UNIVERSITY OF THE FREE STATE
UNIVERSITEIT VAN DIE VRYSTAAT
YUNIVESITHI YA FREISTATA
UFS HEALTH SCIENCES

HEALTH SCIENCES RESEARCH ETHICS COMMITTEE

INVESTIGATOR DECLARATION

Note: The principal investigator, supervisor, as well as all sub- & co-investigators (where applicable) must sign this declaration.

This application will not be processed unless all the required declarations and signatures are completed in wet ink or legal digital signatures. Cut and paste signatures will not be accepted.

1.1 INVESTIGATOR DETAILS AND ROLE IN THIS RESEARCH	
Title, Initials, Surname:	
Department:	
Institution:	
Phone:	
E-mail address:	

1.2 What is your role in this research? [✓]			
Principal investigator	☐	Co-investigator	☐
Sub-investigator	☐	Supervisor	☐
Other: Specify			☐

PROJECT TITLE *(maximum 250 characters for database purposes)*

2. STATEMENT OF CONFLICT OF INTEREST

The **Principal Investigator** is expected to declare any existing or potential conflict of interest that may affect the scientific integrity and ethical conduct of this research. For purposes of this section, 'immediate family' means the Principal Investigator's spouse or domestic partner and dependent children.	
Conflict of interest statement: Please tick ✓ all that apply.	
Neither I, nor any member of my immediate family, nor any member of the research team, have any interest related to this research (e.g. financial interest in the sponsor of the research or intervention being tested.)	☐
Neither I, nor any member of my immediate family, nor any member of the research team, have a proprietary interest in the product being tested in this research (e.g. patent, trademark, copyright, licensing agreement).	☐
Neither I, nor any member of my immediate family, nor any member of the research team, have any relationships related to this research (e.g. board membership, consultative, executive, employment) or any entity with an ownership interest in the research other than the relationship of sponsor-investigator.	☐
As Principal Investigator of this research, **I am aware of a potential conflict of interest**. Please describe and provide a plan to manage the conflict of interest in the space below:	☐

3. PROTECTION OF PARTICIPANT PERSONAL INFORMATION

Each investigator is responsible for ensuring that every reasonable measure is taken to protect the participants' personal information.	
The investigators all commit to do the following:	**Please tick ✓ all that apply.**
This research does not process any personal information *In this case, the following questions in this section do not need to be answered*	☐
To manage and process personal information as specified in the protocol and data management plan	☐

In the case of personal information all data will be: ◯ Pseudoanonymised ◯ De-identified ◯ Anonymised ◯ Identifiable ◯ None of the above	
To only process the data for the purposes for which it was collected as specified in the protocol	☐
Not to share any data with any party other than the parties specified in the protocol and data management plan	☐
To only keep the data on a secure POPIA compliant password-protected platform, namely _____	☐
If applicable: to destroy the research data after _____ years (Refer to the Research Data Retention Plan HSREC Version 01 June 2022 and insert the applicable number of years). Alternatively, only the de-identified / pseudoanonymised / anonymous data will be kept securely on a UFS server, namely _____ where it can be made available to researchers who have applied to use the data for a similar project. Source data must not be destroyed.	☐
To notify the HSREC (and participants if necessary) if there is any breach in the security of any research data	☐
To comply with any corrective measures as recommended by the HSREC in the case of a breach of security of research data	☐
To nominate an investigator who will be ultimately responsible for all elements related to the processing of personal information, namely _____ *In the case of undergraduate and honours students, it is recommended that this person is the supervisor*	☐

4. DECLARATIONS AND SIGNATURES

4.1 Principal investigator

My signature confirms that:

1. Information in this application is true and accurate.
2. I will begin the research only after written HSREC approval is obtained.
3. I accept full responsibility for the conduct of this research and the protection of participants' rights and welfare.
4. I will conduct the research according to all ethical, regulatory and legal requirements stipulated in the HSREC's Standard Operating Procedures.
5. I will provide progress reports to the HSREC as requested, including a final closing report at the end of the research.
6. I will notify the HSREC in writing if any change to the research is proposed and await approval before proceeding with the proposed change except when urgently necessary to protect participants' safety.
7. I will notify the HSREC in writing immediately if any adverse event or unanticipated problem occurs during the research.
8. I will allow an audit of my research if requested by the HSREC.
9. I have the time, training, experience and resources to oversee this research.
10. I will endeavour to publish and disseminate the findings of the study.
11. I acknowledge and concur with all the points under the PROTECTION of PARTICIPANT PERSONAL INFORMATION as above.
12. In the case of a database/registry/repository: I understand that no research activities or export of data from this database/registry/repository may occur without a protocol for each separate study to follow out of the database/registry/repository has been submitted and approved by the HSREC.

Signature of Principal Investigator		Date	
Print full name			

4.2 Student Main Supervisor (if research is for a qualification) ☐ N/A

My signature confirms that:

1. The application is ready for submission for ethical clearance.
2. Information in this application is true and accurate.
3. The student researcher has adequate training and resources to complete the research in the allocated timeframe.
4. The research has scholarly merit.
5. The level of risk inherent in the study is commensurate with the student researcher's experience and the extent of oversight that I will provide.
6. I have time, training, experience and resources to oversee this research.
7. I will meet the student on a regular basis to monitor progress and address any problems that may arise during the study.
8. I will ensure that the research undergoes continuing review as required by the HSREC, including annual progress reports, protocol amendments and a final closing report at the end of the research.
9. I will ensure that no research is done prior to final written approval from the HSREC and that should amendments be made to await HSREC approval before proceeding with the proposed changes except when urgently necessary to protect participants' safety.
10. If applicable, I will ensure that I report unanticipated problems or serious adverse events to the HSREC.
11. I will arrange for an alternative faculty supervisor to take responsibility for this research during periods of absence such as sabbatical or annual leave.
12. I acknowledge and concur with all the points under the PROTECTION of PARTICIPANT PERSONAL INFORMATION as above.

Name		Signature		Date	

4.3 Co-supervisor(s) ☐ N/A

My/our signature(s) confirm that:

1. Information in this application is true and accurate.
2. I/we will begin the research only after final HSREC approval is obtained.
3. I/we accept full responsibility for the conduct of this research and the protection of participants' rights and welfare.
4. I/we will conduct the research according to all ethical, regulatory and legal requirements as stipulated in the HSREC's Standard Operating Procedures.
5. I acknowledge and concur with all the points under the PROTECTION of PARTICIPANT PERSONAL INFORMATION as above.

Name		Signature		Date	
Name		Signature		Date	

4.4 Collaborating Investigator(s) ☐ N/A

My/our signature(s) confirm that:

1. Information in this application is true and accurate.
2. I/we will begin the research only after HSREC approval is obtained.
3. I/we accept full responsibility for the conduct of this research and the protection of participants' rights and welfare.
4. I/we will conduct the research according to all ethical, regulatory and legal requirements as stipulated in the HSREC's Standard Operating Procedures.
5. I acknowledge and concur with all the points under the PROTECTION of PARTICIPANT PERSONAL INFORMATION as above.

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