CAPE PENINSULA UNIVERSITY OF TECHNOLOGY

HEALTH AND WELLNESS SCIENCES RESEARCH ETHICS COMMITTEE

HUMAN PARTICIPANTS' REVIEW APPLICATION

This application to the Health and Wellness Sciences Research Ethics Committee (HWS-REC) must be preceded by approval of the research proposal by the Faculty Research Committee.

The HWS-REC must receive one **(1) hard copy (no back to back copying) and one (1) soft copy** of this application form, all relevant accompanying documentation (i.e. consent forms, questionnaire, instruments, data collection sheets, etc.) and your research proposal. For assistance with the completion of this form, please consult the "Guidelines for completing the HWS-REC 4.1 form".

Address to: Secretary – Research Ethics Committee
Health and Wellness Sciences
Bellville Campus, CPUT

Also forward an electronic copy of the signed documents to: sethn@cput.ac.za

For the attention of Ms. Nomathemba "Thembi" Seth **Phone: 021 959 6917**

FOR COMMITTEE USE ONLY Application No.: Year/…….

I. PRINCIPAL INVESTIGATOR'S DETAILS

Name: **Title:** **Position:**

Department: **Qualification:**

Student No: **Professional Registration Number:**

Postal Address:

Telephone: **Fax:** **e-mail:**

II. TITLE OF PROJECT

III. SIGNATURES

The undersigned acknowledge that:
1. This application represents an accurate and complete description of the proposed research;
2. The research will be conducted in compliance with the recommendations of and only after written approval has been received from the HWS-REC;
3. The principal investigator is responsible for reporting any serious adverse events or problems to the HWS-REC;
4. HWS-REC approval will be requested for any modifications; and
5. A status report (HWS-REC 4.2) must be submitted if an extension is required beyond the period of approval.

A. Investigator: _____
Type Name and Sign ***Date***

B. Supervisor/s: (for student research)_____
Type Name and Sign ***Date***

_____
Type Name and Sign ***Date***

C. Head of Department: _____
Type Name and Sign ***Date***

_____ _____ Approved ☐ Not Approved ☐

HWS-REC SIGNATURE DATE

Subject to the following conditions: _____

_____

*Period of approval is one year, from _____ to _____

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

_____

IV. CO-INVESTIGATORS AND RESEARCH ASSISTANTS

Name: **Title:** **Position:**

Department: **Faculty:**

Professional Registration Number:

Postal Address:

Telephone: **Fax:** **e-mail:**

RESEARCH ASSISTANTS

Minimum qualifications needed:

Training to be given:

Supervision/Monitoring plan:

_____

V. INDICATE FUNDING SOURCES OR CONTRACT RELEVANT TO THIS APPLICATION

A. Type of proposal: ☐ Un-funded Research ☐ Contract

☐ CPUT student grant ☐ Subcontract ☐ Other, Specify ……..

B. Name of principal investigator:
C. Name of funding agency:
D. Agency's number (as assigned):
E. Title of proposal:

Does the researcher or any member of the research team have a financial interest in the research or its products?

☐ No ☐ Yes

If "yes", include documentation that this has been cleared.

VI. SUMMARY OF ACTIVITY

In lay language, provide a short description of the research goals and their significance.

A. BACKGROUND AND RATIONALE FOR THIS STUDY

Provide relevant background information and explain **in lay language** what research question(s) this activity is designed to answer.

B. METHODOLOGY

1. Provide a complete description of: a. the study design, and b. sequence and timing of all study procedures that will be performed, e.g. volume of blood, questionnaire. Provide this information for each phase of the study (pilot, screening, intervention and follow-up). Attach study flow sheet, if available.
   Use lay language.

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2. Would participants undergo these or similar procedures (medical, educational, etc.) if they were not taking part in this research?

   ☐ No ☐ Yes

   If "No", describe how the study procedures differ from what participants would otherwise undergo.

_____

C. PARTICIPANTS

1. How many participants will you need to complete this study?

   Number _____ Age range _____

_____

2. What are the inclusion criteria for participants in this study? Answer for each participant group, if these criteria are different.

_____

3. What are the exclusion criteria for participants who are otherwise eligible from this study? Answer for each participant group, if the criteria are different.

_____

4. Describe the participant recruitment strategies you will use for each group of participants.

_____

5. Explain participant recruitment and how this will be done to protect participants' privacy and identity.

_____

6. Explain what steps you will take during the recruitment process to minimize potential coercion or the appearance of coercion.

7. Will you give participants gifts, payments, services without charge, or extra course credit?

☐ No ☐ Yes

If "yes", explain:

8. Will any of the participants or third parties be charged for any procedures?

☐ No ☐ Yes

If "yes", explain:

9. Where will the study procedures be carried out? Attach letters of permission from all sites.

D. RISKS AND BENEFITS (participants, researchers, public etc.)

1. Describe the nature and degree of risk to **participants** through possible injury, stress, discomfort, invasion of privacy from all study procedures. Include psycho-social risks as well as physiological risks.

2. Describe the nature and degree of risk to the **researcher/s, research assistants, members of the public,** etc. through possible injury, exposure to hazardous substances or organisms etc.

3. Explain what steps you will take to minimize risks of harm and to protect the rights and welfare of participants and all persons affected by this research. Please identify the group(s) and answer this question for each group.

_____

4. Describe the anticipated benefits of this research for individual participants in each participant group. If none, state "None."

_____

5. Describe concisely the anticipated benefits of this research for society, and explain how the benefits outweigh the risks.

_____

E. ADVERSE EVENTS OR EFFECTS

Who will handle adverse events?

☐ Investigator ☐ Referral ☐ Other, elaborate:

_____

F. CONFIDENTIALTY OF RESEARCH DATA

1. Will you retain any direct identifiers (names, patient, hospital, addresses, telephone numbers, etc.)?

☐ No ☐ Yes

If "yes", explain why this is necessary.

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2. Will you retain a link between study code numbers and direct identifiers?

☐ No ☐ Yes

If "yes", explain why this is necessary and for how long you will keep this link.

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3. Describe how you will protect data against disclosure to the public or to the other researchers or non-researchers.

   a. Explain who will have access to data.

   b. Describe the data protection procedures (password protected computers, locked files in locked rooms, etc.) that you will put in place to protect the study data from inadvertent disclosure.

   c. Identify any group, which will have access to identifiable data, and explain why the group has such access. This information should be included in the "Other Information" section of the consent form.

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4. Will you place a copy of the consent form or other study information in the participant's medical or other personal record?

   ☐ No ☐ Yes

   If "yes", explain why this is necessary.

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5. Do you anticipate using any **data** (information, specimens, etc.) from this study for other studies in the future?

   ☐ No ☐ Yes

   If "yes", explain and include this information in the consent form.

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6. Will feedback be given to participants?

   ☐ No ☐ Yes

   Briefly describe how feedback will be given.

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7. Will you need access to participants' medical, academic or other personal records for screening purposes or any other purpose during the course of this study?

☐ No ☐ Yes

If "yes", specify types of records, what information you will take from the records, and how you will use them.

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8. Will you make audio-visual or tape recordings or take photographs of participants?

☐ No ☐ Yes

If "yes", explain what type of recordings you will make, how long you will keep them, and if anyone other than the researcher will be able to see them.

G. EQUIPMENT

Will your study involve use of equipment?

☐ No ☐ Yes

If yes, describe safety testing and quality control procedures you will use to ensure participant safety.

H. ADDITIONAL INFORMATION

Give any additional information relevant to this application.

I. CONSENT FORMS

☐ **Written**
Attach copies of all consent and assent forms for each participant group

☐ **Oral**
Attach written scripts of oral consent and assent for each participant group

☐ **Waiver**
Attach written justification of waiver of consent

J. DRUGS, SUBSTANCES AND DEVICES

1. List **all** drugs or other substances used to conduct this research. Include products used for standard clinical care if they are used in this study for research purposes.

Name	Source	Dose	How administered

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2. Provide copies of a concise summary of drug information prepared by the investigator with this application.

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3. List all investigation devices you will use. Provide information as requested below.

a. Name of the device

b. Name of the manufacturer

c. Description of its purpose and how you will use it in this study

d. Description of previous studies in humans and animals