

PRIVATE BAG 0038  
GABORONE  
BOTSWANA  
REFERENCE:



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REPUBLIC OF BOTSWANA

MINISTRY OF HEALTH AND WELLNESS

REFERENCE NO: HPDME 13/18/1

18<sup>th</sup> February 2019

Health Research and Development Division

Notification of IRB Review: **New application**

Annette Gerritsen  
28 Dales Avenue  
3201 Pietermaritzburg  
South Africa

Dear Annette Gerritsen

**Protocol Title:** **IMPACT EVALUATION OF AN INTERVENTION PACKAGE  
FOR ADOLESCENTS LIVING WITH HIV IN BOTSWANA**

**HRU Approval Date:** 18 February 2019  
**HRU Expiration Date:** 17 February 2020  
**HRU Review Type:** Expedited Review  
**HRU Review Determination:** Approved  
**Risk Determination:** Minimal risk

Thank you for submitting new application for the above referenced protocol. The permission is granted to conduct the study.

This permit does not however give you authority to collect data from the selected sites without prior approval from the management. Consent from the identified individuals should be obtained at all times.

The research should be conducted as outlined in the approved proposal. Any changes to the approved proposal must be submitted to the Health Research and Development Division in the Ministry of Health for consideration and approval.

Furthermore, you are requested to submit at least one hardcopy and an electronic copy of the report to the Health Research, Ministry of Health and Wellness within 3 months of completion of the study. Approval is for academic fulfillment only. Copies should also be submitted to all other relevant authorities.

### **Continuing Review**

In order to continue work on this study (including data analysis) beyond the expiry date, submit a Continuing Review Form for Approval at least three (3) months prior to the

**Vision:** *A Healthy Nation by 2036.*

**Values:** *Botho, Equity, Timeliness, Customer Focus, Teamwork, Accountability*



protocol's expiration date. The Continuing Review Form can be obtained from the Health Research Division Office (HRDD), Office No. 7A.7 or Ministry of Health website: [www.moh.gov.bw](http://www.moh.gov.bw) or can be requested via e-mail from Mr. Kgomotso Motlhanka, e-mail address: [kgmmotlhanka@gov.bw](mailto:kgmmotlhanka@gov.bw) As a courtesy, the HRDD will send you a reminder email about eight (8) weeks before the lapse date, but failure to receive it does not affect your responsibility to submit a timely Continuing Report form

### Amendments

During the approval period, if you propose any change to the protocol such as its funding source, recruiting materials, or consent documents, you must seek HRDC approval before implementing it. Please summarize the proposed change and the rationale for it in the amendment form available from the Health Research Division Office (HRDD), Office No. 7A 7 or Ministry of Health website: [www.moh.gov.bw](http://www.moh.gov.bw) or can be requested via e- mail from Mr. Kgomotso Motlhanka, e-mail address: [kgmotlhanka@gov.bw](mailto:kgmotlhanka@gov.bw) . In addition submit three copies of an updated version of your original protocol application showing all proposed changes in bold or "track changes".

### Reporting

Other events which must be reported promptly in writing to the HRDC include:

- Suspension or termination of the protocol by you or the grantor
- Unexpected problems involving risk to subjects or others
- Adverse events, including unanticipated or anticipated but severe physical harm to subjects.

If you have any questions please do not hesitate to contact Mr. K. Motlhanka at [kgmmotlhanka@gov.bw](mailto:kgmmotlhanka@gov.bw), Tel +267-3632751. Thank you for your cooperation and your commitment to the protection of human subjects in research.

Yours sincerely

  
Ms S. Mosweunyane  
for /**PERMANENT SECRETARY**

