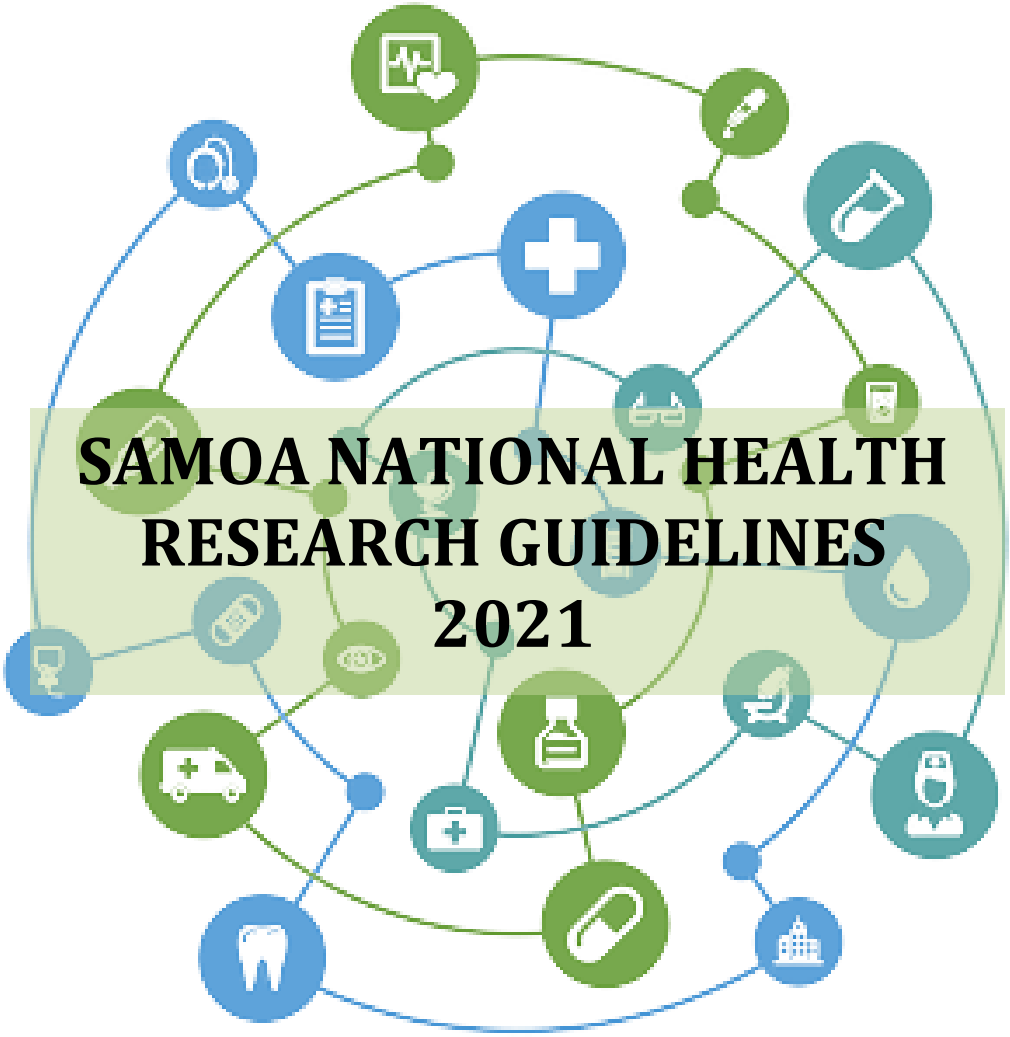
Government of Samoa



SAMOA NATIONAL HEALTH RESEARCH GUIDELINES 2021

Ministry of Health

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INTRODUCTION

Samoa National Health Research Committee (SNHRC) develops this National Health Research Guideline for Samoa 2021 to assist researchers who intend to undertake biomedical, public health or clinical research involving people of Samoa or research on issues relevant to the health of Samoa's population. This includes research proposals or projects focusing on Samoa as a cohort and as part of the wider population being studied. This is the revised version of the Health Research Guidelines produced in 2001.

PURPOSE

The purpose of this document is to set out the policies and procedures to be used by the Samoa National Health Research Committee (SNHRC) in relation to research conducted by external agencies involving Health data and information, documents or staff. They cover the processes associated with the approval, and management of such research projects.

The guidelines are intended to ensure that the research is ethical, of high quality, respects human and cultural values, and is of benefit to the Samoan community and available to the health sector.

The guidelines make clear what is expected of an external researcher and of the Health Sector and hence assist the Samoa National Health Research Committee (SNHRC) to fulfil its responsibilities and the researcher to understand what is required by the SNHRC.

HEALTH RESEARCH PROJECT GUIDELINES

All research projects submitted to be assessed by the SNHRC should complete the Health Research Project Guidelines Form attached as Attachment 1, and consider the following:

The organisation, or an individual, or government ministry or agency writes to the Chair of the SNHRC with the research proposal. The proposal should comply with the following suggested structure for research proposal:

a. **Title and Authors**: this section includes details of the Researcher or Researchers, qualifications, address and the name of the organisation conducting the research and any partners or associates in the research.

b. **Summary or Abstract**: a brief summary or abstract should be provided outline the aim, objectives of the study, the research methodology and data analysis**.**

c. **Introduction**: this section provides the summary of relevant literature around the problem and the problem statement.

d. Motivation: the motivation should indicate the importance of the research on public health and outline the benefits of conducting such a research.

e. Aim or Purpose: the aim or purpose should be clear and feasible

f. Objectives: objectives should be specific, measurable, achievable, realistic and time-bound and describe exact issues to be investigated by the Researcher or Researchers

g. Methodology:

i. *Study design*: study design should specify whether the study is descriptive, analytical or an intervention

ii. *Study population*: the study population should be clearly stated in terms of gender, age, geographical location and any related relevant information

iii. *Sampling*: the sampling frame should include techniques used in sampling participation as well as the sample size

iv. *Inclusion and exclusion criteria*: the criteria used should be clearly stated

v. *Data collection*: instruments used for data collection should be specified and included with the research proposal submitted tot eh SNHRC

vi. *Data analysis*: data analysis techniques that will be used when the research project is completed

vii. *Pilot study*: the research proposal should outline the undertaking of a pilot study (where necessary) to evaluate the data collection instruments before the main study

viii. *Ethical Consideration*: this section indicates what ethical issues were considered during the development of the research proposal including informed consent issues and should provide proof of ethical clearance from an accredited ethics committee

ix. *Feedback and dissemination of research findings*: this section clearly outlines a strategy for feedback and dissemination of information to relevant stakeholders. It includes reports, presentations and publications. It is important to note that reports, presentations and publications should formally acknowledge the Ministry of health and the Government of Samoa

x. *Budget*: the research budget should clearly outline. Application for funding for research projects will have to be arranged with funding institutions by the Researcher. The MoH has no funding allocation for research projects.

xi. *Time Frame*: Researchers have to provide a realistic time frame for research projects

xii. *Expected Outcomes of the Research*: in this section, the Researchers states what he or she expects to achieve from the research activity that will contribute towards public health knowledge

xiii. *References and appendices*: literature used during the development of a research proposal should be properly referenced. Relevant appendices should be inserted at the end of the research proposal and should include the data collection instruments or tools and any relevant documentation referred to in the research proposal

Other areas for consideration and inclusion in proposal include:

i. The adequacy if the site including the supporting staff, available facilities and emergency procedures
ii. Characteristics of the population from which the research will be reported and published
iii. The means by which full information is to be conveyed to potential research participants or their representatives
iv. Inclusion and exclusion criteria for research participants
v. Care and protection of research participants
vi. The suitability of the investigator's qualification and experience for the proposed study
vii. Any plans to withdraw or withhold standard therapies for the purpose of the research, and the justification for such action
viii. If required medical care to be provided to research participants during and after the course of the research
ix. The adequacy of medical care supervision and psychological support for the research participants
x. Steps to be taken if research participants voluntarily withdraw during the course of the research
xi. The criteria for extended access to, the emergency use of and/or the compassionate use of study products
xii. A description of any plans to make the study product available to the research participants following the research
xiii. A description of all financial costs to research participants
xiv. Ensure there is no conflict of interest by financiers to the subject under research that may compromise the findings
xv. The rewards and compensation for research participants (including money, safety, and well-being)
xvi. If appropriate the provisions for compensation/treatment in the case of the injury/disability/death of a research participant attribute to participation in the research
xvii. The insurance and indemnity arrangements

Protection of research participant confidentiality

i. Description of the persons who will have access to personal data of the research participants, including medical records and biological samples

ii. The measures taken to ensure the confidentiality and security of personal information concerning research participants

Informed Consent Process

i. A full description of the process for obtaining consent including the identification of those responsible for obtaining consent
ii. The adequacy, completeness, and clarity of written and oral formation to be given to the research participants and when appropriate, their legally acceptable representative(s)
iii. Clear justification for the intention to include in the research individuals
iv. Assurances that research participants will receive information that becomes their rights, safety and well being
v. The provisions made for receiving and responding to queries and complaints from research participants or their representatives during the course of the research project.

Community Considerations

i. The impact and relevance made for the research on the local community and on the concerned communities from which the research participants are drawn
ii. The steps taken to consult with the concerned communities during the course of designing the research
iii. Proposed community consultation during the course of the research
iv. The extent to which the research contributes to capacity building, such as the enhancement of local healthcare, research and the ability to respond to public health needs
v. A description of the availability and affordability of any successful study product to the concerned communities following the research
vi. The manner in which the results of the research will be made available to the research participants and the concerned communities

For proponents from overseas, a copy of a letter of authorization and/or permit from the Prime Minister's Office must be included. ***A Research Permit is expected to be paid upon approval of the Study by the SNHRC, and the receipt sighted before the Memorandum of Agreement (MoA) is signed.***

TYPES OF RESEARCH COVERED BY THESE GUIDELINES

1. **Research directly involving the health sector using health information and/or involving Health personnel**

   Example: A government ministry, an external agency, a university or an individual wishes to conduct research in health.

   Example: An individual or an external agency, including a university, or a government Ministry wishes to conduct a research using Health

data/information, documents or involving interviews with Health personnel (this could be an organisation in Sāmoa or an international agency).

2. **Research conducted in partnership with an external organisation/agency**
   Example: MoH wishes to work jointly with an external organisation, e.g. A university, on a research project.

Process for Research Situation Type One

1. **Research directly involving the health sector, using Health data and information and/or involving Health personnel.**

   Example: A government ministry, an external agency, a university or an individual wishes to conduct research in health.

   Example: An individual or an external agency, including a university, or a government Ministry wishes to conduct a research using Health data, documents or involving interviews with Health personnel (this could be an organisation in Sāmoa or an international agency).

   i. The organisation, or an individual, or government ministry or agency writes to the Chair of the SNHRC with the research proposal. The proposal should comply with the suggested guideline for development of research proposal outlined in Section B of the Guidelines and attached as Attachment 1.

   ii. If the research proposal does not include all the information required by the SNHRC to make an assessment of the proposal, the SNHRC requests additional information from the proponent.

   iii. For proponents from overseas, a copy of a letter of authorization from the Prime Minister's Office must be included with the proposal.

   iv. The SNHRC assesses the research against the following criteria:
   The research:
   - ✓ is ethical
   - ✓ respects the privacy of individuals
   - ✓ respects cultural and other value
   - ✓ is consistent with the values of the Government of Sāmoa and Health Sector, as articulated in the Health Sector Plan 2010 – 2018 – See Attachment 2 for a copy of the Health Sector Values; Attachment 3 for Health Sector Principles
   - ✓ uses appropriate consent forms (when applicable)
   - ✓ does not duplicate existing or current research
   - ✓ uses sound methodology
   - ✓ timeline is suitable

   The proposed uses of the research findings are beneficial to public health in Sāmoa.

v. The SNHRC writes to the research proponent with a decision as to whether approval for the research has been granted and outlines any conditions that the researcher must agree to.

The conditions will include those particular to the research proposal and also that the researcher agrees to give an undertaking:

- ✓ to be ethical in undertaking the research
- ✓ to meet timelines
- ✓ not to identify individuals in the report
- ✓ provide feedback to the SNHRC liaison person during the research
- ✓ to provide a copy of the completed research to the SNHRC
- ✓ that the SNHRC has the right to terminate the research at any time

The letter will provide the name and contact details of the officer who has been assigned to be the SNHRC liaison person for the research project.

vi. The researcher, (individual, organisation, or government ministry) writes agreeing to the conditions set by the SNHRC.

vii. The SNHRC Chairperson writes to the health sector partners affected and/or Health corporate staff involved and includes a copy of :

- ✓ the research brief
- ✓ the letter from the SNHRC to the Researcher setting out the conditions, and
- ✓ a copy of the letter from the proponent agreeing to the conditions.

viii. The research is undertaken.

ix. The SNHRC liaison person monitors the progress of the research, in particular against agreed conditions, and provides briefings to the SNHRC if any issues arise.

x. The researcher sends a copy of the final report to the SNHRC.

xi. The SNHRC liaison person for the research provides a briefing paper for the SNHRC on the findings of the research and any implications for the Health Sector.

Process for Research Situation Type Two

MoH wishes to work jointly with an external organisation, e.g. a university, or a development partner on a research project.

1. Research projects are identified from MOH responsible division as counterpart. The MoH Management approves the Research Program.

2. New research projects are included in responsible division's budget.

3. A Research Proposal is to be developed by the responsible division in collaboration with the Researcher.

4. The ACEO or Manager of the responsible division liaises with the university or a development partner to further develop the Research Proposal and to work out functions and responsibilities of both parties, including the contribution of funds, other resources and staff. At this stage it is vital to work out who is doing what and who is responsible for managing aspects of the research and the overall research project. There may be situations where MoH staff is doing some of the work, e.g. providing specific reports from health data, and university researchers are doing other aspects of the research.

5. The Research Proposal is finalised and includes:
   - Deliverables and timelines for each deliverable;
   - Composition and role of Steering Group;
   - Detailed description of the role of MoH and that of the university.

   Note the Research Proposal template should be adapted to include extra sections where the roles and responsibilities of all parties are clearly set out.

6. Draw up a Memorandum of Understanding (MOU) between MoH and the external organisation (eg University body). It should include:

   (i) Research Proposal;
   (ii) Functions, responsibilities and contribution of both parties and of the individuals from the two organisations who will be working on the research project;
   (iii) The roles of SNHRC Secretariat and University Project Leader;
   (iv) Copyright information that makes clear who owns the copyright of the final product of the research. Joint copyright might be an option;
   (v) If health electronic data is being accessed, it should include protocols for accessing the data, which is usually a written request to the DG, through whom all data requests must be forwarded. It should also include a clause that states that the Researcher must not use the data for any other purpose.
   (vi) A clause that states that all documents and data used in the research remain the property of the MoH.

7. The MOU is signed by the DG of Health and the head of the university or equivalent.
8. The research is conducted.
9. There is regular monitoring by the SNHRC liaison person during the conduct of the research.
10. The SNHRC meets at key stages during the research, at a minimum to consider any reports of the Researcher that are part of the deliverables. The SNHRC must consider the draft final report and as appropriate suggest amendments to the Researcher.

11. The SNHRC Secretariat provides briefings to the SNHRC at key stages of the research, in particular if there are any issues with regards to the MOU or the conducting of the research.
12. The SNHRC Secretariat person and the ACEO SPPRD are responsible for attaining copies of the final report. A copy of the final report is submitted to the Director General of Health by the Assistant Chief Executive Officer of the Strategic Planning, Policy and Research Division.
13. The SNHRC liaison person for the research provides a briefing paper for the DG and the SNHRC on the findings of the research, to whom the research should be circulated and any implications of the research for the Health Sector.
14. SNHRC or the DG in liaison with the university, decides about circulation, publication and any further work flowing from the research findings.
15. The SNHRC or the DG decides about any further work flowing from the research findings.

RESEARCH AGREEMENTS / MEMORANDUM OF AGREEMENT:

All health research proposals approved must sign a Memorandum of Agreement (MoA). The Agreement must be signed by the Principal Researcher, the Director General of Health and the MoH Legal Advisor/Consultant.

The Researcher must also obtain a research permit from the Ministry of the Prime Minister and Cabinet, and attach it to the research proposal when submitted to the NHRC.

If a Researcher is a medical doctor, nurse or allied health professional, and is required as a part of the research to treat patients / participants, the researcher or researchers must obtain temporary registration from the Ministry of Health Registrar for Health Care Professionals when the research proposal is approved and submit proof to the Chair of the National Health Research Committee before the research is conducted.

REPORTING OBLIGATIONS AND RESPONSIBILITY OF THE RESEARCHER

1 The Research Agreement binds the Researcher to provide research findings and data as well as complete/full research report to the Ministry of Health.

2 The data set from any research approved by the National Health Research Committee and Director General of Health belongs to the Government of Samoa.

3 The Researcher must also seek permission of the Director General of Health in using research findings and data for further publications, and must fully acknowledge the Ministry of Health and the Government of Samoa.

ANNEX 1: SAMOA NATIONAL HEALTH RESEARCH GUIDELINE

MINISTRY OF HEALTH
Tel: (0685) 68100
Website: www.health.gov.ws
(Please address all correspondence to the Chief Executive Officer)

HEALTH RESEARCH PROJECT GUIDELINES

1. Project Title:
2. Aims/ Objectives of the Project:
3. Summary of the Project:
4. Project Duration:
5. Describe the Study Design:
6. List all the methods used for obtaining information:
7. Interviews & Questionnaires (Samoan & English):
8. Who will carry out the research procedures?
9. Where will the research procedures take place?
10. Will the research be conducted overseas?

11. If the study is based overseas, explain what special circumstances arise and how they will be dealt with. Include any special requirements of the country (e.g: research visa/permit) and/or the community with which the research will be

12. How much time will participants need to give to this research?

13. Does the research involve a conflict of interest of the appearance of a conflict of interest for the researcher?

14. Is there any compensation or reimbursement of expenses to be made to participants?

15. Who are the participants in the research?

16. How many organisations both private and public will participate?

17. How many individual participants will participate in your project?

18. How will you identify potential participants and by which method are participants invited to take part in the research?

19. Will the participants be audio-taped, video-taped or recorded by any other electronic means such as digital voice recorders?

20. Describe any arrangements to make results available to participants.

21. Are there any aspects of the research that might raise any specific cultural or religious issues?

22. What are the possible benefits of your research to Samoa?

23. How will the participants be informed of the outcome of your research?

ATTACHMENT 2: ETHICS APPROVAL PROCEDURE & CHECKLIST

Please address all correspondences to the Chief Executive Officer

Government of Samoa
Ministry of Health

Office of the Chief Executive Officer
Private Mail Bag, Motootua
Tel: (685) 23330
or 68100 ext 102
Facsimile: (685) 26553

ETHICS APPROVAL PROCEDURE & CHECKLIST

The MoH process for the approval and management of research projects involving MoH data, health information or staff includes an Ethics Approval procedure. The Samoa National Health Research Committee (SNHRC) will consider each research proposal submitted against the Ethics Checklist below.

If proposals have already been submitted to and received approval through an external ethics process (e.g. from a University) the documentation involved should be attached to the MoH proposal. While external approval will be taken into account by the Samoa National Health Research Committee, Ethics Approval Procedure it will not automatically lead to approval by the SNHRC.

Ethics Checklist

The research content:	YES	NO
Is the choice of research area/topic/focus ethical?		
Do the questions address ethically sound issues?		
Does the research meet the needs of those studied/the health system?		
Research Methods:		
Are the methods well chosen?		
Are they likely to provide answers to the research questions?		
To what extent will they intrude on participants' lives?		
If children are involved are they suitable to their age and ability?		
Permissions:		
Have the necessary permissions to do the research been granted by the relevant		

institutions/people?		
Will additional consent be required (from patients or the children themselves)?		
Access:		
Do the participants have the right to withdraw from the research?		
Do they understand the nature of the research?		
Will they have access to the findings?		
Safety:		
Is the safety of the patient / participant / children ensured if alone in the presence of a researcher?		
Data collection:		
Has there been consideration of how data will be gathered fairly without bias?		
Will the participants – the patients, participants, MoH Staff – be anonymous (as far as possible)?		
Data analysis:		
Is it clear how data will be validated for accuracy and relevance?		
Is there awareness of researcher bias (especially with 'insider' research)?		
Findings:		
Is there awareness of the need for fair and honest judgment in arriving at findings?		
Is there recognition that researchers' beliefs and opinions should not influence findings?		
Publication:		
Who are the research study's intended audience (s)?		
How will findings be disclosed to the participants and other stakeholder groups?		