Ministry of Health

Republic of Botswana

GUIDE - CONSENT FORM

Consent is a process involving the free interchange of information between the prospective subjects and the investigator. Informed consent must be sought under circumstances that provide subjects *(or their legally authorized representative)* sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. Researchers have the duty to ensure that the participants comprehend the information given. The verbal and written briefing of the participants must be in a manner, level and language that they understand.

A Consent form should at a minimum include the following information:

1. Title of study

2. Introduction

An introductory statement

3. Purpose of the study

A statement on what the research is for. What are the expectations? Etc.

3. Eligibility Criteria

4. Study Procedure

State whether procedure is experimental or not experimental, description of all procedures which will be followed and all treatments or procedures. It should state how treatment will be administered and include visit schedules etc. If the study is clinical, indicate study design i.e. Randomized Trial, Blind Trial, Case Cross-over or Placebo. State the approximate number of subjects to be involved in the study and the duration of the study.

4. Alternative Procedures

A disclosure of appropriate procedures or courses of treatment, if any that might be advantageous to the subject and their attendant risk and benefit. To enable a rational choice about participating in the research study, subjects should be aware of the full range of options available to them.

5. Blood tests

State if blood samples will be collected from subjects and name the types of tests that will be performed on the sample as well as the volume of blood that will be collected during each visit.

6. Risks and/or discomfort

This is a description of any foreseeable risk or discomforts to the subjects. If there are risks to participation, describe them for each procedure or drug. List all expected and occasional side effects. List all side effects, no matter how rare, that are life altering or potentially life altering. State if there are risks associated with the research. Describe more than minimal risks.

7. Handling of Research Related Injury

Describe how research related injuries would be handled by the researcher.

8. Benefits

A description of any benefits to the subject or others which may reasonably be expected from the research. If no direct benefit is anticipated, that should be stated.

9. New information

A statement that participants will be informed of any new findings which develop during the course of study that may relate to their willingness to continue in the study.

10. Costs to Subjects and Compensation

State any additional cost to the subject that may result from the research. State if there is any compensation to the participant.

11. Voluntary Participation

A statement that participation is voluntary (right not to participate) and that refusal to participate will involve no penalty or loss of benefits to which the subjects are otherwise entitled to.

12. Right to Withdraw

Subjects should be informed on their right to withdraw at any point in time and consequences of a subject's decision to withdraw from research. If applicable, describe circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent (but subject must be informed).

13. Privacy, Anonymity and Confidentiality

Information on the extent of privacy, anonymity and confidentiality that will be provided to participants. This should describe measures to be used to maintain confidentiality of records and data pertaining to the subjects. A statement on institutions that will be allowed to review/inspect records should be included.

14. Future use of Information

The future possible use of the information and data obtained, including use as a database, archival research or recordings for educational purposes.

15. Storage of specimen

State the period of storage for specimens, where specimens will be stored, explain how you might use stored specimens in the future, blinded or unlinked, procedures for requesting withdrawal of specimens and what procedures will be followed for future use of these stored specimens.

16. Who to contact

Give contact details for
Information on the rights of the participants in the trial (Name of IRB representative)
Questions and Injuries related to study (Name of Researcher)

17. Statement of consent

Write a statement of consent, dates and signature of the participant and study staff member conducting consent.