



REPUBLIC OF BOTSWANA

**HEALTH RESEARCH & DEVELOPMENT COMMITTEE**

TELEPHONE - (+267) 3914467

DATE RECEIVED: \_\_\_\_\_

REVIEW DATE: \_\_\_\_\_

**CONTINUING REVIEW APPLICATION FORM**

1. DATE:

2. PROTOCOL NUMBER:

3. PROTOCOL TITLE:

4. PRINCIPAL INVESTIGATOR:

5. ADDRESS:

6. TELEPHONE:

7. E-MAIL:

8. CO-INVESTIGATOR(S):

9. KEY PERSONNEL:

10. GRANT AWARDS TITLE:

11. SPONSOR(S) NAME:

12. STATUS: (PLEASE CHECK ALL THAT APPLY)

- ☐ Continuing
  - ☐ Accrual complete with treatment intervention and/ or participant interviews /surveys continuing
  - ☐ Subject interventions/data collection ended on (date): \_\_\_\_\_
  - ☐ Open for analysis only. Expected end date: \_\_\_\_\_
  - ☐ Complete (including all analysis). Date completed: \_\_\_\_\_
  - ☐ Cooperative Review
  - ☐ Other, Please describe: \_\_\_\_\_
  - ☐ Study never activated, closure requested-
- (Submit this page only with PI Initial/date) \_\_\_\_\_

PI Initial      Date

13. SUBJECT INFORMATION:

- a. Total approved sample size (of evaluable subjects):
- b. Total enrolled during past approval period (excluding ineligible subjects):
- c. Total enrolled to date (excluding ineligible subjects):
- d. Enrollment breakdown to date by gender and race (excluding ineligible subjects):
- d. Enrollment breakdown in past approval period (excluding ineligible subjects):
- e. Total eligible subjects yet to be recruited:
- f. Percentage of total enrolled to date who withdrew, were excluded, or otherwise were not evaluable subjects:  
In past approval period:

14. OUTLINE GOALS OF STUDY: (a short description **must** be included)

15. DESCRIBE ANY UNEXPECTED OUTCOMES OR PROBLEMS (physical, psychological, social, or with the consent process or enrollment) EXPERIENCED BY SUBJECTS SINCE LAST REVIEW. **Serious Adverse Events, both expected and unexpected, must be reported in writing to HRDC immediately.**

16. WAS ANY SUBJECT WITHDRAWN OR DID ANY SUBJECT VOLUNTARILY WITHDRAW FROM THE STUDY? Yes ☐ No ☐ IF SO, DESCRIBE:

17. HAS THE COMMITTEE APPROVED ANY REVISIONS TO THE STUDY SINCE THE LAST REVIEW? Yes ☐ No ☐ IF SO, DESCRIBE:

18. DO YOU WISH TO REQUEST APPROVAL FOR ANY REVISIONS AT THIS TIME? Yes ☐ No ☐

- If you propose any change to the protocol, summarize the changes you propose, the reasons for them, and submit two copies of an updated version of your original protocol application, one indicating the proposed changes in bold or "track changes," and the other without bold or track changes.
- If you have changes to co-investigators or study representatives, please list them and describe their proposed contribution.

**(Remember that no changes may take place until you receive HRDC approval, unless necessary to prevent imminent serious harm to subjects! However, you must report details to the HRDC)**

19. SUMMARIZE YOUR FINDINGS FOR:

a. THE PAST APPROVAL PERIOD:

b. TO DATE:

20. ATTACH COPIES OF LITERATURE BY AUTHORS OTHER THAN YOU THAT PROVIDE NEW INFORMATION BEARING ON THIS STUDY'S RISK: BENEFIT ANALYSIS. Attached ☐

If, after performing a search in good faith, you believe there are none, check here ☐

21. ATTACH A COPY OF THE CONSENT FORMS (English and Setswana) YOU PLAN TO USE DURING THE NEXT YEAR, Attached ☐ N/A ☐
22. IF YOU DO NOT PLAN TO TRANSLATE YOUR CURRENT FORM TO SETSWANA, PLEASE EXPLAIN WHY? \_\_\_\_\_  
\_\_\_\_\_
23. ATTACH A COPY OF ANY ADVERTISEMENTS OR RECRUITMENT MATERIALS YOU PLAN TO USE IN THE NEXT YEAR. Attached ☐ None attached ☐  
Will submit as amendments ☐
24. ATTACH THE CURRENT, UNEXPIRED APPROVAL AND/OR REAPPROVAL FORM(S) FROM ALL OTHER INSTITUTIONS INVOLVED WITH YOUR STUDY.  
Attached ☐ N/A ☐ From: \_\_\_\_\_

**I certify that this protocol is being conducted in strict adherence to national and international guidelines on the protection of the rights and welfare of human subjects in research.**

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**Principal Investigator's signature**

**Date**