CAPE PENINSULA UNIVERSITY OF TECHNOLOGY
Institutional Ethics Review Board (IERB)

HUMAN PARTICIPANTS' REVIEW APPLICATION
Researchers not affiliated to a faculty or external to CPUT

This application to the Institutional Ethics Review Board (IERB) must be preceded by permission from CPUT Executive Management for the data collection to take place.

Questions to guide and Documents required this application:

Do you have approval from or have you applied to another Ethics Committee?

- Provide evidence of all other Research Ethics applications/approval.

Has your full proposal been approved by a Research Committee of CPUT?

- Provide evidence.

The IERB must receive a scanned/electronic copy of:

- Evidence of permission from the institution (Prof A Staak)
- evidence from departments that will be data collection sites or cput staff who will offer research assistance that they are able to respond to the request
- completed, signed application form
- research proposal
- relevant accompanying documentation (i.e. consent forms, questionnaire, instruments, data collection sheets, etc.)

Send to:
jantjieslg@cput.ac.za and engelhillsp@cput.ac.za

Note:

- The application should be typed directly onto the electronic version.
- All information requested must be provided.
- Applications will be forwarded to the relevant Faculty Research Ethics Committee at CPUT for review at the earliest possible meeting

I. PRINCIPAL INVERSTIGATOR'S DETAILS

This is the primary researcher who has ultimate authority for the study and in whose name the application is filed. All correspondence from the IERB-REC will be directed to this person.

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

Institution: **Department:**

Postal Address:

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

II. TITLE OF PROJECT:

Provide a concise, descriptive title. Title must be the same as the title of your proposal.

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III. SIGNATURES:

Principal investigator to sign and date the application on Line A., supervisor (in the case of student research) on Line B, and Head of Department on Line C. One copy must contain original signatures (or scanned signatures on electronic copy).

The undersigned acknowledge that: 1. this application represents an accurate 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 CPUT, 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 to approve any modifications and, 5. a status report (HWS-REC 4.2) will be submitted if an extension is required beyond the period of approval.

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

B. Supervisors:(for student research)_____
Type Name and Sign ***Date***

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

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

IV. CO-INVESTIGATORS

Provide all the information requested for each co-investigator. Primarily this means all researchers who will have contact with human participants and will perform study procedures with them. Add sections as necessary. This is the place to show if you are part of a larger research project. This is not meant to include consultants, laboratory technicians, or others who perform consulting or analysis services. Indicate if the co-investigator/s is/are registered with a regulatory body e.g. the Health Professions Council of South Africa (HPCSA), Nursing Council etc.

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

Department: **Faculty:**

Professional Registration Number:

Postal Address:

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

RESEARCH ASSISTANTS

Provide all the information requested for research assistants linked to this study. This information is generic to all research assistants and not necessarily specific to individuals. Primarily this means all research assistants who will have contact with human participants and will perform study procedures with them.

Minimum qualifications needed:

Training to be given:

Supervision/Monitoring plan:

V. INDICATE FUNDING SOURCES OR CONTRACT RELEVANT TO THIS APPLICATION.

This section asks for funding sources, which support the research activity. Include as many funding sources as are relevant to the activity. Explain what kind of funding mechanism is involved, the name of the principal investigator (this may be different from the listed investigator on the HWS-REC application), the name of the agency to which the proposal was submitted, the reference number (if the agency has assigned one), the title of the proposal submitted (this may be different from the title on the HWS-REC application), the proposed dates of funding.

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

☐ Subcontract ☐ Other, Specify ……..

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

VI. SUMMARY OF ACTIVITY.

This selection should include a short description of the research environment and purpose that is sufficient to provide Committee members with a context in which to review the activity. Because the Committee includes non-scientists as members, please avoid technical terms and jargon. Do not reference the pages of an accompanying research proposal.

A. BACKGROUND AND PURPOSE OF RESEARCH.

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

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B. RESEARCH PROCEDURES INVOLVED.

The purpose of this section is to provide the reviewers with information on the research methods and sequence of activities.

In the second part, the Committee wants to know how the study procedures compare with what would usually happen to a participant. This is most relevant when participants are patients, but it could also be important when participants are students or clients receiving a service

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). **Use lay language**. Attach study flow sheet, if available.

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

☐ Yes ☐ No

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

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C. PARTICIPANTS

Committee members will use this information to analyze the risks and benefits of the activity.

1. How many participants will you need to complete this study?
Number _____ Age range _____

_____

Information on inclusion and exclusion criteria is used to assess equitability and safety of participant selection.

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

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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.)

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Explain how you will recruit each group of participants (for example, from a clinic practice, from a certain school, company, from members of a club or organization). Provide examples of the flyers, letters to physicians, etc., that you will use.

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

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*Explain who will be recruiting participants and how participants will be approached to participate in the study. Provide a **letter of support** from non-University agencies indicating approval of the project.*

5. Explain who will approach participants to take part in the study and how this will be done to protect participants' privacy and identity. Attach letters of cooperation from agencies, institutions or others involved in participant recruitment.

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Include an explanation of how the investigator will insure the participants will feel free to decline participation and are not coerced into participating in the study.

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

_____

If participants will receive payments, service, extra course credit etc. explain why thisis necessary and not coercive.

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

☐ No ☐ Yes

If yes, explain:

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Explain what charges, if any, participants or third parties (including government agencies) will be asked to bear. If the study is of no benefit to participants, include a justification of why participants should be asked to bear these costs.

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

☐ No ☐ Yes

If 'yes', explain:

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Include a statement of the site(s) at which the study will take place (for example, University Hospital, Symphony High School). The site will be assessed for both safety and appropriateness and to determine if other approvals are necessary.

9. Where will the study procedures be carried out? (Attach letters of cooperation from sites, if necessary.)

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

It is important for the committee to understand the researcher's view of the possible risks due to this study.

1. Describe the nature and degree of risk to participants through possible injury, stress, discomfort, invasion of privacy, and other side effects from all study procedures, drugs and devices (standard and experimental), interviews and questionnaires. Include psycho-social risks as well as physiological risks. Include risks if standard care or procedures are being withheld.

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

The Committee's charge is to make sure that the researcher has minimized the risks of harm (physical, emotional, economic, etc.) and taken steps to protect the rights and welfare of participants, researchers and all persons who may be affected by this research. For vulnerable groups (i.e. minors, prisoners, fetuses in utero, pregnant woman, decisionally impaired, or economically or educationally disadvantaged participants etc.) the Committee would like to see evidence that the researcher recognizes the special needs of these groups and has taken steps to reduce the possibility of damage to their rights and welfare.

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

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Describe concisely and realistically the benefits of the proposed study for participants (if none, state this), and for society.

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

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The Committee must determine that the risk of harm to individual participants is out-weighted by the potential benefit for society, especially if there is little or no potential benefit for the participants themselves.

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

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E. ADVERSE EVENTS OR EFFECTS

Who will handle adverse events? ☐ Investigator ☐ Referral ☐ Other, explain:

Provide an explanation of how the investigator will handle adverse events that might result from the study both immediately and in the future, if relevant. If the investigator will handle all possible adverse events, the Committee must determine that the investigator has these capabilities. If the research team will handle some adverse events, and refer others, this should be explained.

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F. CONFIDENTIALTY OF RESEARCH DATA

Ideally, researchers retain no direct participant identifiers. Sometimes, however, it is necessary for researchers to retain identifiers in order to conduct longitudinal studies or to link data from one data set to another. If this is necessary, provide an explanation

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

   ☐ No ☐ Yes

   If yes, explain why this is necessary.

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*Data which will be kept confidential should be coded using a **study code**. If data are coded, a **master list** linking the data to individual participants should be maintained securely and separately from the data. All data should be identified only with the code number, and not with the identifier.*

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. Explain who will have access to data. 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. Identify any group, which will have access to identifiable data, and explain why the group has such access.

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If you anticipate using data collected for this study in the future, include a description of the possible future uses in the consent form. Depending on the specificity with which you are able to describe future uses, the degree of similarity between the current and future use, and whether the data will be linkable to participant identifiers, the Committee may or may not allow the consent obtained for this study to apply to future studies.

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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G. ADDITIONAL INFORMATION

1. Will you need access to participants’ medical, academic or other personal records for screening purposes or during 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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If audio-visual or tape recordings (videos, photographs, movies, or voice recordings) are study procedures, check “yes.” If the recordings will be shared in any way (through publications, presentations, or classroom use) with anyone who is not a member of the investigating team, participants should be offered the opportunity to review the recordings and to delete any portions, insofar as possible the identity of the participants should be obscured in the recording.

2. Will you make audio-visual or tape recordings or 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.

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Investigators must describe the methods for insuring that equipment is safe for use with human participants.

3. 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.

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Researchers with a financial interest in the research must go through a disclosure procedure. If this situation applies to you or members of your research team, please provide the Committee with documentation that the Faculty Research Committee has cleared all conflicts of interest.

4. 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 documentations that this has been cleared.

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H. CONSENT FORMS

Standard procedure is that research participants should provide documentation of informed consent through a written and signed consent form. If there is good reason why this approach should be different in your study, provide the relevant information and include an example of how consent will be obtained. For instance, if you are requesting that consent be obtained orally, provide an explanation of why ***oral consent*** *is appropriate, and include an example of the statement, which will be read to participants. In most cases in which consent is obtained orally, participants should be provided with a written* ***information statement****, which includes all of the elements of informed consent except the signature of the participant. If you are requesting that informed consent be waived, attach an explanation of why this is appropriate.*

Consent documents should be prepared for each group of participants in the study. ***Assent forms*** *should be prepared for minors appropriate to their ages, and consent form(s) for parents or legal guardians should also be prepared. For children too young to comprehend a simple explanation of participation, parental consent is sufficient only if the research will provide direct benefit to the participant, a member of the participant's family, or other children with the same condition as the participant.*

Language used in the consent form should be appropriate for the intended group. Avoid medical or scientific jargon. Use short words and short sentences.

☐ **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)
