CAPE PENINSULA UNIVERSITY OF TECHNOLOGY
Health and Wellness Sciences Research Ethics Committee

HUMAN PARTICIPANT STATUS REPORT

Previous HWS-REC Application Number:

BOX FOR COMMITTEE USE ONLY
REVISED APPILICATION Number:

PRINCIPAL INVESTIGATOR

NAME: TITLE:

POSITION:

TELEPHONE NUMBER: FAX NUMBER:

EMAIL:

RESEARCH TITLE:

APPROVAL FOR THIS STUDY EXPIRES ON:

Complete this form according to the instructions below and send it to the Health and Wellness Sciences Research Ethics Committee (HWS-REC) six weeks before the expiry date.

If you plan to propose changes or additions, send the details of these changes with the Status Report.

Please note that you may not recruit new human participants or continue your activity with previously enrolled participants unless you have active HSREC approval.

You should maintain approval until the data analysis for this activity is complete.

Send **one** typed, completed and signed original and **one** copy of the Status Report plus one copy of each currently approved consent and assent form.

I acknowledge that this Status Report represents an accurate and complete description of my research.

_____ _____

Type name and sign (principal investigator) Date

The box marked "Committee Use Only" provides the investigator with important information about whether the application was re-approved and what the new period of approval is. If the Ethics Committee has imposed any conditions on re-approval, these will be explained.

BOX FOR COMMITTEE USE ONLY

_____ _____ Approved ☐ Disapproved ☐

HWS-REC Name and Signature Date

Subject to the following conditions: _____

_____

Period of approval is one year, from _____ to _____

*** VALID ONLY AS LONG AS APPROVED PROCEDURES ARE FOLLOWED***

A. Activity Status

- ☐ New participant enrolment still in progress.
- ☐ Enrolment closed but participants are still undergoing study procedures.
- ☐ Enrolment closed, participants have completed study procedures, but are still involved in follow-up activities.
- ☐ Participant involvement completed, researcher needs approval for data analysis only.
- ☐ No enrollment, study never begun.

B. Participant Numbers

	Controls	Participants
1. No. participants enrolled since initial approval		
2. No. of additional participants needed to complete study		

C. Summaries

Provide a condensed version of what was included in the initial application for approval, indicating any amendments or modifications made since the initial approval.

1. **Abstract summarizing the purpose of this research activity, the procedures participants undergo, and a description of the participant population/s**.

Provide a summary statement that includes a description of how the study is progressing, from recruitment to enrolment to preliminary findings.

2. **Progress to date. If you have not yet enrolled participants, please explain why.**

This summary should describe amendments to study design, data collection etc.

3. **Summarize any changes you have made during the period of approval.**

If new findings from outside or from within the research have changed the level of risks or benefits that might result from this study, summarize them here. Include a recommendation about whether or not the consent form should be modified to reflect these changes.

4. **Describe changes in the risks or benefits to participants over the last period of approval.**

5. **If you propose changes in the activity for the next period of approval, attach five copies of a memorandum describing the changes. Also attach five copies of the revised consent or assent forms and any other revised study materials.**

D. Adverse Events

Provide this information for participants enrolled for the period since your last report. If there were none, enter 0.

1. No. of adverse events: _____
   Explain how you handled each adverse event.

   Were any of these adverse events unexpected or more serious than expected?

   ☐ Yes ☐ No
   If "yes" then explain.

2. No. of complaints: _____
   Explain how you handled each one.

3. No. of participant withdrawals: _____
   For each, explain why the participant chose to withdraw or why you withdrew the participant from the study.

Protocol violations include anything from neglecting to obtain informed consent from a participant before enrolling them in the study to a participant missing a dose of study medication.

4. No. of protocol violations: _____
   Explain how you handled each one.

E. Funding

Please review and update the grant and contact information on the following page(s).

Is there new funding proposed for this activity? ☐ Yes ☐ No
If "yes", please give details.

Please include all funding, current and pending, for this application.

Funding Type:

☐ Research Grant ☐ CPUT Research Grant ☐ Contract ☐ Other, Specify:

Funding Agency:

Principal Investigator (on proposal):

Agency Reference Number (if known):

Proposal Title:

Status: ☐ New Start Date: End Date: Funded? ☐ Yes ☐ No