MIWATJ HEALTH ABORIGINAL CORPORATION

RESEARCH GOVERNANCE CHARTER

September 2020

1. Introduction

1.1 About Miwatj Health Aboriginal Corporation

Miwatj Health Aboriginal Corporation (Miwatj) was established in 1992. It is an independent, Aboriginal-controlled health service registered under the *Corporations (Aboriginal and Torres Strait Islander) Act 2006* and administered by a Board of Directors representing communities across East Arnhem Land.

Miwatj Health's mission is to ensure and expand Aboriginal community control of quality healthcare services and public health programs across the East Arnhem region.

1.2 Our Vision

The Vision of Miwatj Health is:

> *Building the capabilities of Miwatj mala so they can take control of their lives, and direct their own futures.*

The underlying philosophy of Miwatj Health is the fundamental right of Aboriginal people to control their own health services.

This supports the Alma Ata Declaration of the World Health Organisation, which emphasised people's right to participate in the planning and implementation of primary healthcare services, and supports the long-accepted principle of self-determination for Indigenous peoples.

We implement this through our Board governance structure, and through our daily involvement in health issues at a grass-roots community level.

Miwatj believes the way forward in Aboriginal health lies in the implementation of comprehensive primary health care. This includes primary medical care, but also goes beyond that to emphasise a wide-ranging and holistic approach.

1.3 Objectives of Miwatj

Miwatj's primary objective is to alleviate the sickness, destitution, suffering and disadvantage, and to promote the health and the well-being, of the members of the communities in the Miwatj region including through the delivery of Comprehensive Primary Health Care Services.

To assist in achieving its primary objective, Miwatj's secondary objectives are to:

- assist residents of the communities in the Miwatj region in promoting health and well-being amongst their communities;
- assist the establishment, support and resourcing of community-controlled organisations to work for improved health in the communities in the Miwatj region;
- promote and/or provide training and training facilities, resources and staff for improved knowledge of good health in the communities in the Miwatj region;
- promote and provide educational facilities and resources for the training of Aboriginal and other health workers;
- encourage the preservation and practice of the traditional Aboriginal medicine of the Miwatj region;
- undertake and/or promote research into the causes of illness among Aboriginal people of the Miwatj region and the means for their prevention and/or other form of remedy;

- receive, expend and acquit grants from the Northern Territory and Commonwealth Governments and other agencies to further the objectives of the corporation;
- serve as a coordinating body for Comprehensive Primary Health Care in the Miwatj region;
- advocate for positive changes to the status of the health of the communities in the Miwatj region, especially the Aboriginal members of those communities; and
- undertake activities or actions that the directors deem relevant to achieving the objectives of the corporation, including the infrastructure and support mechanisms required directly or incidentally to achieve the objectives.

2. Scope

This Research Charter governs all research undertaken with Miwatj Health Aboriginal Corporation ("Miwatj Health"), including requests for access to existing Miwatj Health data or engagement with Miwatj Health employees or communities in the Miwatj region, as defined in the Miwatj Ward Map (contained in Apppendix I).

Lead Investigators and Research Teams should familiarise themselves with this Charter, the Research Agreement and the information available on Miwatj Health's website to ensure their proposed research aligns with Miwatj Health's values, strategic goals, research priorities and approach.

3. Purpose

The purpose of this Research Charter is to ensure that:

- research in which Miwatj Health participates is valuable and solution-focused, improves Indigenous health outcomes, acknowledges traditional practices and knowledge, and provides Miwatj communities with ownership and self-determination in discussions about their health;
- research is aligned with Miwatj Health's values and strategic goals;
- all research proposals are given appropriate consideration and are assessed fairly and consistently, against established factors;
- the Miwatj Board, through its Research Committee (RSC), and other Miwatj personnel are appropriately informed and have oversight of all research conducted in Miwatj communities;
- there is clear accountability and responsibility for activities to be undertaken under this Charter;
- the personal and cultural safety of Miwatj communities are protected when participating in research projects; and
- research projects deliver information and options to Miwatj Health so as to inform its clinical and other priorities.

4. Values

In conducting and participating in research, Miwatj Health aligns with the following values:

- we *show compassion, care and respect for our clients and employees* by empowering our community to own and direct research projects through community representatives participating in the design, monitoring and evaluation of research projects;
- we have *pride in the results of our work*, using our research findings to build an evidence base for the services we offer;

- we bring *cultural integrity and safety, while recognising cultural and individual differences*, to research projects by first listening and learning Miwatj Communities' perspectives of health and wellbeing;
- we prioritise *fairness, accountability and transparency* through ongoing monitoring and reporting for all research projects and by presenting research results to the community in language; and
- we *build the capacity of our organisation and community* by appointing Indigenous Lead Researchers to all research projects so that more research is conducted by Indigenous people for Indigenous people.

5. Strategic Goals

Miwatj Health aims to support research which aligns with its strategic goals. Miwatj Health's strategic goals are outlined in the organisation's Strategic Plan.

6. Definition of Research

Miwatj Health takes a broad view of what constitutes 'research'. Miwatj Health defines 'Research' to include asking Miwatj Health to do any of the following:

- allow Miwatj Health employees to undertake data collection which is peripheral to their role, such as the development of a thesis or other contribution to academic study;
- disclose existing data or information to Research Institutions (RIs) for analysis by Research Teams;
- support of RIs with collection of data by Research Teams from members of the community within the Miwatj region;
- facilitate discussions between Research Teams and Miwatj community members;
- make Miwatj Health staff available for interviews or for the collection of data;
- input into research papers; and
- support with the establishment of trials.

Research by Miwatj Health employees for Miwatj Health, such as for a Miwatj Health program, is outside of the scope of the Research Charter.

The Research Charter, its principles and procedures may be considered and applied to research projects instigated by Miwatj Health with any of its research partners.

7. Research Lifecycle

There are **five key stages** in research projects with Miwatj Health:

Identifying potential research projects: Miwatj Health receives a significant number of applications and proposals to conduct research in the Miwatj region every year. Miwatj Health's intent is to ensure research projects can be managed within existing research activities and have a positive impact in Miwatj communities.

Collecting data: The Board takes seriously the obligation that Miwatj Health has to the communities it services. Data collection activities must respect the privacy, autonomy and agency of the individuals and communities that participate in research.

Analysing data: Lead Investigators must keep the Board, through the RSC, informed about the progress of data analysis and findings after they have finished collecting data and/or left community.

Delivering results: The results and findings of every research project must be presented to the Board by the Research Team. The Research Team must also meet with the community that has participated in the project to discuss their findings.

Project evaluation: Every research project will be evaluated by the Board, to reflect on the value gained from each project and to ensure that lessons learned can be applied to future research.

8. Research Roles and Responsibilities

Miwatj Health Officers

The Board: approves research proposals. The Board can decide to change, suspend or cancel a research project if it is not satisfied with the progress of a research project or the conduct of the Research Team.

Research Committee: recommends projects to the Board and monitors the progress of approved projects against the agreed milestones and timeframes. The Research Committee ("**RSC**") can recommend that the Board change, suspend or cancel a research project.

CEO of Miwatj Health: as the person responsible for Miwatj Health's operations, the CEO, working with the Director of Public Health ("**DPH**"), the Director of Medical Services ("**DMS**") and any other relevant Director, ensures that research projects complement its clinical services and benefit Miwatj Communities. The CEO is ultimately accountable for the Human Health Research and initially determines which applications or proposals should be developed into a Project Plan for the Board and the Research Committee to consider. The CEO has delegation to approve certain types of research as exceptions.

Health Directors: the DPH, DMS or other relevant Director (and their delegates) (each a "**Health Director**") are the Miwatj Health officers responsible for oversight of research projects conducted by RIs and are accountable for the interactions of Research Teams with communities (depending on the subject matter of the research).

Clinical Governance Team: the Clinical Governance Team provides subject matter expertise and operational/practical support to Health Directors. The Health Directors meet regularly with the Clinical Governance Team to maintain oversight of current research projects and understand their relevance to, and interaction with, service delivery. The Health Directors may delegate certain of their own responsibilities to the Clinical Governance Team or other Miwatj Health employees.

Miwatj Health employees: the Lead Investigator and Research Team will work closely with Miwatj Health employees to understand their experience and perspectives, as well as ensure that the research project complements, or does not interfere with, clinical work. A employee of Miwatj Health will be responsible for the day-to-day interaction with the Lead Investigator and for communicating to Miwatj Community personnel with respect to the research project.

Community Members

Community Representative: the Research Team must appoint a Community Representative for every research project. The Community Representative must be a Miwatj community member to act as a point of contact between the community that is the subject of the research project, a Health Director

and the Research Team. Their role is to ensure the ongoing safety of the community by providing the Research Team and Miwatj Health with feedback and advice about the design and implementation of the research project.

East Arnhem Clinical and Public Health Advisory Group ("CPHAG"): Miwatj Health will share research decisions and provide updated and feedback to CPHAG regarding research proposals and research projects undertaken in the Miwatj region.

Research Team

Research Institution: the RI, on behalf of which the Research Team conducts the research project, is accountable for the research project, including any acts or omissions of its members.

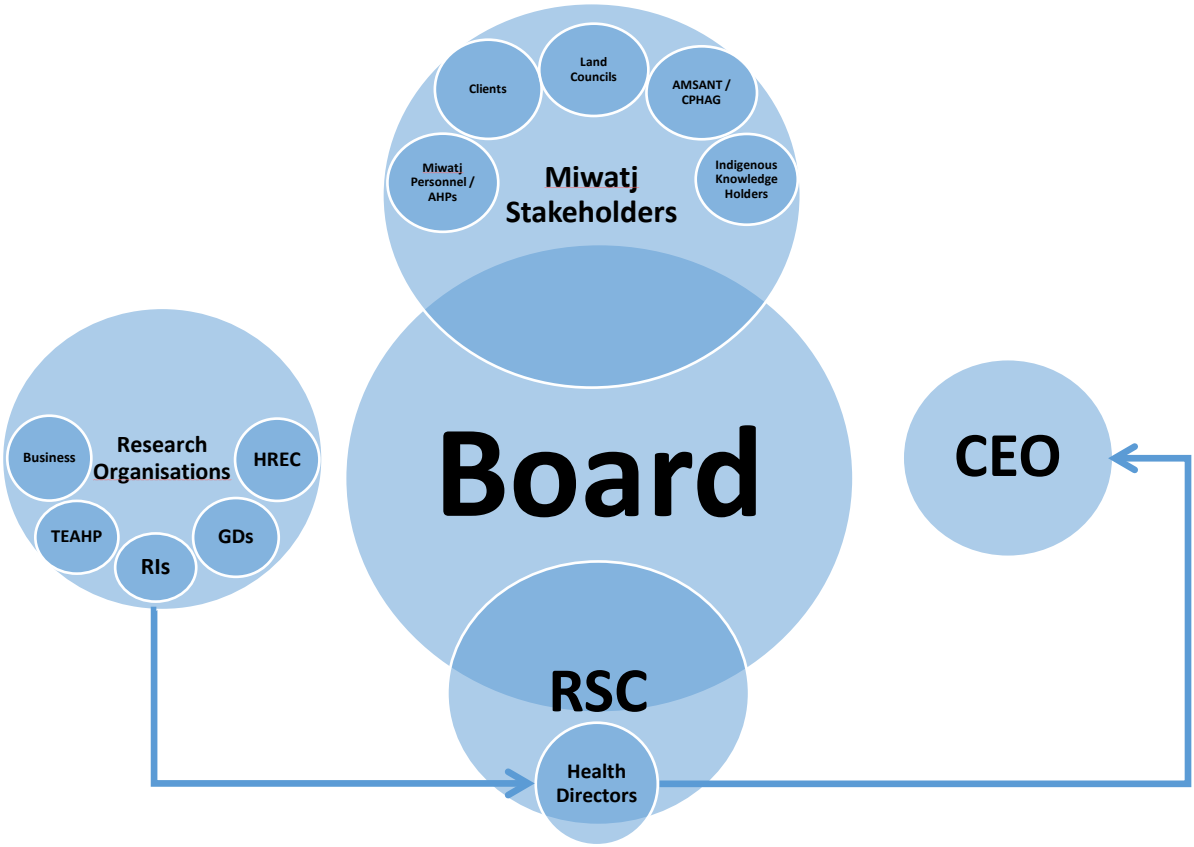
Lead Investigator: the individual nominated in the Project Plan as the person responsible for the day-to-day running of the research project and production of its output. The Lead Investigator is accountable to the RSC for the progress of the research project and the conduct of the Research Team.

Indigenous Lead Researcher: every Research Team must include an Indigenous person from a Miwatj Community as an Indigenous Lead Researcher. Depending on the number and nature of the Miwatj Communities engaged in the research, it may be appropriate to appoint more than one Indigenous researcher to the Research Team.

Research Team: All individuals working on the research project.

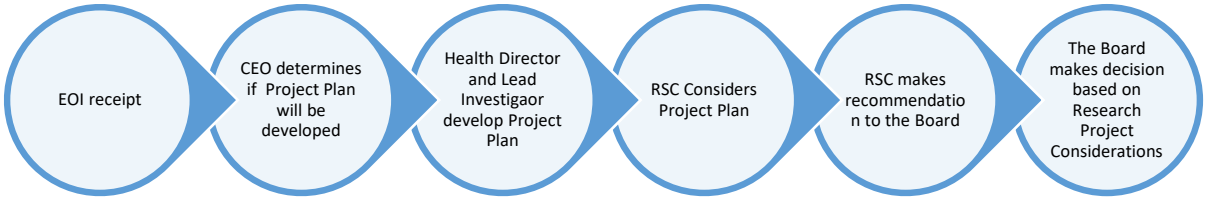
9. Miwatj Research Evaluation Model

Miwatj Health and the Research Evaluation Model is structured to ensure that Miwatj Communities, Miwatj personnel and Reseach Institutes have an opportunity to provide input into research projects.

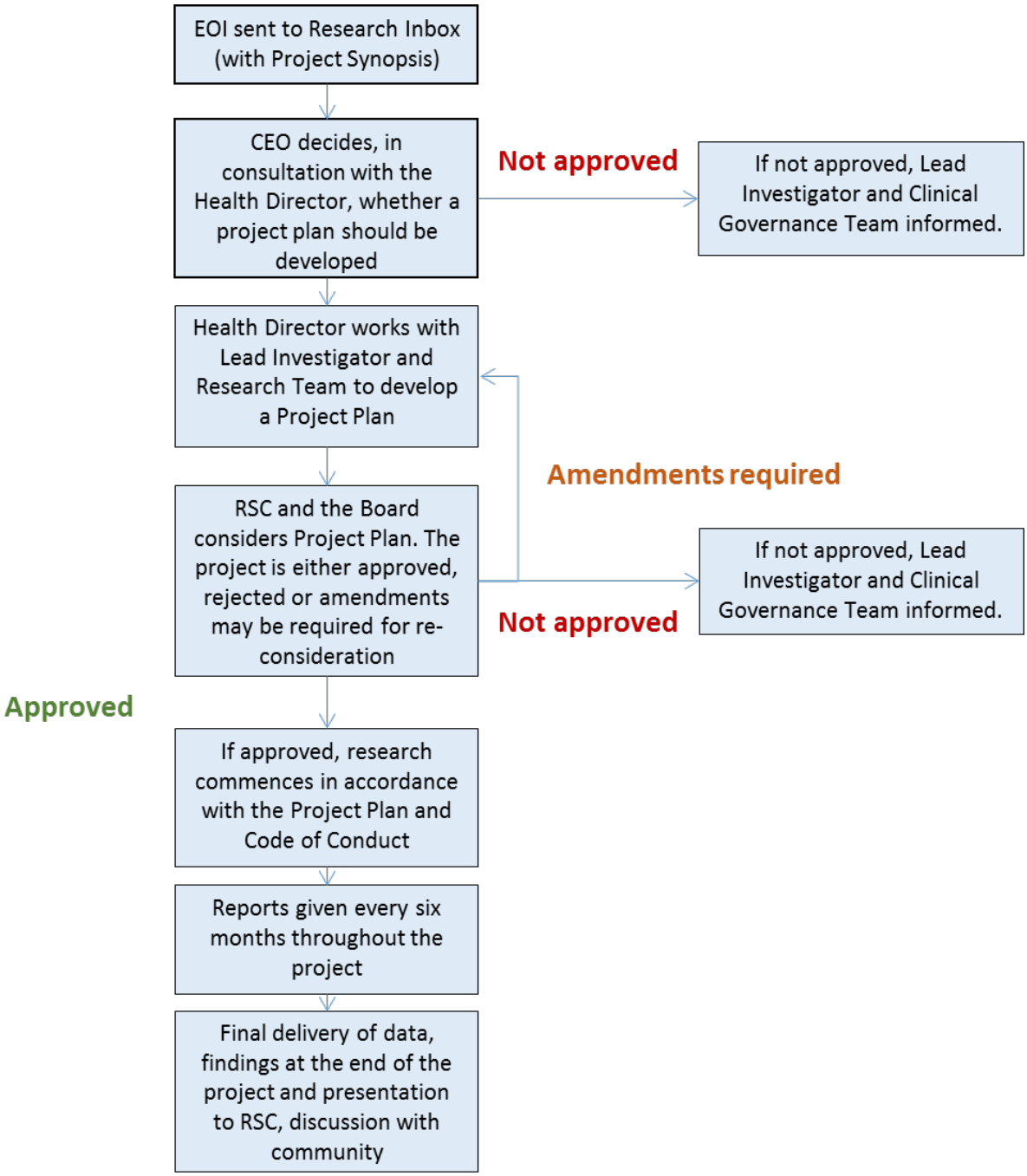


Research Evaluation Model

10.Research Approval Process



The CEO, Health Directors, Research Committee and the Board consider research projects in line with the following high-level process. See the Research Project Flowchart below for more detail.



10.1 Submitting an EOI

Lead Investigators should complete an Expression of Interest ("**EOI**") and email this to the Miwatj Health Research Inbox.

Research Teams are responsible for planning; however, it is recommended that this step is completed before settling the research project, seeking ethics approval or applying for funding.

Any Miwatj Health officer's (including the CEO or a Health Director) intent or agreement to progress any research project does not guarantee that the proposal will be endorsed by the Research Committee or approved by the Board.

10.2 Research Project Proposal Submission

Research Proposals

Lead Investigators for Research Institutions (including any research partner institutions) must submit an EOI, including detail regarding:

- the proposed Research Team for the research project; and
- if the Research Team has approached another health service provider working in Indigenous communities with the same (or a similar) proposal.

Research by Miwatj Health Officers

If a Miwatj Health officer proposes to conduct research to contribute to their academic study, they must submit an EOI with a cover email specifying whether the research:

- forms part of their Miwatj Health activities; or
- is for another purpose (e.g. for an organisation with which Miwatj Health partners) and, if so, which organisation/Reseach Institution is overseeing/facilitating the research project.

In-community Health Trials ("Health Trials")

Health Trials such as those that involve trials of testing or treatment may be undertaken with the participation of Miwatj Health clinics. Health Trials will be considered by the Research Committee and the Board in line with this Charter, but may be subject to different contractual arrangements, to be determined on a case-by-case basis.

Establishing Long-Term Research Partnerships – *out of scope*

Miwatj Health has long-term research partnerships with organisations that share its research priorities and have complementary approaches to research in Indigenous communities.

Each research partnership is governed by a Memorandum of Understanding ("MoU") between the organisations. Proposed research partnerships and MoUs will be considered on a case-by-case basis and will be subject to similar considerations as set out in this Charter, but are out of scope for the purpose of this Charter.

Research projects undertaken by Research Teams from such research partners will be subject to the terms of any MoU, this Research Charter and any relevant Research Agreement.

10.3 Consideration of Proposed Research Projects "EOI"

Proposed research projects are first considered by the Health Directors. The DPH is generally responsible for projects relating to public health programs, while the DMS is responsible for projects involving clinical or medical based research. Project proposals that fall outside the scope of the DPH and DMS will be directed to the relevant Health Director responsible for the speciality.

All EOIs will be discussed with the CEO, who determines (with input from the Health Directors and Clinical Governance Team) which proposals should have a full Project Plan developed for the Research Committee and subsequently the Board to consider. The Rearch Committee will have oversight, and must be regularly informed, of progress of the research project proposal.

A member of Miwatj personnel will contact the Lead Investigator to advise whether Miwatj Health wants to proceed with developing a Project Plan. Research Teams should expect to settle their

Project Plan with input from a Health Director and the Miwatj Community that will be the subject of research.

10.4 Development of a Project Plan

10.4.1 Appoint a Community Representative

The Research Team must appoint a Community Representative. The Clinical Governance Team will provide the Lead Investigator with a list of members of the community that may be suitable.

The role of the Community Representative may include:

- advocating for the interests and concerns of the community participating in the research, both in relation to the subject of the research and also the manner in which it is conducted;
- providing input to the Lead Investigator regarding the Research Team's methodology and the design of the Project Plan;
- providing assurance that the research design is appropriate to the community's needs and expectations;
- facilitating discussions between the Research Team and the community to ensure consensus about the scope of the research project and the methodologies to be used;
- identifying matters of sensitivity for the community that is participating in the research; and
- assisting the Research Team to identify appropriate ways to seek participant consent from community members.

The Research Team must consult the Community Representative throughout the research project. The Community Representative must ensure that the community remains informed about the progress of the research and raise any questions or concerns on behalf of the community.

The Community Representative must be remunerated by the Research Team in recognition of their work to support the research project. The Research Team must ensure that funding is obtained to remunerate the Community Representative.

For assistance with appointing a Community Representatives(s), please contact Miwatj Health through the Miwatj Health Research Inbox in the first instance and the Research Committee may be able to suggest a suitable member of the Miwatj Community or Miwatj Health personnel.

10.4.2 Appoint an Indigenous Lead Researcher

Building the capacity of our community is a core purpose of Miwatj Health. The health and well-being of our communities is intimately linked to sharing skills and capabilities, empowering Miwatj Communities to lead research about issues that affect them.

All research projects with Miwatj Health must include an Indigenous Lead Researcher and any other Indigenous researchers from Miwatj Communities, unless the Board agrees otherwise. If the Research Team does not already include an Indigenous Lead Researcher when the EOI is submitted, a Health Director may identify an appropriate member of

Miwatj Health personnel or provide the Lead Investigator with contact details for organisations that may assist with the appointment.

The Indigenous Lead Researcher should receive pay and benefits equal to senior members of the Research Team (e.g. PHD level). This may require the Research Team's organisation to engage the Indigenous Lead Researcher as an employee or contractor. The Research Team must ensure that funding is obtained to remunerate the Indigenous Lead Researcher and any other Indigenous researchers.

For assistance with appointing an Indigenous Lead Researcher and other Indigenous researchers, in the first instance, please contact Miwatj Health through the Miwatj Health Research Inbox and the Research Sub-committee may be able to suggest a suitable member of the Miwatj Community or Miwatj Health personnel.

10.4.3 Determine the Scope of the Research and Key Milestones

The Lead Investigator must develop the first draft of the Project Plan (including input from the Community Representative and Indigenous Lead Researcher) for input from the Health Director. The Project Plan must include the minimum detail set out in Appendix E – *Project Plan Requirements.*

10.4.4 Settle the Project Plan

The Research Team must incorporate any agreed input provided by a Health Director into the Project Plan and provide a final version to the Health Director for submission to the Research Committee.

10.5 Consideration by the Research Committee and the Board

10.5.1 Consideration by the RSC and the Board

Once a Project Plan is settled with the Research Team, the Health Director will brief the Research Committee regarding the proposed research project. The Research Committee and the Board will consider the factors set out in Appendix D – *Research Project Considerations*.

The Research Committee and/or the Board can:

- approve the Project Plan (in the case of the Research Committee for submission to the Board for its consideration);
- choose not to endorse the project; or
- require amendments to the Project Plan for reconsideration at a subsequent meeting.

10.5.2 Decide not to Endorse the Project

The Research Committee or the Board may decide not to endorse a research project for any reason, including any of the following:

- the research project does not align with the Board's strategic or research priorities;
- the research project does not align with other research projects being undertaken in-community;
- a similar project is already underway, or has recently taken place; and

- there are other projects that the RSC or the Board prefers to pursue ahead of the proposed research project.

The Research Committee or the Board will provide reasons for the decision and Miwatj Health will advise the Research Team of the outcome.

10.5.3 Request Amendments to the Project Plan for Reconsideration

The Board or Research Committee may request amendments to a Project Plan for reconsideration at a later meeting. These changes may include:

- the communities or groups identified to participate in the project;
- timeframes for project;
- scope of the project; and
- types of data to be collected.

If the Research Team does not agree to the requested amendments, the Project Plan is treated as not endorsed.

10.5.4 Approve the Project Plan

Board approval will be subject to ethics and project funding. I f the Board approves a Project Plan for a research project:

- the CEO and the Research Institution's Corporate Representative must enter into a Research Agreement to govern the conduct of the research project; and
- each member of the Research Team must sign the Research Acknowledgement.

The Research Team must then seek ethics approval and project funding, as proposed in the Project Plan.

10.6 Conducting Research

All research projects must be conducted following the principles in the AIATSIS Guidelines for ethical research in Australian Indigenous studies and the NHMRC National Statement on Ethical Conduct in Human Research.

10.6.1 Listening and Learning: Community Introduction

The Board values the knowledge and capabilities of its community. Researchers that partner with Miwatj Health must respect and understand the knowledge held by members of the community, and the context in which the community has agreed to participate in research.

In addition to meeting with the Community Representative, and unless otherwise agreed by the Board, the Lead Investigator must organise for all researchers to participate in listening and learning before commencing data collection and analysis. This must consist of completing cultural training with Miwatj Health to learn from leaders in the local community about their knowledge of the research topic, the context of the approved research project, and Miwatj Community perspectives of health and wellbeing.

The Lead Investigator must ensure that funding is obtained to participate in these activities.

10.6.2 Collecting Data

The Research Team must conduct its data collection activities using the methodology approved by the Board, in accordance with the Project Plan.

If the Research Team wants to change the methodology in any way during the research project, the Lead Investigator must contact the Health Director to discuss the proposed change and reasons for the change.

The Health Director will then discuss with the CEO if the proposed change should be put to the Board for approval. If the proposed change is considered minor or technical, the CEO may approve the change. Changes to the data collection methodology should only be made after the Health Director has confirmed in writing that the change is approved. The Research Team is responsible for ensuring that notice of the change is provided to the relevant HREC(s), to the extent required, for consideration.

The Research Team is responsible for ensuring that informed consent (including through the use of interpreters) is obtained from research participants with respect to: (i) participation; and (ii) collection, use and disclosure of personal information, and is adequately documented. Where participants meet with the Research Team on multiple occasions, the Research Team must confirm that consent is current and continuing.

10.6.3 Reporting to the Board

The Lead investigator must contact Miwatj Health (and keep Miwatj Health updated) regarding any delays to the research project or barriers to its continuation as soon as reasonably practicable following becoming aware of such delays or barriers.

The Lead Investigator must provide bi-annual (or such other frequency as agreed) reports to Miwatj Health for the duration of a research project in accordance with the milestones agreed in the Project Plan. The purpose of these reports is to monitor progress of the research project against the Project Plan. It also provides a formal avenue for the Research Committee and the Board to oversee the development of the research project and ensure that community expectations are being met, and cultural safety is maintained throughout the research project.

Reporting templates are available on the Miwatj Health website and must be submitted to the Miwatj Health Research Inbox.

The Research Committee may also discuss the research project directly with the Community Representative and Miwatj Health personnel participating in the research project. Their feedback will be taken into account when determining whether the research project is being conducted in accordance with the Project Plan and community expectations for the research project.

The Lead Investigator may be required to provide further information or supplement the interim project report.

Taking into account the interim project report and any supplementary information, the RSC may recommend that the Board:

Endorse the interim report: This option is appropriate where the Board and Rsearch Committee are satisfied that the research project is on track and progressing in

accordance with the Project Plan or that any minor deviations which have not justified amendment to the Project Plan (such as minor delays) are acceptable, other research projects are not impacted, and the safety of the community is not at risk;

Agree to amend the Project Plan: This option may be appropriate where the Board is satisfied that the reasons why a project is not following the Project Plan are acceptable and the safety of the community is not at risk;

Suspend the research project: This option may be appropriate if the Board has concerns that other research projects may be impacted or community safety may be at risk. The Board may require the Research Team to make changes to the Project Plan and/or provide mitigation strategies to manage risks, and provide further report at a later Board meeting before research resumes; or

Cancel the research project: This option may be appropriate where the Board has concerns for community safety or there is repeated failure to follow the Project Plan, failure to amend the Project Plan as requested by the Board or there are extensive delays in completing the research project (such as key milestones not being met).

10.7 Delivering Results to the Board and Community

10.7.1 Presenting Findings to the Board and the Community

The Research Team must present its findings to the Research Committee and/or to the Board. The Indigenous Lead Researcher must be given the opportunity to participate in such presentations.

The Research Team must visit (and document and inform the Research Committee and/or the Board regarding such visits) the Miwatj communities that participated in the research project to discuss the results of the project with them directly.

The Research Team must obtain funding for the cost of these presentations and any related travel that is required.

10.7.2 Identifying Solutions

Where a research project identifies an issue for the community to address, the Research Team is expected to identify possible solutions for the Board and community to consider in response to the findings. This can include recommending further research and, where appropriate, identifying researchers with relevant expertise.

10.7.3 Use of Interpreters

To support accountability and transparency in research, it may be appropriate for an interpreter to attend presentations with the Board and community to deliver findings in language. The Research Team must obtain funding for the cost of an appropriately qualified interpreter to attend all presentations to the Board and communities.

10.8 Obligations on Researchers after the Research Project is Concluded

10.8.1 Publishing and Presenting Findings

If a paper about the research project is to be published or presented, the Lead Investigator must submit the paper to Miwatj Health through the Miwatj Health Research Inbox and the Community Representative for review and comment.

The Research Team must ensure that the community is consulted in relation to any discussion of Miwatj community culture or knowledge when preparing its findings, publishable reports or presentations.

The Research Team must not publish (or allow to be published) any paper regarding the research project, its findings, or any data collected during the research project, without approval of the Board.

Taking into account the interim project report and any supplementary information, the Research Committee may recommend that the Board:

Endorse the paper for publication: This option is appropriate where the Research Committee and the Board are satisfied that the paper accurately represents the community and the findings of the research project and that the safety and culture of the community is not at risk;

Recommend amendments to the paper: This option may be appropriate where the Research Committee and the Board consider that the paper does not adequately represent the findings of the research project, the interests of the community, or any data collected, or conclusions drawn, by the research project; or

Deny publication of the paper: This option may be appropriate where the Research Committee and the Board have concerns for community safety or if the data collected, or conclusions drawn, by the research project are misrepresented or distorted or otherwise misrepresent the community, its cultural practices, or issues faced by the community.

The Research Team must secure the agreement of the Board and community before submitting an application or abstract to the publisher/conference organiser.

All papers and presentations must:

- acknowledge the support of Miwatj Health and the relevant Miwatj Community;
- appropriately attribute the Community Representative, the Indigenous Lead Researcher and any Miwatj Health authors or contributors to the research project and any papers; and
- appropriately attribute Miwatj Health as owner of any data or other intellectual property licensed to the RI or Research Team for the purposes of publishing the paper.

10.8.2 Project Evaluation

Evaluation is a critical element of ensuring accountability and transparency in our research. The Board is committed to continuous improvement of its research governance and maximising the value of research conducted in our community.

The Lead Investigator must submit a final report to Miwatj Health through the Miwatj Health Research Inbox.

10.9 Intellectual Property Rights

10.9.1 Research Agreement

The Research Agreement sets out in more detail the arrangements regarding data collected by the Research Team and materials developed during the research project, including requirements and restrictions with respect to publication of the results of the research. Resarch Institution representatives and the Research Team should familiarise themselves with the Research Agreement and implement any measures to ensure compliance.

10.9.2 Community Ownership of Data

Community ownership of research is critical to the Board's research agenda. The Research Team must provide a copy of the collected data and its findings and analysis to the Board before publishing the results generally.

The Board, through Miwatj Health, will own all data collected by the Research Team, and may provide access to community members to use the data for future research and analysis in accordance with the relevant consents, applicable law, and ethical guidelines. The Board may also grant a licence to use the data to the Research Institution, other organisations or individuals.

10.9.3 Licence to Use and Sub-License Publications etc

Miwatj Health must be granted a perpetual, world-wide, irrevocable licence to use and disclose the Research Team's findings, publications, papers or presentations. The licence must include a right to grant sub-licences to use these materials to service providers, members of the community or researchers engaged in related future research projects.

APPENDIX A

Privacy

The Board takes seriously the obligation that Miwatj Health has to the communities it services. Data collection activities must respect the privacy, autonomy and agency of the individuals and communities that participate in research.

Any personal information collected by, or disclosed to, researchers must be collected, used, and disclosed in accordance with privacy law and industry guidelines, including:

- the Privacy *Act 1988* (Cth) ("**Privacy Act**") (such as the Australian Privacy Principles ("**APPs**");
- s16B (*Permitted health situations in relation to the collection, use or disclosure of health information*) and s95A (*Guidelines for Australian Privacy Principles about health information*) of the Privacy Act;
- *Healthcare Identifiers Act 2010* (Cth) ("**Healthcare Identifiers Act**");
- the National Health and Medical Research Council ("**NHMRC**") guidelines relating to the collection, use and disclosure of health information; and
- any other relevant Federal, State or Territory based legislation and regulation, and any applicable mandatory and non-mandatory guidelines or codes of conduct,

(together, "**Privacy Law**").

To facilitate Miwatj Community ownership, use of and benefit from research data, research participants must be informed, understand, and be comfortable that Miwatj Health may receive, use and disclose the data collected by Research Teams for a purpose directly related to the primary purpose, e.g. for the purpose of developing, advocating for, improving and providing health services to Miwatj communities based on the research, including providing health services to the individuals from whom data has been collected.

For example, each Research Teams must:

- ensure that participants' personal information is managed in an open and transparent way (APP 1.1);
- take reasonable steps to implement practices, procedures and systems that will ensure that the Research Team:
    - complies with the APPs and is able to deal with related inquiries and complaints (APP 1.2); and
    - does not act in a manner which may result in breach by Miwatj Health of Privacy Law;
- have a clearly expressed and up-to-date privacy policy about how the Research Team manages personal information (APP 1.3 and 1.4);
- take reasonable steps to make its privacy policy available free of charge in an appropriate form (APP 1.5) upon request;
- notify, and obtain consent from, individuals of the collection of their personal information (including sensitive information) in accordance with APPs 3 and 5;
- ensure that individuals are aware, and have consented to, the disclosure of personal information to any third party service providers and to Miwatj Health in accordance with APP 6 and APP 8 (to the extent relevant);
- not receive, use or disclose any government identifiers (as defined in the Privacy Act) or healthcare identifiers (as defined in the *Healthcare Identifiers Act*, being a number assigned to uniquely identify a healthcare recipient), unless required or permitted by law;
- not adopt a government related identifier or healthcare identifier of an individual as its own identifier;
- ensure that the personal information is accurate, up-to-date and complete (APP 10.1);
- take reasonable steps to protect personal information it holds from misuse, interference and loss, as

well as unauthorised access, modification or disclosure in accordance with APP 11; and

- ensure that it has the capability to, on request by an individual, give the individual access to their personal information (APP 12).

The Office of the Australian Information Commissioner ("**OAIC**") makes available guides to the Privacy Act and APPs which should be considered by Research Teams, for example see:

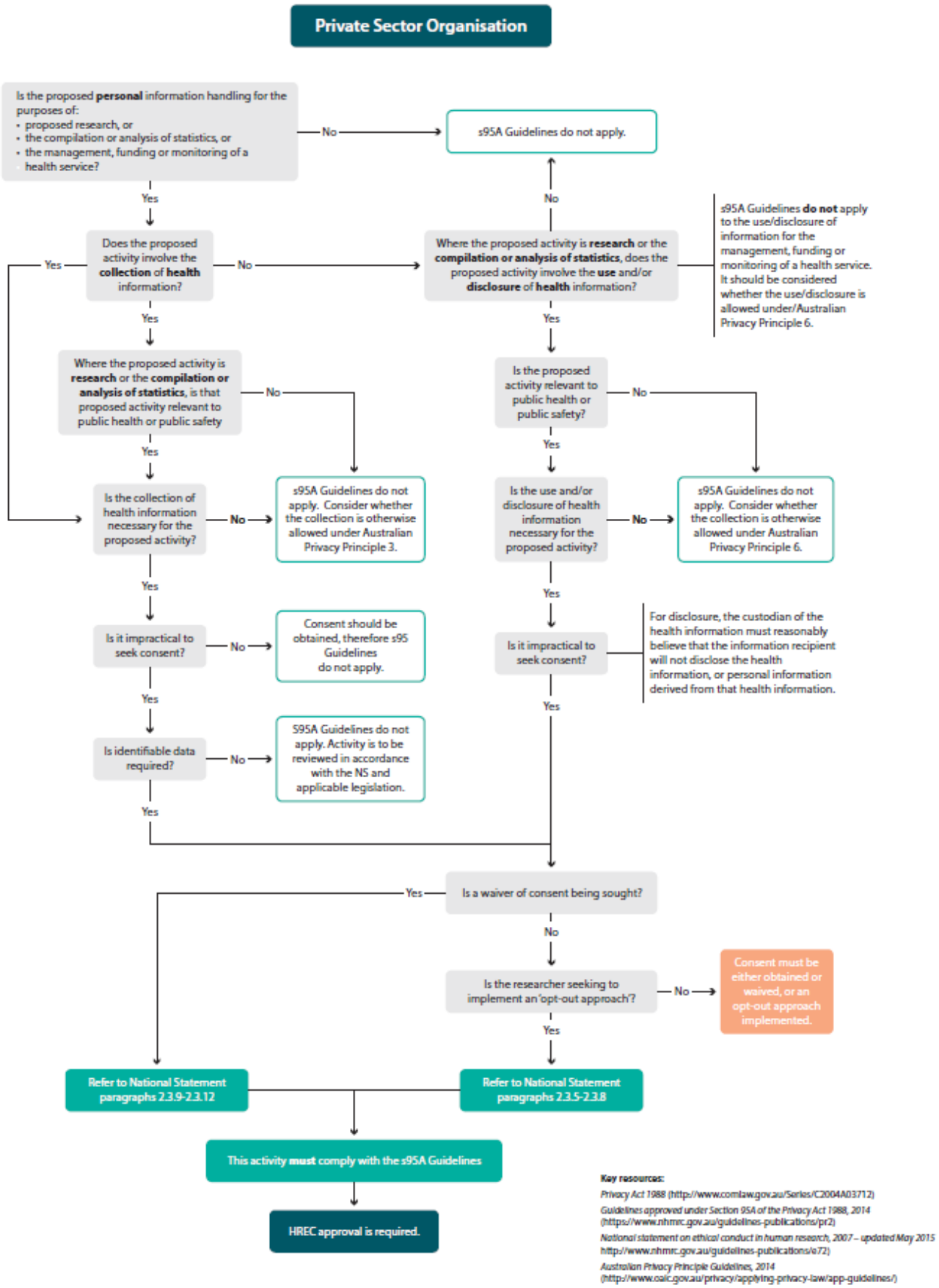
https://www.oaic.gov.au/agencies-and-organisations/app-guidelines/; and

https://www.oaic.gov.au/privacy-law/privacy-act/health-and-medical-research.

In practice EOIs (to lower degree of detail) and Project Plans (as a minimum) must address:

- the data to be collected (e.g. any data from individuals and/or from Miwatj Health);
- the Research Team's proposed approach to ensuring that appropriate consents are obtained from participating individuals (including whether written or oral consent is appropriate and suitable interpretation and/or translation options to ensure consent is informed) that discharge the Research Team's ethical responsibilities and also allow Miwatj Health and any relevant indigenous communities to use any data collected for their own purposes;
- proposed consent and privacy policy wording which must inform individuals about the disclosure of health information to Miwatj Health, RIs, GDs, indigenous communities and any other relevant stakeholders (or service providers) for the purposes of research, public health, publication, and any other relevant purposes. See the following OAIC guides for detail:
    - **APP 5 — Notification of the collection of personal information** - https://www.oaic.gov.au/agencies-and-organisations/app-guidelines/chapter-5-app-5-notification-of-the-collection-of-personal-information;
    - **APP 6 — Use or disclosure of personal information** - https://www.oaic.gov.au/agencies-and-organisations/app-guidelines/chapter-6-app-6-use-or-disclosure-of-personal-information; and
    - **Guide to developing an APP privacy policy** - https://www.oaic.gov.au/ancies-and-organisations/guides/guide-to-developing-an-app-privacy-policy;
- how the Research Team proposes to ensure its own, and Miwatj Health's, compliance with Privacy Law;
- consistency with frameworks and principles for data collection from Indigenous communities which are endorsed by recognised national health bodies;
- the proposed approach to obtaining appropriate Human Research Ethics Committee ("**HREC**") approvals, see Appendix A (Section 95A Permitted health situations flow chart) and the following guidance:
    - **NHMRC Guidelines approved under Section 95A of the Privacy Act 1988** - https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988
    - **The National Statement on Ethical Conduct in Human Research -** https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#block-views-block-file-attachments-content-block-1
    - **Management of Data and Information in Research - A guide supporting the Australian Code for the Responsible Conduct of Research -** https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018
- proposed technical and organisational measures to protect the security of data and privacy of individuals including:
    - restrictions on use of, and access to, personal information, and notification of unauthorised access or disclosure;

  - de-identification of personal information, see - https://www.oaic.gov.au/agencies-and-organisations/guides/de-identification-decision-making-framework;
  - details of any industry recognised data management frameworks implemented by the RI and Research Team; and
  - technical detail of any applications / software / systems involved in the collection of any data, including any overseas disclosure and use or access by third party service providers;
- stakeholders in the research project including any arrangements (such as technical and contractual) in place to ensure appropriate control of, and maintenance of ownership in, collected data or processes developed through the research project;
- proposed / anticipated outputs of the research project and any systems and processes to ensure disclosure of such outputs to, or allow access by, Miwatj Health; and
- any other information that Miwatj Health and the Research Team consider is appropriate.


Private Sector Organisation
Is the proposed personal information handling for the purposes of:
• proposed research, or
• the compilation or analysis of statistics, or
• the management, funding or monitoring of a health service?
No
s95A Guidelines do not apply.
Yes
No
Does the proposed activity involve the collection of health information?
Yes
No
Where the proposed activity is research or the compilation or analysis of statistics, does the proposed activity involve the use and/or disclosure of health information?
s95A Guidelines do not apply to the use/disclosure of information for the management, funding or monitoring of a health service. It should be considered whether the use/disclosure is allowed under/Australian Privacy Principle 6.
Yes
Yes
Where the proposed activity is research or the compilation or analysis of statistics, is that proposed activity relevant to public health or public safety
No
Is the proposed activity relevant to public health or public safety?
No
Yes
Yes
Is the collection of health information necessary for the proposed activity?
No
s95A Guidelines do not apply. Consider whether the collection is otherwise allowed under Australian Privacy Principle 3.
Is the use and/or disclosure of health information necessary for the proposed activity?
No
s95A Guidelines do not apply. Consider whether the collection is otherwise allowed under Australian Privacy Principle 6.
Yes
Yes
Is it impractical to seek consent?
No
Consent should be obtained, therefore s95 Guidelines do not apply.
Is it impractical to seek consent?
For disclosure, the custodian of the health information must reasonably believe that the information recipient will not disclose the health information, or personal information derived from that health information.
Yes
Yes
Is identifiable data required?
No
S95A Guidelines do not apply. Activity is to be reviewed in accordance with the NS and applicable legislation.
Yes
Yes
Is a waiver of consent being sought?
No
Is the researcher seeking to implement an 'opt-out approach'?
No
Consent must be either obtained or waived, or an opt-out approach implemented.
Yes
Refer to National Statement paragraphs 2.3.9-2.3.12
Refer to National Statement paragraphs 2.3.5-2.3.8
This activity must comply with the s95A Guidelines
HREC approval is required.
Key resources:
Privacy Act 1988 (http://www.comlaw.gov.au/Series/C2004A03712)
Guidelines approved under Section 95A of the Privacy Act 1988, 2014 (https://www.nhmrc.gov.au/guidelines-publications/pr2)
National statement on ethical conduct in human research, 2007 – updated May 2015 http://www.nhmrc.gov.au/guidelines-publications/e72)
Australian Privacy Principle Guidelines, 2014 (http://www.oaic.gov.au/privacy/applying-privacy-law/app-guidelines/)

APPENDIX B

Data Access Guidelines

1. Guidelines

1.1 Introduction

These Data Access Guidelines form part of the Miwatj Health Research Goverance. Capitalised terms used in this document are defined in the Human Health Research Governance Framework, the Code of Conduct, Privacy Guidelines and related documents.

Any personal information collected by, or disclosed to, Research Teams must be collected, used, and disclosed in accordance with Privacy Law. This means that individuals are notified and, when relevant, provide consent to the collection, use and disclosure of their personal information (including sensitive information), and such personal information is used and disclosed in accordance with such notifications and consents.

These Data Access Guidelines set out considerations for when a Research Team requests access to Miwatj Health Data such as whether, and how, information should be provided.

1.2 Privacy

Privacy is different to secrecy or confidentiality and different principles and laws apply accordingly.

The fundamental principle of privacy law is that organisations collect, use, store and disclose information from which an individual may be identified (or sets of information) in a way that is:

- transparent and open;
- secure and reliable; and
- accessible to the individual.

1.3 Definition of Personal Information

To understand whether Privacy Law applies to any information that Miwatj Health holds or collects from individuals or Research Teams, Miwatj Health personnel must understand whether the information in question constitutes "**personal information**".

The definition of "personal information" is broad. Personal information is:

> *"Information or an opinion about an identified individual, or an individual who is reasonably identifiable:*
>
> - *whether the information or opinion is true or not; and*
> - *whether the information or opinion is recorded in a material form or not."*

This also includes any information which, *in combination* with other information that Miwatj Health holds, (including if Miwatj Health would reasonably have access to other information or which a third party to whom Miwatj Health discloses information would reasonably have access to) would identify an individual.

Common examples are a person's name, date of birth, address and telephone number.

By itself, information that allows an individual to be contacted — such as a telephone number or a street address — may not be about an 'identifiable' individual. However, that individual is likely to be identified where this information can be used to search a patient or client database, locating an entry about that individual.

1.4 Definition of Sensitive Personal Information

"**Sensitive information**" is a sub-set of personal information and is considered more sensitive than other types of personal information. As such, more stringent rules apply to sensitive information and generally consent of the individual is required to collect, use and disclose such information.

Sensitive information includes information or opinion about an individual's:

- racial or ethnic origin;
- political opinion;
- religious beliefs;
- sexual orientation;
- criminal record; and
- health information.

"**Health information**" is sensitive information and means:

- information or an opinion about:
  - the health or a disability (at any time) of an individual; or
  - an individual's expressed wishes about the future provision of health services to him or her; or
  - a health service provided, or to be provided, to an individual,

  that is also personal information; or
- other personal information collected to provide, or in providing, a health service; or
- other personal information about an individual collected in connection with the donation, or intended donation, by the individual of his or her body parts, organs or body substances; or
- genetic information about an individual in a form that is, or could be, predictive of the health of the individual or a genetic relative of the individual.

1.5 De-identification or Pseudonymisation

If personal information is de-identified or pseudonymised (and the resulting information cannot be re-identified) then the information is no longer personal information. As the individual that the information was about can no longer be identified, the risk to that person from the information is effectively neutralised. As such, Privacy Laws no longer apply to the use and disclosure of such de-identified or pseudonymised information.

Care must be taken when de-identifying personal information and regard must be had to the context in which the information is to be used and disclosed. For example, if the name fields of a database have been removed, it does not necessarily mean that the person is not identifiable from other information in the database, or other information reasonably accessible to the person who is holding the information or to whom it is disclosed.

To be considered - If Miwatj Health deletes the name field of a record and discloses to a Research Team the age and gender of an individual and the area in which that individual lives, but that individual is the only person of that age in the area, it is likely that the information will constitute personal information and Privacy Law will apply. Further, if information that a Research Team

collects in the field will allow them to re-identify the person that the record is about, the information to be disclosed is likely to be personal information.

1.6 Aggregated data

If information is aggregated (e.g. 1000 males living in Nhulunbuy have brown eyes) and it is not possible to identify any individual from such aggregated information (or other information held by a Research Team) the information will not constitute personal information and Privacy Law does not apply.

1.7 Use and disclosure of personal information

The meaning of "use" under Privacy Law is broad and effectively includes any act that can be done with any information contained in a hard copy or digital record.

Miwatj Health 'uses' personal information if it controls how the information is handled. For example if Miwatj Health (including any of its employees or contractors):

- searches its records for personal information;
- accesses and reads the personal information Miwatj Health holds about an individual;
- makes a decision based on the personal information they hold about an individual; and
- passes personal information from one part of the organisation to another.

The meaning of "disclose" under Privacy Law is broad and may effectively include any act of disclosure that can be done with any record.

Miwatj Health 'discloses' personal information if it gives access to it, or shows it to another individual, organisation or agency. This includes situations where the individual, organisation or agency receiving the personal information already knows it.

"Disclosure" is not limited to downloading or emailing personal information. For example, disclosure can include showing an individual's record to another person on a computer screen or the remote or logon access to a database by an IT supplier or Research Team.

1.8 Sharing Personal Information with Research Teams

Before sharing any personal information held by Miwatj Health, Miwatj Health personnel will need to consider implications of doing so.

If a Research Team requests to access Miwatj Health data, whether by way of a one-off disclosure or as part of a large-scale data sharing arrangement, Miwatj Health must consider whether it has the legal power or ability to do so. T his will to depend on a number of legal and factual factors including the nature of the information in question (for example whether it is sensitive information), the notifications provided, or consents obtained, at collection and whether any legally permitted situations exist.

1.9 Health Identifiers

The meaning of "health identifier" is defined in the *Healthcare Identifiers Act 2010* (Cth) (**Healthcare Identifiers Act**), being a number assigned to uniquely identify a healthcare recipient or healthcare provider. It is an offence to use or disclose health identifiers unless:

- the use or disclosure of the healthcare identifier is required or authorised under the Healthcare Identifiers Act or other Commonwealth law; or

- certain permitted general situations exist under the Privacy Act (such as to prevent a serious threat to life or safety).

1.10 Government Related Identifiers

The meaning of "government related identifier" is defined in the Privacy Act, being an identifier of an individual that has been assigned by an agency, a State or Territory authority, an agent of an agency, or a State or Territory authority, acting in its capacity as agent, a contracted service provider for a Commonwealth contract, or a State contract, acting in its capacity as contracted service provider for that contract.

Miwatj Health must not use or disclose a government related identifier of an individual unless:

- the use or disclosure of the identifier is reasonably necessary for the organisation to verify the identity of the individual for the purposes of the organisation's activities or functions;
- the use or disclosure of the identifier is reasonably necessary for the organisation to fulfil its obligations to an agency or a State or Territory authority;
- the use or disclosure of the identifier is required or authorised by or under an Australian law or a court/tribunal order;
- certain permitted general situations exist under the Privacy Act (such as to prevent a serious threat to life or safety); or
- it reasonably believes that the use or disclosure of the identifier is reasonably necessary for one or more enforcement related activities conducted by, or on behalf of, an enforcement body.

2. Guidelines

These Data Access Guidelines set out the factors to be considered prior to providing access, or disclosing, Miwatj Health data to Research Teams. The principles engaged in Privacy Law can be subjective and context dependent. As such, some circumstances may require further information, consideration or legal advice prior to disclosure.

If reasonably possible, notification and consent to any new use or disclosure of personal information (particularly health information) should be obtained. It is useful to ask yourself, '*would I be comfortable if this information was about me and would I want to know and have the opportunity to consent, or refuse consent, prior to its use or disclosure*'? However, these guidelines also provide for situations when it may not be reasonable in the circumstances to obtain consent and to ensure use and disclosure is done lawfully.

If consideration is not properly given to these guidelines and Privacy Law, use of, and access to, Miwatj Health data may constitute an *interference with the privacy of an individual* and a breach of Privacy Law for which Miwatj Health may be liable to concerned individuals and its regulators.

2.2 Factors to Consider – Steps

a) What is the sharing meant to achieve? *Go to next step.*

b) What information needs to be shared? *Go to next step.*

c) Can the goal be achieved by sharing aggregated information (i.e. not personal information)? If yes, share aggregated information only – Privacy Law doesn't apply. If no, *go to next step.*

d) Can the goal be achieved by sharing de-identified or pseudonymised information? If yes,

irretrievably de-identify information – Privacy Law doesn't apply to the de-identified information. If no, *go to next step.*

e) Can the goal be achieved through sharing a more limited data set? If yes, plan to do so and *go to next step*.

f) What risk does the data sharing pose? Consider and *go to next step*.

g) Who needs access to the information? Can it be limited to certain researchers? If yes, plan to do so and *go to next step*.

h) Can the frequency or period of sharing be limited? If yes, plan to do so and *go to next step*.

i) What security can be implemented to prevent unauthorised access? For example:

- password protected zip and encryption of files;
- remote, read only, access to limited data sets; and
- user access management, restricted privileges, auditable user logs,

the security measures should be relative to the risk of the information causing harm to individuals. *Plan to implement and go to next step*.

j) Is the requested information personal information? If yes, Privacy Law applies and existing scopes of ***notification*** should be considered (i.e. is the use and disclosure in accordance with existing notification?). *Go to next step*.

k) Is the requested information sensitive information (including health information)? If yes, Privacy Law applies and existing scopes of ***consent*** should be considered (i.e. is the use and disclosure in accordance with existing consent?). *Go to next step*.

l) Does the individual need to be notified; does consent need to be obtained? If notifications and / or consents are not sufficient, consider if the individual should be notified and consent obtained (and whether it is reasonably possible to do so). *Go to next step*.

m) Is the use or disclosure for a secondary purpose (related (for PI) or directly (for sensitive PI) related to the purpose in the existing notification or consent) ? If yes, no new notification or consent is required and personal information must be treated in accordance with Privacy Law.

n) Does a permitted general situation exception apply? If yes, no new notification or consent is required and personal information must be treated in accordance with Privacy Law.

o) Does a permitted health situation exception apply? If yes, the flow chart in section 2.3 must be applied prior to disclosure and personal information must be treated in accordance with Privacy Law. *Go to section 2.3.*

2.3 Factors to Consider

The Project Plan Requirements and Privacy Guidelines require Research Teams to address many of these factors in the Project Plan.

With reference to the Project Plan, Miwatj Health personnel should ensure that the following detailed factors are considered and documented (by Miwatj Health and/or the Research Team) prior to sharing personal information to a Research Team.

What is the sharing meant to achieve? You should have a clear objective, or set of objectives. Being clear about this will allow you to work out what data you need to share and who with.

What information needs to be shared? You shouldn't share all the personal information you hold about someone if only certain data items are needed to achieve your objectives. For example, you might need to share somebody's current name and address but not other information you hold about them.

Who requires access to the shared personal data? You should employ 'need to know' principles, meaning that other organisations should only have access to your data if they need it, and that only relevant staff within those organisations should have access to the data. This should also address any necessary restrictions on onward sharing of data with third parties.

When should it be shared? For example, should the sharing should be an on-going, routine process or whether it should only take place in response to particular events.

How should it be shared? This involves addressing the security surrounding the transmission or accessing of the data and establishing common rules for its security.

How can we check the sharing is achieving its objectives? You will need to judge whether it is still appropriate and confirm that the safeguards still match the risks.

What risk does the data sharing pose? For example, is any individual likely to be damaged by it? Is any individual likely to object? Might it undermine individuals' trust in Miwatj Health?

Could the objective be achieved without sharing the data or by anonymising it? It is not appropriate to use personal information to plan service provision, for example, where this could be done with information that does not amount to personal information.

Does the notification or consent envisage the sharing? Does the notification provided to the individual at collection (e.g. a medical consult or attendance at a clinic) envisage disclosure to Research Teams?

Does the individual need to be notified; does consent need to be obtained? If the individual was not informed of disclosure to the Research Team and its use of personal individual, unless the use and disclosure is for a secondary use (see below) or an exception applies (see below), or is otherwise required by law, the individual should be notified. If the information is sensitive information, consent should be obtained.

Is the use or disclosure for a secondary purpose? Miwatj Health can only use or disclose personal information for the purpose for which it was collected (known as the "**primary purpose**" **of collection**), unless an exception applies. Where an exception applies Miwatj Health may use or disclose personal information for another purpose (known as the "**secondary purpose**"). Exceptions include:

- the individual consented to a secondary use or disclosure (APP 6.1(a)); and
- the individual *would reasonably expect the secondary use or disclosure*, and that is related to the primary purpose of collection or, in the case of sensitive information, *directly related to the primary purpose* (APP 6.2(a)).

An example of where a secondary purpose is related to the primary purpose of collection may include when Miwatj Health collects health information about an individual for the purpose of providing treatment, and then decides, for ethical and therapeutic reasons, that they cannot treat the individual. The health service provider then advises another provider at the medical

clinic of the individual's need for treatment and of the provider's inability to provide that treatment. T his disclosure to the other provider is directly related to the purpose for which the information was collected, and would be within the individual's reasonable expectations.

The factors to be considered regarding consent, 'reasonable expectations', 'direct' relationship to the primary purpose, and the relationship between the primary and secondary purposes can be complicated and are context dependent – please see https://www.oaic.gov.au/privacy/australian-privacy-principles-guidelines/chapter-6-app-6-use-or-disclosure-of-personal-information/ for more guidance.

Does a permitted general situation exception apply? The information handling requirements imposed by some APPs do not apply if a 'permitted general situation' exists. This exception applies in relation to the collection of sensitive information (APP 3), the use or disclosure of personal information (APPs 6 and 8) and the use or disclosure of a government related identifier (APP 9).

For circumstances when a Research Team would like access to data, unless the Research Team are undertaking an activity which is likely to have the effect of *lessening or preventing a serious threat to the life, health or safety of any individual, or to public health or safety* (see APPs 3.4(b), 6.2(c), 8.2(d) and 9.2(d)), a permitted general situation is unlikely to apply.

Does a permitted health situation exception apply? The information handling requirements imposed by APP 3 (collection of personal information) and APP 6 (use and disclosure of personal information) do not apply to an organisation if a 'permitted health situation' exists. This exception applies to the collection, use or disclosure of health information or genetic information by an organisation.

There are five permitted health situations listed in s 16B of the Privacy Act:

- the collection of health information to provide a health service (s16B(1)) (see APP 3.4(c));
- the collection of health information for certain research and other purposes (s16B(2)) (see APP 3.4(c));
- the use or disclosure of health information for certain research and other purposes (s16B(3)) (see APP 6.2(d));
- the use or disclosure of genetic information (s16B(4)) (see APP 6.2(d)); and
- the disclosure of health information for a secondary purpose to a responsible person for an individual (s16B(5)) (see APP 6.2(d)).

The exceptions relating to the collection, use or disclosure of health information which is necessary for research, or the compilation or analysis of statistics, relevant to public health or public safety are most likely to apply to a Research Team's request for information.

If information is requested for the above purposes, the following conditions must be met prior to disclosure of any health information by Miwatj Health to a Research Team:

- it is impracticable for Miwatj Health or the Research Team to obtain the individual's consent to the use or disclosure; and
- the use or disclosure is conducted in accordance with guidelines approved under section 95A for the purposes of this paragraph; and
- in the case of disclosure— Miwatj Health reasonably believes that the Research Team will not disclose the information, or personal information derived from that information.

The Project Plan Requirements require Research Teams to provide evidence of compliance with section 95A of the Privacy Act, which, among other things, establish that a waiver for the obtaining of consent for research using personal information in medical research may be granted by a Human Research Ethics Committee for a permitted health exception.

Evidence of any such HREC approval and waiver must be obtained from the Research Team prior to disclosure of any health information by Miwatj Health.

APPENDIX C

Human Health Research Expression of Interest

*This Expression of Interest ("**EOI**") is to be completed by researchers proposing to conduct research in Miwatj Communities and emailed to research@miwatj.com.au.*

To be considered by the Miwatj Health Board, EOIs and Project Plans should align with the Research Governance Charter.

Researcher and Research Institution Details		
Project Title:		
Research Institution(s):		
Research Institution(s) Representative(s):		
Phone number:		
Email:		
Postal address:		
Lead Investigator: *(include experience, qualifications and any current courses)*		
Publications: *(list three most recent / relevant from any team member)*		
Phone number:		
Email:		
Postal address:		
Researchers (other): *(include experience, qualifications and Research Institutions)*		
Previous research projects with Miwatj Health:		
Other research project applications in the Miwatj region:		
Miwatj Health Division to be engaged	☐ Clinical Services ☐ Medical Services ☐ Public Health	☐ Programs ☐ NDIS ☐ People & Strategy
Are you Miwatj Health personnel? *(if yes, will the research form part of Miwatj Health activities or be for another purpose?)*		

Strategic Goals
How does the research project align with Miwatj Health's values and strategic goals?

Project Details and Project Synopsis
Proposed research question:
Research rationale
Miwatj Communities to be engaged *(including any planned Indigenous Lead Researchers and Community Representative – and planned remuneration)*
Indicative timeframes for research and key milestones
Ethical considerations and clearances
Miwatj Health resources required *(including data, clinic files, access to personnel, facilities)*
Plans for project funding
Plans for data collection *(including any privacy considerations and legal compliance – see RES 104: Privacy Guidelines for more detail)*

Plans for presentation of results

APPENDIX D

Research Project Consideration

The Health Directors, CEO, Research Committee and the Board are more likely to approve a proposed research project if it:

- aligns with current Miwatj Health strategic goals;
- the proposed high-level timetable for conducting research aligns with other research being conducted with Miwatj Health;
- shows long-term engagement (or an intention for long-term engagement) with Miwtaj Communities;
- is solution-focused, and intends to both deliver findings and identify options for future research for the community to consider;
- demonstrates understanding of the context in which Miwatj Health operates;
- has Miwatj Community members represented on the Research Team and remunerated;
- identifies possible benefits to Miwatj communities such as opportunities or methods for skills transfer to Miwatj Communities;
- sets out processes to respect Miwatj community intellectual property (such as performance, images, identity, stories, literary, dramatic, artistic, and musical works);
- constitutes evidence-based best practice for Indigenous health;
- demonstrates compliance with:
    - Project Plan Requirements;
    - Privacy Law and any applicable industry guidelines; and
    - the *AIATSIS Guidelines for ethical research in Australian Indigenous studies* and the *NHMRC National Statement on Ethical Conduct in Human Research*;
- sets out the Research Team's proposed approach to ensuring that appropriate consents are obtained that discharge the Research Team's ethical responsibilities and also allow Miwatj Health and any relevant Indigenous communities to use any data collected for their own purposes, including through the use of interpreters;
- demonstrates consistency with frameworks and principles for data collection from Indigenous communities which are endorsed by recognised national health bodies; and
- clearly sets out the proposed approach to obtaining appropriate Human Research Ethics Committee approvals.

APPENDIX E

Research Project Requirements

The draft Project Plan to be proposed by a Research Team must (as a minimum) address the below topics for feedback by Miwatj Health. To the extent possible, EOIs should contain the same/similar/high level content regarding the requirements.

Procedure

The Lead Investigator must develop the first draft of the Project Plan (including input from the Community Representative and Indigenous Lead Researcher) for input from the Health Director.

The Project Plan must detail:

- the hypothesis or topic of research;
- the data to be collected;
- the methodology (or methodologies) to be used for data collection;
- the period(s) of data collection;
- frequency of meeting with the Community Representative;
- frequency of meeting with the Miwatj Community;
- the members of the Miwatj Community with whom the Research Team intends to engage;
- the proposed means of communications with the Miwatj Community (including whether interpreters will be engaged);
- key milestones in the research project, including:
    - proposed date for completion of data collection;
    - expected due dates for data analysis, findings, and other key milestones;
    - proposed dates for providing interim reports to the RSC; and
    - the date for delivery of the final research paper to the RSC and community;
- how consent will be sought from participating individuals, including whether written or oral consent is appropriate and identifying suitable interpretive and/or translation options to ensure consent is informed;
- proposed consent and privacy policy wording which must inform individuals about the disclosure of health information to Miwatj Health, Research Institutions, indigenous communities and any other relevant stakeholders (and service providers) for the purposes of research, public health, publication, and any other relevant purposes;
- how the Research Team propose to ensure its own and Miwatj Health's, compliance with Privacy Law (such as, if relevant, s16B and s95A of the Privacy Act and the related NHMRC guidelines relating to the collection, use and disclosure of health information);
- proposed technical and organisational measures to protect the security of data and privacy of individuals including:
    - restrictions on use of, and access to, personal information, including notification of unauthorised access or disclosure;
    - de-identification of personal information;
    - details of any industry recognised data management frameworks implemented by the RI and Research Team; and

    - technical detail of any applications / software / systems involved in the collection of any data, including any overseas disclosure and use or access by third party service providers;
- stakeholders in the research project including any arrangements (such as technical and contractual) in place to ensure appropriate control of, and maintenance of ownership in, collected data or processes developed through the research project;
- proposed HREC approval process and funding sources;
- proposed/anticipated outputs of the research project and any systems and processes to ensure disclosure of such outputs to, or allow access by, Miwatj Health;
- proposed publication and/or presentation of the results (if known); and
- any other information that Miwatj Health and the Research Team consider is appropriate.

APPENDIX F

Research Project Progress Report

This report should be completed and emailed to research@miwatj.com.au every six months (or as otherwise agreed) for the duration of your research project.

Project Name:
Report prepared by (name & position): **Contact phone number & email:**
Date of report:
Lead Investigator: Please provide an email address and phone number if the Lead Investigator has changed since your last report
Report number:
Report period:
Please describe the key achievements and milestones reached since the last progress report.

Part Two: Challenges and Delays

Please describe any aspects of the research project that have not gone according to plan. Please discuss: - the mitigation or correction activities is the Research Team implementing to address the identified issues - any missed key milestones? - for challenges and delays reported in earlier reports, are the identified mitigation strategies working? Are the challenges now fully rectified?

Part Three: Next steps

Please describe the key activities for the research project that will take place over the next reporting period.

Part Four: Financial Update

Please provide an update about the financial status of the project. In particular, please provide information about: - whether funding has been obtained in accordance with the Project Plan; - If not, whether other sources of funding have been identified and their quantum; - key expenditure during the report period; - Whether the project is still on-budget; - If not, why the budget has been exceeded and how the research team plans to reduce costs or seek additional funding;

Part Five: Other Matters

Is there anything else the Board should know? For example: changes to the Research Team membership, upcoming presentations related to the research project, any observations or issues that the Research Team wants to raise with the Board.

APPENDIX G

Research Project Final Report

This report should be completed and emailed to research@miwatj.com.au at the end of your research project as part of preparing to present your findings to the Board.

Project Name:
Report prepared by (name & position): **Contact phone number & email:**
Date of report:
Lead Investigator: Please provide an email address and phone number if the Lead Investigator has changed since your last report
Report number:
Please describe the key findings and results of the research project.

Part Two: Achievements

What were the key achievements of the research project? What new or novel information was identified from the project?

Part Three: Challenges

What were the key challenges in the research project? Did they affect the outcome of the research?

Part Four: Publication

Does the research team intend to publish the results of the research? If so, please provide summary details of the planned publication.

Part Five: Change and Impact

Are there any recommendations arising from the research that Miwatj Health could pursue? If so please provide details of any advocacy or programs that could be established or other health policy related actions from which the Miwatj region may benefit.

Part Six: Future Research

Do the findings and results of this research project lead to future research needs or opportunities for Miwatj Health? If so, please advise of researchers or experts that you know of who could partner with Miwatj for these future projects.

Part Seven: Financial acquittal

Please provide a final acquittal of the funding for the research project. Please breakdown the expenditure by categories (eg: Research Team remuneration, travel, participant expenses etc). Was the budget in the Project Plan sufficient? Were there unforeseen expenses? How were these met?

Part Eight: Other Matters

Is there anything else the Board should know? For example: are there planned publications or presentations of the findings/results, do you have any other observations or issues/lessons learned to raise with the Board?

APPENDIX H

Research Acknowledgment

Personal details

Name: _____

Title: _____

Research Institution: _____

Research project: _____

Date approved by Board: _____

I acknowledge that:

- the research institution through which I am conducting research has entered into a research agreement with Miwatj Health and that I must act in accordance with its terms when undertaking the research project;
- I must act, and conduct the research project, in accordance with the approved Project Plan and the *MHAC Research Governance Charter,* including any related documents as updated from time to time;
- I must uphold the Miwatj Health research values at all times during the research project;
- I must ensure the personal and cultural safety of research participants at all times;
- I must clearly explain the scope and purpose of my work each time I meet with research participants and seek their informed consent to participate (using interpreters and/or translators if necessary);
- I will work with Miwatj Health officers to ensure that the research project does not adversely impact on their relationships with community members, the delivery of clinical care, or their daily work programs;
- any changes to the Project Plan must be approved by the Miwatj Health Board before they are implemented, including changes to the timeframe for analysing data, making findings and delivering results;
- Interim Project Reports must be submitted to Miwatj Health every six months (or as otherwise agreed) for the duration of the research project;
- the data collected by the Research Team for the research project will be owned by Miwatj Health, subject to the terms of the research agreement;
- Miwatj Health and the community may use any findings, papers or presentations developed by the Research Team to inform future research related to this research project;
- Miwatj Health and the community must be acknowledged in any publications or presentations resulting from the research project;
- at least one member of the Research Team must attend a meeting of the Board and also meet with the community to deliver the Research Team's findings from the research project; and
- I may be asked to participate in an evaluation of the research project after it is completed.

Signed: Date:

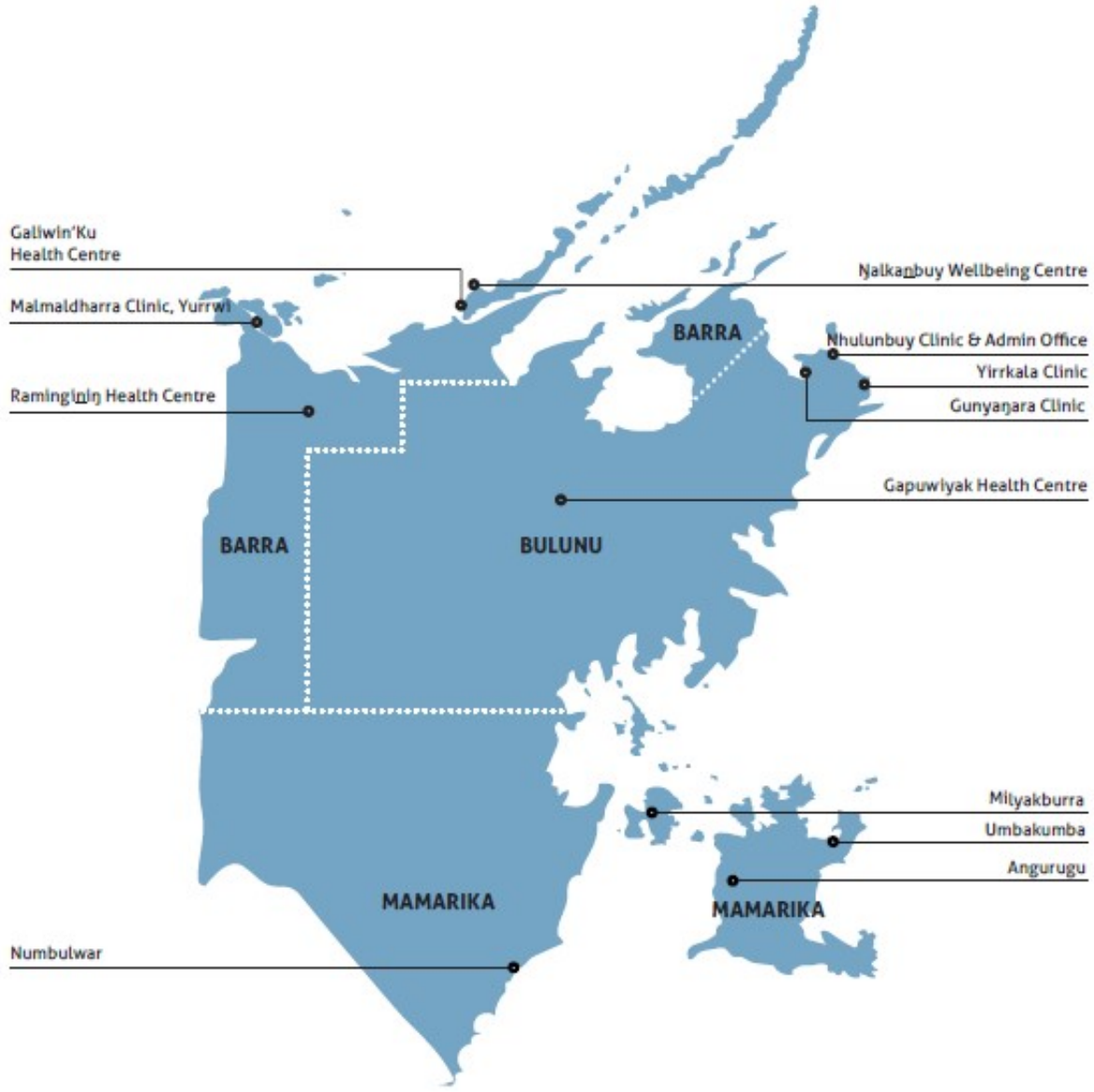
_____ _____

Print:

_____

APPENDIX I

Ward Map



Appendix A – Research RACI

R = Responsible A = Accountable C = Consulted I = Informed

#	Activity	Board (Miwatj Health)	Research Sub-committee (Miwatj Health)	CEO (Miwatj Health)	Health Director (Miwatj Health)	Research Governance Admin (Miwatj Health)	Community Representative (Yolngu)	Research Institution Corporate Representative	Lead Investigator (Research Team)
EOI									
1.	Expression of interest	-	-	-	-	I	-	A	R
2.	Research proposal consideration by RSC and Board	C	C	A	R	R	-	-	-
3.	Approval of research proposal	R	R	A	R	I	C	I	I
4.	Notification of approval of research proposal	-	-	-	A	R	I	-	I
Project Plan									
5.	Provision of list of suitable Community Representatives	-	-	-	I	R	I	I	I
6.	Appointment of Community Representative	I	I	I	C	C	C	A	R
7.	Remunerating Community Representative and	-	-	-	C	C	C	A	R
8.	Approval of Community Representative and remuneration	I	I	A	R	R	C	A	C
9.	Appointment of Indigenous Lead Investigator	-	-	-	C	C	C	A	R
10.	Remunerating Community Representative	-	-	-	C	C	C	A	R
11.	Approval of Indigenous Lead Investigator and remuneration	I	I	A	R	R	C	-	I
12.	Engagement and consultation with Miwatj Communities	I	I	I	C	C	R	A	R
13.	Setting frequency of meetings with Community Representative	-	-	-	C	C	C	A	R
14.	Development of first draft of the Project Plan	-	-	-	C	C	C	A	R
15.	Finalising the Project Plan	-	-	-	C	C	C	A	R

Consideration by the RSC and Board									
16.	Preparation of brief to the RSC and the Board	C	C	A	R	-	C	-	I
17.	Consideration of Project Plan (incl providing reasons)	R	R	A	C	I	I	I	I
18.	Informing Research Team of outcome of RSC and Board consideration	I	I	A	C	R	I	-	I
19.	Enter into Research Agreement	C	C	A & R	C	R	-	A & R	R
20.	Each Research Team member sign Research Acknowledgements	-	-	-	I	I	-	A	R
21.	Compliance with Research Agreement	I	I	A	R	R	C	A	R
22.	Obtaining HREC approval and project funding	-	-	I	I	I	I	A	R
Conducting research									
23.	Cultural training	-	-	-	I	I	C	A	R
24.	Project kick-off with Community Representative	-	-	-	I	I	R	A	R
25.	Informing community of research project	C	C	A	C	R	C	-	I
26.	Informing Miwatj stakeholders and clinicians of research project and any relevant restrictions	-	-	A	C	R	-	-	I
27.	Conduct of research in communities	I	I	I	A	C	R	A	R
28.	Acts of Research Team members when conducting research	-	-	-	I	I	C	A	A
29.	Changes to methodology / approach	I	I	C	R	R	C	A	R
30.	Bi-annual progress report	I	I	I	I	I		A	R
31.	Bi-annual report to the RSC	I	I	A	R	R	C		
32.	Bi-annual report to the Board	C	R	A	R	C	-	-	-
33.	Research project milestone decision point	R	R	A	R	-	C	-	I
Delivering results									
34.	Presentation of findings to the RSC	-	C	I	C	R	I	A	R
35.	Presentation of findings to the Board	C	I	A	R	C	-	A	R
36.	Presentation of findings in-community	C	I	I	A	R	C	A	R

Publication									
37.	Circulation of draft paper for publication to Miwatj Health	-	-	I	C	C	C	A	R
38.	Consideration of paper by the RSC	-	C	A	R	R	C	-	I
39.	Consideration of the paper by the Board	R	I	A	R	R	C	-	I
40.	Submission of final report	I	I	I	C	C	C	A	R
41.	Evaluation of research project and Research Governance Framework	-	I	A	R	R	-	-	-