

Vanuatu Health Research Screening Checklist

Ministry of Health, 2021

**Checklist for proposals submitted for ethics review*

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? <i>Please circle which group is being studied and comment</i> <ul style="list-style-type: none"> 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? <i>(Comment)</i>	
1.4 Have adequate provisions been made to ensure that the vulnerable population is not being exploited? <i>(Comment)</i>	

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

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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?	

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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)?	

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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?	

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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?	

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