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Approved

Response to Modifications

7 March 2018

Project ID #: 1841

HREC/UREC Reference #: U17/10/053

Title**:** Mobility Transition in Older Adults in Worcester using an Occupational Lens

Dear Miss Kay De Villiers

The **Response to Modifications** received on 3 March 2018 was reviewed by members of the **Undergraduate Research Ethics Committee (UREC)** via Minimal Risk Review procedures on 6 March 2018 and was approved.

Please note the following information about your approved research protocol:

Protocol Approval Period: This project has approval for 12 months from the date of this letter.

Please remember to use your HREC/UREC reference number (U17/10/053) on any documents or correspondence with the HREC/UREC concerning your research protocol.

Translation of the consent document/s to the language applicable to the study participants should be submitted.

Please note that this decision will be ratified at the next HREC full committee meeting. HREC reserves the right to suspend approval and to request changes or clarifications from student applicants. The coordinator will notify the applicant (and if applicable, the supervisor) of the changes or suspension within 1 day of receiving the notice of suspension from HREC. HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

After Ethical Review:

Please note a template of the progress report is obtainable on https://applyethics.sun.ac.za/Project/Index/2023 and should be submitted to the Committee before the year has expired. The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.

Provincial and City of Cape Town Approval

Please note that for research at a primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms Claudette Abrahams at Western Cape Department of Health (healthres@pgwc.gov.za Tel: +27 21 483 9907) and Dr Helene Visser at City Health (Helene.Visser@capetown.gov.za Tel:+27 21 400 3981). Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.

For standard HREC forms and documents please visit: https://applyethics.sun.ac.za/Project/Index/2023

If you have any questions or need further assistance, please contact the HREC office at 021 938 9677.

Sincerely,

Debbie Marais

UREC Coordinator

Undergraduate Research Ethics Committee

Federal Wide Assurance Number: 00001372

Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2015 (Department of Health).

INVESTIGATOR RESPONSIBILITIES

Protection of Human Research Participants

Some of the responsibilities investigators have when conducting research involving human participants are listed below:

- Conducting the Research: You are responsible for making sure that the research is conducted according to the HREC approved research protocol. You are also responsible for the actions of all your co-investigators and research staff involved with this research.
- Participant Enrolment: You may not recruit or enrol participants prior to the HREC approval date or after the expiration date of HREC approval. All recruitment materials for any form of media must be approved by the HREC prior to their use. If you need to recruit more participants than was noted in your HREC approval letter, you must submit an amendment requesting an increase in the number of participants.
- Informed Consent: You are responsible for obtaining and documenting effective informed consent using **only** the HREC approved consent documents, and for ensuring that no human participants are involved in research prior to obtaining their informed consent. Please give all participants copies of the signed consent documents. Keep the originals in your secured research files for at least fifteen (15) years.
- Continuing Review: The HREC must review and approve all HREC approved research protocols at intervals appropriate to the degree of risk but not less than once per year. There is **no grace period**. Prior to the date on which the HREC approval of the research expires, **it is your responsibility to submit the continuing review report in a timely fashion to ensure a lapse in HREC approval does not occur.** If HREC approval of your research lapses, you must stop new participant enrolment, and contact the HREC Office immediately.
- Amendments and Changes: If you wish to amend or change any aspect of your research (such as research design, interventions or procedures, number of participants, participant population, informed consent document, instruments, surveys or recruiting material), you must submit the amendment to the HREC for review using the current Amendment Form. You **may not initiate** any amendments or changes to your research without first obtaining written HREC review and approval. The **only exception** is when it is necessary to eliminate apparent immediate hazards to participants and the HREC should be immediately informed of this necessity.
- Adverse or Unanticipated Events: Any serious adverse events, participant complaints, and all unanticipated problems that involve risks to participants or others, as well as any research-related injuries, occurring at this institution or at other performance sites must be reported to the HREC within **five (5) days** of discovery of the incident. You must also report any instances of serious or continuing problems, or non-compliance with the HREC's requirements for protecting human research participants. The only exception to this policy is that the death of a research participant must be reported in accordance with the Stellenbosch University Health Research Ethics Committee Standard Operating Procedures www.sun25.sun.ac.za/portal/page/portal/Health_Sciences/English/Centres%20and%20Institutions/Research_Development_Support/Ethics/Application_package. All reportable events should be submitted to the HREC using the Serious Adverse Event Report Form.
- Research Record Keeping: You must keep the following research-related records, at a minimum, in a secure location for a minimum of fifteen years; the HREC approved research protocol and all amendments; all informed consent documents; recruiting materials; continuing review reports; adverse or unanticipated events; and all correspondence from the HREC.
- Reports to the MCC and Sponsor: When you submit the required annual report to the MCC or you submit a required report to your Sponsor, you must provide a copy of that report to the HREC. You may submit the report at the time of continuing HREC review.
- Provisions of Emergency Medical Care: When a physician provides emergency medical care to a participant without prior HREC review and approval, to the extent permitted by law, such activities will not be recognized as research nor will the data obtained by any of such activities be used in support of research.
- Final Reports: When you have completed (no further participant enrolment, interactions, interventions or data analysis) or stopped work on your research, you must submit a Final Report to the HREC.
- On-Site Evaluations, MCC Inspections, or Audits: If you are notified that your research will be reviewed or audited by the MCC, the Sponsor, any other external agency or any internal group, you must inform the HREC immediately of the impending audit/evaluation.