APPLICATION FOR RECERTIFICATION
(Continuing Review)

The HSRC Research Ethics Committee (HSRC REC) must, according to its Terms of Reference, Standard Operating Procedures and South African Department of Health guidelines, review all approved ongoing research projects at least annually.

Please complete the recertification form fully. Attach any other documents that may be relevant.

Deadline date: Submit three copies of this application two months before current approval expires. If the required information is not received by the deadline date, the application may not be reviewed and recertified in time, leading to noncompliance with HSRC REC Terms of Reference and suspension of the study until the protocol is recertified.

Please complete all applicable sections below. If a section is not applicable, mark it clearly as "N/A".

Project Title:

Biomedical Research Ethics Committee Reference No:

Date of BREC ethics approval:

Principal Investigator:

Department/Institution:

Co-Investigator/s:

Funding source/agency:

Grant/Contract No:

Project period:

Study site(s):

Other ethics approvals received from:

Other ethics approvals pending from:

MCC approval date:

If a clinical trial, provide SA National Clinical Trials Registry (SANCTR) number:

1. PROVIDE A BRIEF DESCRIPTION OF PROJECT AIMS, SAMPLE AND METHODS:

2. SUMMARY OF PREVIOUS YEAR'S EXPERIENCE WITH PROJECT:

Please provide brief notes, for the past year, under each of the headings below. If not applicable, indicate "N/A".

1.1 Progress with recruitment:
1.1.1: Is recruitment on schedule?
1.1.2: If recruitment is slow or delayed, please give reasons:

1.2 If closed to recruitment, how many enrolled?

2.3 The protocol for this research project involves the following participants:

TYPE	Number planned:	Number enrolled to date:
Adult non-patients (≥ 18 years)		
Adult patients (≥ 18 years)		
Minor non-patients (< 18 years)		
Minor patients (< 18 years)		
Legally incompetent participants		
HIV positive participants		
Participants with substance abuse		
Prisoners		
Pregnant women		
Persons with mental disability		
Persons certified by Mental Health Care Act		
Other vulnerable persons (Describe)		

2.4 Is follow-up still active?

2.5 Problems encountered (provide number and brief description of each category of event listed below and confirm whether or not these were all reported to the HSRC REC and acknowledged by HSRC REC):

2.5.1: Adverse Events:
2.5.2: Serious Adverse Events:
2.5.3: Protocol deviations:
2.5.4: Protocol violations:
2.5.5: Complaints from participants:
2.5.6: Did any participants withdraw prior to their completing the study? If 'yes', how many and for what reasons?

2.6 Amendments requested and approved by HSRC REC (provide list and HSRC REC approval dates if applicable):

2.7 Change of study personnel approved by HSRC REC (provide list and HSRC REC approval dates if applicable):

2.8 Is there any new information, not previously submitted, relevant to the recertification of this project? If 'yes', please describe below or attach an appendix to this form.

2.9 If applicable, please provide a summary of recent literature that may be relevant to the study.

2.10 If applicable, attach any relevant multi-centre trial reports.

2.11 If applicable, provide any post-approval information about risks associated with the research.

2.12 Attach a current Information sheet and consent form.

3. APPENDICES: Please list any documents sent as appendices to this recertification application:

4. DECLARATION:

I the undersigned declare that:

1. To the best of my knowledge the above information accurately represents the past year's experience and future plans with regard to this protocol.
2. The research procedures and design have not changed without approval of the HSRC Research Ethics Committee.
3. Changes to research procedures and/or design from those approved by the Biomedical Research Ethics Committee will be submitted in advance for approval, on the standard HSRC REC Amendment Application Form (available at http://www.hsrc.ac.za/en/about/research-ethics

Signature of Principal Investigator: _____
Date:_____

PI Full name:
Title:
Contact details:
Phone:
Fax:
Email:

Send this application and supporting documents to:

Postal Address:

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