VANUATU HEALTH RESEARCH ETHICS COMMITTEE (VHREC) PROCESS

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MINISTRY OF HEALTH

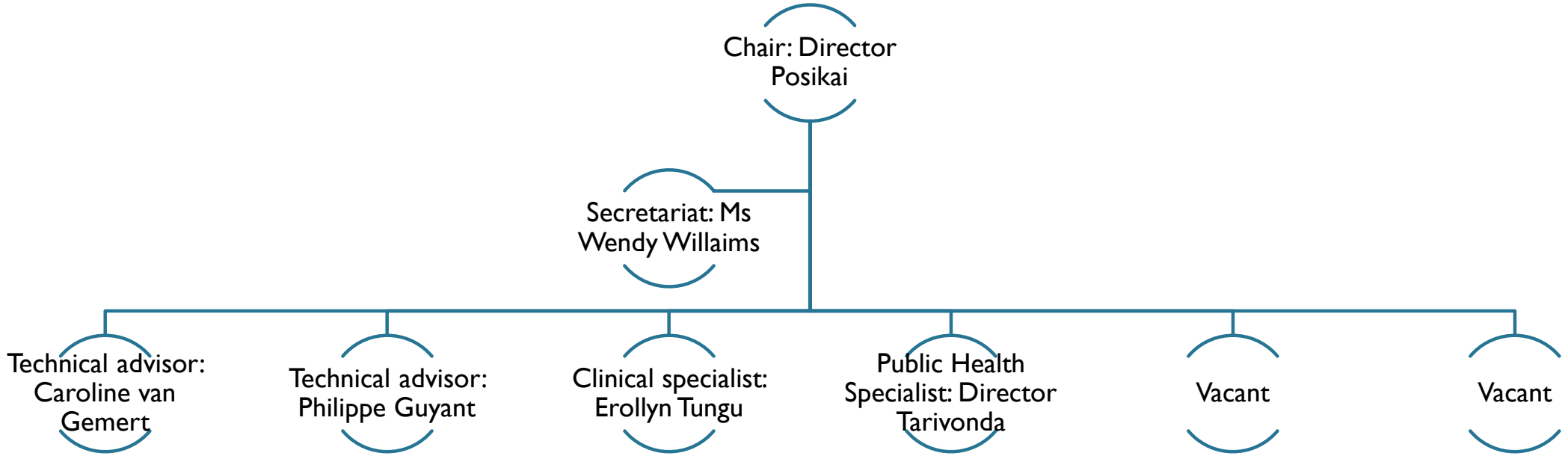
VANUATU 2ND HEALTH RESEARCH SYMPOSIUM

Holiday Inn, Port Vila
23 – 24 September 2021

INTRODUCTION

- The objective of the Vanuatu Health Research Ethics is to promote and support health-related research as a tool for health development in Vanuatu
- The committee serves as both technical and ethical review body
- Provide guidance to researchers and to responsible authorities
- Ensures research involving persons is carried out safely and ethically
- Committee ensures that requirements of the law are met

STRUCTURE OF VANUATU HEALTH RESEARCH ETHICS



APPLICATION PROCESS FOR VANUATU HEALTH RESEARCH ETHICS APPROVAL

1. Complete the Vanuatu Health research Application form (request via email vhresearch@vanuatu.gov.vu)
2. Submit form (with required documents) to
   - E-mail: vhresearch@vanuatu.gov.vu
   - Hard copy address to: The Chair, Vanuatu Health research Ethics Committee, Ministry of Health
3. VHREC review application for decision

CHECKLIST FOR APPLICATION

1 Vulnerable/High-Risk Groups*

	Comments* Write in Yes/No/Not Applicable and attach evidence
1.1 Is a vulnerable population being studied?	
1.2 If yes, which vulnerable group is being studied? *Please circle which group is being studied and comment* a. Children 0<5 years b. School children 6-14 years c. Adolescents 15-19 years d. Pregnant women e. Women of child-bearing age 15-49 years f. Elderly g. Person with mental ill health h. Person with a disability i. Very sick people (HIV/AIDS patients, severe stroke patients, unconscious patients) j. Prisoners k. Other (please specify)	
1.3 Is the justification for studying the vulnerable group adequate? *(Comment)*	
1.4 Have adequate provisions been made to ensure that the vulnerable population is not being exploited? *(Comment)*	

***All sections must be completed with comments and evidence attached to support statements**

2 Scientific and Technical Issues*

	Comments* Write in Yes/No/Not Applicable and attach evidence
2.1 Is the rationale for the study clearly stated?	
2.2 Is the hypothesis to be tested fully explained?	
2.3 Is the project design scientifically sound?*	
2.4 Are the inclusion & exclusion criteria complete and appropriate?	
2.5 Are the methodologies for subject allocation appropriate?	
2.6 Are the participant recruitment, admission, follow up and completion appropriate?	
2.7 Are the drug, devices, and equipment to be used fully described?	
2.8 Does the project design include appropriate criteria for stopping & discontinuing the research?*	
2.9 Are the clinical procedures, laboratory, and diagnostic tests to be carried out fully described and appropriate?*	
2.10 Is the statistical basis for the study design appropriate and is the work plan for analysis of the data appropriate?	

***All sections must be completed with comments and evidence attached to support statements**

3 Informed Consent*

	Comments* Write in Yes/No/Not Applicable and attach evidence
3.1 Are separate informed consent forms developed for this study?	
3.2 Is the information sheet written in at least two (2) languages: English, French, Bislama?	
3.3 Does it describe clearly the proposed study, its purpose, objective, goal and duration?	
3.4 Does it describe clearly the procedures to be carried out?	
3.5 Does it provide information on the risks and discomforts of participating in such a study?	
3.6 Does it describe benefits for the research participants, if any & for others?	
3.7 Does it describe the nature of any compensation or reimbursement to be provided?	
3.8 Does it specifically mention that participation is voluntary and refusal to participate (or discontinue participation) will involve no penalty or loss of medical benefits to which participant was otherwise entitled?	
3.9 Does it provide name and contact information of the investigator/person/institution that can provide more information about the research project at any time?	
3.10 Does it include a Statement of what they have read/had read to them and have the opportunity to ask questions about the study and their rights to participate or withdraw from the study?	
3.11 Has the provision been made for subjects incapable of reading, writing and signing the written consent form?	
3.12 Has provision been made for subjects incapable of giving personal consent (e.g. for cultural reasons, children or adolescent less than 18 years, subjects with mental ill health or very ill patients)?	

***All sections must be completed with comments and evidence attached to support statements**

4 Clinical Trials & Human Biological Material*

	Comments* Write in Yes/No/Not Applicable and attach evidence
4.1 Is it a new drug or vaccine trial?	
4.2 Is clearance from the Vanuatu Drugs Therapeutic Committee attached?	
4.3 Is the Investigator's Brochure (including safety information) attached?	
4.4 Is the Adverse Drug Reaction Adverse Event Reporting Form attached?	
4.5 Has a Data Safety Monitoring Board been established? Names of chairperson and members available for records?	
4.6 Will human biological materials be obtained during the study?	
4.7 Does the consent form describe the nature, number & volume of samples to be collected?	
4.8 Does the consent form indicate the procedures to be used for obtaining routine or experimental samples?	
4.9 Does it describe how specimens will be coded as to provide confidentiality of the participant?	

***All sections must be completed with comments and evidence attached to support statements**

5 Other Attachments*

	Comments* Write in Yes/No/Not Applicable and attach evidence
5.1 Does it provide information on who is funding the study?	
5.2 Does it provide full CV details of the Principle Investigator and co-investigators?	
5.3 Does it provide participant recruitment materials, such as advertisement, notices, media, messages in any of two languages: English, French, Bislama?	
5.4 Does it provide questionnaires, diaries & study instruments & study design and population sample?	
5.5 Does it maintain the privacy and confidentiality of the participant?	
5.6 Are there any long-term benefits after the completion of the study to the population being studied?	

***All sections must be completed with comments and evidence attached to support statements**

1. VANUATU HEALTH RESEARCH APPLICATION | 2. INFORMED CONSENT | 3. CONSENT FOR SPECIMEN STORAGE | 4. WITHDRAWAL FROM STUDY FORMS

Vanuatu Health Research & Ethical Application Form

Ministry of Health, 2021

[All applications for ethics approval should be submitted using this form. The application form must be completed/filled out on a computer, printed and then signed in relevant places as this allows space for input. Please attached evidence to support statements where mark by an asterisk)]*

1 Title of Project

2 Description of Project (background in detail)

2.1 Methodology (in detail)

a. Sample study

b. Study design

c. Analysis method to be used

2.2 Work plan

3 Principal Investigator*

Please forward completed form to the Vanuatu Health Research Ethics Committee on E-mail: vhresearch@vanuatu.gov.vu

Vanuatu Health Research & Ethical Application Form

Ministry of Health, 2021

3.1 Location/Address/CV of Principle Investigator*

3.2 Co-Investigators name and position*

4 Commencing Date of the Project *(please complete in full – e.g. 08-November-2018)*

4.1 Completion Date of the Project

4.2 Duration of the Project
(A final report will be required 3 months off completion of study)

5 Budget Cost & Timetable of Expenditure

Consultation Fee	
Volunteer Fee	
Stationaries	
Equipment	
Transport	
Accommodation	
Cost of data questionnaire, data coding & analysis of study	
Health Research Fee ≠ *(Non-Refundable)*	In Vatu or US$ currency only 50,000vt (US$500)
Deposit Fee (to be reimbursed after a soft & hard copy is deposited with the Vanuatu Health Research & Ethics Committee)	
Miscellaneous	

NOTE:
≠Ni-Vanuatu local researchers with no grants are exempted from paying the fee.
*Local Ni-Vanuatu researchers that have grants will pay a research fee of 10,000vt**
*Overseas researchers will pay a fee of US$500 and a deposit fee of US$500**
**Before commencement of research*

Please forward completed form to the Vanuatu Health Research Ethics Committee on E-mail: vhresearch@vanuatu.gov.vu

Vanuatu Health Research & Ethical Application Form

Ministry of Health, 2021

6 Informed Consent from Vanuatu Government Authority*

6.1 Informed Consent of Community Subjects*

For Official Committee use only:

- ◊ Approval in full:
- ◊ Approval but resubmitted for slight amendments to proposal:
- ◊ Pending:
- ◊ Needs to be resubmitted for further modifications and more detail
- ◊ Not approved:

Vanuatu Health Research Withdrawal from Study Form

Ministry of Health, 2021

Name of participant

Title of Research Study

"I formally wish to withdraw my consent to participate in the research proposal described above and understand that such withdrawal will not jeopardise any treatment or my relationship with the health services involved in the research project."

Please clearly indicate preferences for any samples collected during the course of your participation with the research proposal.

- ☐ Any stored biological material should be discarded immediately
- ☐ Left-over biological material can be stored and used throughout the remainder of the project and discarded once completed
- ☐ Left-over biological material can be stored and used in future research only if it involves the same research subject as this current study

Date

Participant Signature

If illiterate, allow for a thumb print

Signature of parent or guardian (if under-age or very ill)

Vanuatu Health Research Concern form for storage of Specimens

Ministry of Health

Name of participant

Home address of participant

Please clearly indicate below which options (circle - 1a or 1b and 2a or 2b) you wish to choose

Any specimens provided by me for this research study are to be used

1a. Solely for the current health research study and destroyed after the completion of this current study

OR

1b. Left over material can be stored and used in future research but only in the same subject as the current research study

2a. I allow my participation status to be revealed to other researchers

OR

2b. I do not allow my participation status to be revealed to other researchers

Date

Signature of participant

Vanuatu Health Research Informed Consent Form

Ministry of Health

Name of participant

Home address of participant

Telephone Number of participant

Title of Research Study

Duration of Research Study

Benefits of the Research Study

- ☐ I have read the forgoing information, or it has been read to me, and I have had the opportunity to ask questions about it and any questions I have asked have been answered clearly and to my satisfaction.
- ☐ I consent voluntarily to participate as a subject in this study and understand that I have the right to withdraw from the study at any time without it in any way affecting my further health care services.
- ☐ I also understand that I will receive a signed copy of the Vanuatu Health Research Informed Consent Form and all information relevant to the research I am participating in.

Date

Participant Signature

If illiterate, allow for a thumb print

Signature of parent or guardian (if under-age or very ill)

ACKNOWLEDGEMENTS

- AVI – Ms. Courtney Hammer for drafting the TOR and Forms

THANK YOU FOR LISTENING

ANY QUESTIONS ????????