual and collective, of those involved in research.

1.11 Researchers and their institutions should respect the privacy, confidentiality and cultural sensitivities of the participants and, where relevant, of their communities. Any specific agreements made with the participants or the community should be fulfilled.

1.12 Respect for human beings involves giving due scope, throughout the research process, to the capacity of human beings to make their own decisions.

1.13 Where participants are unable to make their own decisions or have diminished capacity to do so, respect for them involves empowering them where possible and providing for their protection as necessary.

Application of these values and principles

Research, like everyday life, often generates ethical dilemmas in which it may be impossible to find agreement on what is right or wrong. In such circumstances, it is important that all those involved in research and its review bring a heightened ethical awareness to their thinking and decision-making. The National Statement is intended to contribute to the development of such awareness.

This National Statement does not exhaust the ethical discussion of human research. There are, for example, many other specialised ethical guidelines and codes of practice for specific areas of research. Where these are consistent with this National Statement, they should be used to supplement it when this is necessary for the ethical review of a research proposal.

These ethical guidelines are not simply a set of rules. Their application should not be mechanical. It always requires, from each individual, deliberation on the values and principles, exercise of judgement, and an appreciation of context.

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Research Participation Policy

Healthy Living NT receives requests from researchers who would like:

- To offer opportunities to our consumers and clients to participate in their chronic disease-related research project;
- Healthy Living NT to co-participate in research activities; or
- Healthy Living NT to provide a letter of support for research funding applications.

We have developed a policy for managing requests for research participation. If you would like to seek our assistance with recruitment of participants for your research or are seeking co-participation in, or support for, your research, please download the interactive Research participation application form which you can type your responses into, and send to ceo@healthylivingnt.org.au.

Healthy Living NT role in participating in research

Healthy Living NT recognises the value of all levels of research and the welfare and experiences of those affected. Likewise, Healthy Living NT recognises that many consumers are interested in research and want to be involved in research projects relevant to them.

Healthy Living NT may endeavour to assist with the recruitment of participants to take part in the design and execution phases of research projects and studies; however Healthy Living NT cannot guarantee that participants will be available.

All requests for Healthy Living NT to assist with the recruitment of participants for research projects or to co-participate in a research activity must be made on the appropriate application form. Requests for participants required in the execution of a study must be accompanied by a copy of Ethics Committee applications and approval for the study and participant information sheet. Only applications seeking assistance with study design or letters of support for funding applications can be considered by Healthy Living NT prior to ethics approval.

Promotion of approved applications will be through mechanisms deemed appropriate by Healthy Living NT which may include letters of support, social media, through our website, membership or client database and health professional networks.

Healthy Living NT retains the right to remove listings/postings that do not meet the agreed criteria, and/or if complaints are received concerning the research project.

How decisions will be made

Healthy Living NT has developed the below set of criteria to assess applications:

1. Aims and purpose of the research: the research must have the potential to lead to benefits to people living with, or at risk of, chronic disease.
2. Ethics approval: the project must have ethics approval from a Research Ethics Committee, particularly if the researcher is seeking participants to execute the study.
3. If the researcher is seeking participants to execute the study, a participant information sheet and communication plan must also be included. This should also address protection of, and respect for, consumer rights and information and include any surveys or questionnaires.

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After receiving applications from a researcher for assistance recruiting participants to their study, Healthy Living NT will assess and notify them of the outcome. Requests for general promotion of, or support for, a research opportunity will normally be decided within two weeks; research study requests involving specific participant recruitment or co-participation will normally be decided within two months.

Other important information

To ensure compliance with privacy legislation, Healthy Living NT will not release consumer details to researchers without the express permission of the individual and will at all times ensure compliance with our Privacy Policy. Subject to compliance with Healthy Living NT's Privacy Policy, stakeholders will be provided with the researcher's contact details via methods deemed appropriate by Healthy Living NT and asked to contact the researcher directly.

All researchers that receive help from Healthy Living NT recruiting research participants are asked to:

- Acknowledge that Healthy Living NT takes no responsibility for the research and is not liable for any claims concerning negligence, harm or oversight that might arise during the course of the research.
- Acknowledge that providing the researchers with access to potential participants, does not represent Healthy Living NT's endorsement of, or participation in, the research project.
- Note that Healthy Living NT will publish a disclaimer on the website which will contain a register of research projects that are being listed by Healthy Living NT.
- Note that Healthy Living NT retains the right to remove listings and postings of research projects that do not meet the agreed criteria, if complaints are received concerning the research project or if the implementation of the project differs materially from the parameters of the Ethics Approval.

If you have any questions please contact ceo@healthylivingnt.org.au

Responsibility for Policy

The Board of Diabetes Association of the NT Inc. is responsible for ensuring this policy is up to date and complied with.

Approval

Approval

Submission Date:	Board Meeting 6/18 of 8 December 2018
Approval Date:	Board Meeting 6/18 of 8 December 2018
Circulation:	Public.

Related Documents, References and Resources

- HLNT Privacy Policy
- HLNT Research Participation and Assessment Framework
- HLNT Ethical Relationship Guide

Research Participation Application Form

All requests for Healthy Living NT to provide access to stakeholders for chronic disease related research projects, to co-participate in a research activity or provide support for a research activity must be made on the appropriate application form. This form should be read in conjunction with Healthy Living NT's Research Participation Policy.

Requests for participants in the execution of a study must be accompanied by a copy of ethics application and approval for the study, participant information sheet and communications strategy. Although Healthy Living NT can endeavour to provide access to stakeholders who may be interested in taking part in research projects, it cannot guarantee securing participants.

Please fill in this form and send to ceo@healthylivingnt.org.au Fax: 0889 278515 or post to PO Box 40113, CASUARINA NT 0811.

1. Title of research project:

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2. Chief Investigator Details:

Full Name:		Contact number:	
Job Title:		Email:	
Institution:		Postal Address:	

3. Name of research funders:

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4. Supporting Information – Please attach:

☐ Ethics Committee Application and Approval

☐ Project Description

☐ Participant Information Sheet and Communication Plan including any surveys or questionnaires.

5. What form of support are you seeking from Healthy Living NT?

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6. Where are you recruiting participants from?:

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7. **Please provide a short statement covering the aim of the study, what participants need to do and who they should contact? If approved, this will be posted on our website: (max 200 words)**

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8. **End date of recruitment: (This is the date the project will be removed from the website)**

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9. **Declaration of any conflicts of interest or potential conflicts of interest:**

Acknowledgement

I, _____, agree to:

1. Acknowledge that Healthy Living NT takes no responsibility for the research and is not liable for any claims concerning negligence, harm or oversight that might arise during the course of the research;
2. Acknowledge that providing the researchers with access to potential participants does not represent Healthy Living NT's endorsement of, or participation in, the research project;
3. Provide Healthy Living NT with a copy of the final research paper and a plain English report on the research that Healthy Living NT may publish;
4. Note that Healthy Living NT will publish the following disclaimer on our website with all research participation requests that are posted:

   Healthy Living NT recognises the value of all levels of research and promotes the welfare and experiences of people participating in research projects. Healthy Living NT is not responsible for, and does not endorse, any research project, opportunity or other type of project listed. Reasonable attempts have been made to ensure the projects listed have appropriate approval from a recognised body. Participants are responsible for satisfying themselves that appropriate approval procedures have been met before taking part. Participants are advised to read the participant information sheet that the researcher will provide to you. If you do agree to participate and/or you have concerns regarding the project, these should be directed to the researcher and other contacts on the participant information sheet. If you are unable to resolve concerns regarding the project, please advise Healthy Living NT.

Applicant Signature _____ Date _____