Ministry of Health

Republic of Botswana

Application for Approval of Human Research

Section A: Instructions

1. ***For research/academic institutions or PHD students attach:***
   - ***a) 14 copies of the Research Application form***
   - ***b) 4 copies of the following:***
     - ***i. Study proposal.***
     - ***ii. Consent/authorization form or a request for waiver of consent/authorization- Setswana, English and back translation where applicable.***
     - ***iii. Questionnaires to be used. Setswana, English and back translation where applicable.***
     - ***iv. Curriculum vitae/ resume of each member of the Research team***
     - ***v. Approval letter from other IRBs***
     - ***vi. Grant approval letter***
     - ***vii. Any other supporting materials i.e. recruitment scripts, brochures, flyers etc***
2. ***For undergraduates and graduates attach one copy of the above listed items/ documents.***

Section B: Application Details

1. Study Title: (Include Version number and date)
2. Date of submission:
3. Type of Research: **i. Basic Science ( )** **ii. Public Health ( )** **iii. Clinical Research ( )** **iv. Human Biology ( )** **v. Other_____**

4. Principal Investigator*(Name & Qualifications)*:	**4(i). Local Contact Details** ***Name:***
Postal Address:	**Postal Address:**
Phone Number:	**Phone Number:**
E mail Address:	**E mail Address:**
Name of affiliate Institution/Organization:	**Name of Institution/Organization:**
Department *(If Government)*:	**Department *(If Government)*:**

5. Other Investigators /Co-Principal Investigators			
Name:	**Organization:**	**Email:**	**Telephone Number:**

6. Key Personnel working with data that may be linked to human subjects:			
Name:	**Organization:**	**Email:**	**Telephone Number:**

Section C: Description of Research

1. Brief Description of Study

2. Rationale/Justification ***(Why the need to carry out this study in Botswana)*****:**

3. Study Objectives ***(Both General and Specific)*****:**

4. Expected Results ***(Both Primary and Secondary endpoints)*****:**

Section D. Methodology

1. Study Design
2. Study sites ***(Districts, Towns, Villages, Health facilities, Schools etc*** **:**
3. Subject Population(s) ***(Clinical condition, Gender, age, and other relevant Characteristics)*****:**
4. Sample size***(The number of subjects to be involved in the study and how these subjects will be selected from the population)*****:**
5. Subject Recruitment/Sampling Methods ***(Explain all procedures in detail)*****:**

6. Data Collection Methods (*Explain all procedures in detail)*

7. Data Analysis *(Briefly explain how data will be analyzed)*

8. Piloting/Pretesting *(Explain all procedures in details)*

9. Protection of Subjects *(Describe measures to protect subjects from and minimize possible risk of harm, discomfort, or inconvenience*):

10. Approximate Date Study Recruitment will begin:_____

11. Estimated Duration of entire study: _____

Section E: Subject Information

1. Inclusion Criteria

2. Exclusion Criteria:

3. Does the study involve Vulnerable Groups? ***(Tick all that Apply)*****?**

Elderly	**( )**
Children	**( )**
Pregnant women, fetuses, or neonates of uncertain viability or nonviable	**( )**
Prisoners	**( )**
Decisionally impaired Persons	**( )**
Minority and indigenous groups	**( )**
Low Literacy	**( )**
Economically Disadvantaged	**( )**
Other_____	
N/A	**( )**

4. Does this study involve any use of a drug? No ( ) Yes ( ). If yes, is the drug registered or given exemption status (IND studies) by the Drug Regulatory Unit in Botswana? ***If yes attach proof)***_____

5. Reasonably foreseeable risk or discomforts to the subjects (*list in detail)***:**

6. Who will cover Subject Injury-Related Costs?

i.	**Sponsor**	**( )**
ii.	**Third-Party Payers**	**( )**
iii.	**Subjects**	**( )**
iv.	**N/A**	**( )**
v.	**Other**	_____

7. Potential benefits to society and to subjects ***(do not include compensation)*****:**

8. Give details of Botswana based personnel that will be involved ***(Name, functions and qualifications)*****:**
9. Any renumeration given to subjects? Yes ( ) No ( ). If yes, specify:
10. Will the participant incur any financial cost in this study? Yes ( ) No ( ). If yes, specify:

Section F: Data Sources

1. Sources of Data

i. **Focus Group(s)** ( )
ii. **Interviews** ( )
iii. **Questionnaires/Surveys** ( )
iv. **Census/Public Records** ( )
v. **Human Biological Specimen**
( ) **Archive** ( ) **Prospectively Collected** ( ) **Discharged** ( ) **Stored Samples**
vi. **Medical Records** ( )
vii. **Registers** ***(e.g. TB register and Cancer register)*** ( )
viii. **Other** _____

Section G. Study Details

1. Capacity Building (*how will the study build capacity in the country*)
2. Dissemination (*How will the study findings be disseminated)*
3. Other Ethical Body(ies) Involved in the review of the study

Section H: Sponsor Information

1. Name of Sponsor:_____

2. Type of Sponsor:

i.	**Government**	**( )**
ii.	**Private Foundation**	**( )**
iii.	**Industry**	**( )**
iv.	**Internal**	**( )**
v.	**Other**	**( )**

3. Sponsor Contact Person:_____

4. Sponsor Contact Telephone: _____

Section I: Contact Information:

PI or other researchers for answers to questions about the study or research-related injuries*(You must offer at least two contacts)*:	**The HRDC representative who can answer questions about their rights as research subjects**
i). **ii).**	**Name**_____ **Head of Health Research Unit** **Ministry of Health** **Private Bag 0038** **Botswana** **Tel: (+267) 3914467** **Fax: (+267) 3914697**

Section J: Investigator's Statement

INVESTIGATOR'S STATEMENT OF ASSURANCE

I promise to abide with existing relevant International Declarations and National procedures and guidelines when undertaking research involving human subjects within the Republic of Botswana and agree to:

1. Ensure that all studies conducted on human participants are designed and conducted according to sound scientific and ethical standards within the framework of good clinical practice.

2. Report to the Health Research and Development Committee any information requested, serious or unexpected adverse events and any information related to national programs.

3. Unless if an emergency treatment for patient care, obtain prior approval from the HRDC before amending or altering the scope of the project or implementing changes in the approved consent form(s).

4. Submit progress reports as required by the HRDC.

5. Maintain all documentation including consent forms and progress reports.

6. Ensure that all members of the research team are aware of their roles and responsibilities in this study.

7. Ensuring, in accordance with the duties outlined for each member, that all members of the team are fully utilized for tasks assigned to them.

Principal Investigator's Name:

Principal investigator's Signature: **Date:**

Principal Investigator's Position:

Local Investigator's Name:

Local investigator's Signature: **Date:**

Local Investigator's Position:

After Completion

1. **An electronic and hard copy of the report should be submitted to the Health Research Unit, Ministry of Health as well as other relevant Botswana Government Institutions/Organizations within 3 months of producing a bound report.**

2. **All continuing renewals should be submitted at least 6 weeks before the expiration.**

Section K. For Health Research Unit use ONLY.

1. Date Received	**6. Review Body [ ] Health Research Unit [ ] HRDC**
2. Final Outcome	
3. Ref No:	
4. Expiration Date:	
7. Continuing renewals extension **Date 1 _____** **Date 2 _____** **Date 3 _____**	
8. Final Report Submission **( ) Yes Date _____** **( ) No**	