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

UFS
HEALTH SCIENCES

HEALTH SCIENCES RESEARCH ETHICS COMMITTEE

DATABASE/REGISTRY/REPOSITORY DECLARATION

The applicant and collaborator(s) (where applicable) must sign this declaration.

1.1 APPLICANT'S DETAILS AND ROLE IN THIS DATABASE/REGISTRY/REPOSITORY			
Title, Initials, Surname:			
Department/Institution:			
Phone:			
E-mail address:			
1.2 WHAT IS YOUR ROLE IN THIS DATABASE/REGISTRY/REPOSITORY? [✓]			
Applicant	☐	Data manager	☐
Collaborator	☐	Collaborator	☐
Other: Specify			☐

DATABASE/REGISTRY/ REPOSTIORY TITLE *(maximum 250)*

2. STATEMENT OF CONFLICT OF INTEREST

The applicant and all collaborators are 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 applicant/collaborator's spouse or domestic partner and dependent children. **Please tick ✓ all that apply.**	
2.1 No conflict of interest declared:	
Neither I, nor any member of my immediate family, have any interest related to this database/registry/repository (e.g. financial interest in the sponsor of the database/registry/repository, or financial benefit from the data collected)	☐
Neither I, nor any member of my immediate family, have any relationships related to this database/registry/repository (e.g. board membership, consultative, executive, employment) or any entity with an ownership interest in the database/registry/repository.	☐

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2.2 Conflict of interest declared:	☐ N/A
As applicant of this database/registry/repository **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 applicant/collaborator is responsible to ensure that every reasonable measure is taken to protect the participants' personal information.	
The applicant and collaborators all commit to do the following:	
Please tick ✓ all that apply.	
To deidentify data as specified in the application	☐
To only process deidentified personal data (unless otherwise specified in the application)	☐
To only process the data for the purposes for which it was collected as specified in the application	☐
Not to share any data with any party other than the parties specified in the application	☐
To only keep the data on a secure password protected platform, namely _____	☐
To destroy data after _____ years / months (select appropriate, or delete if inappropriate)	☐
To notify the HSREC (and participants if necessary) if there is any breach in the security of any data in the database/registry/repository	☐
To comply with any corrective measures as recommended by the HSREC in the case of a breach of security of data in the database/registry/repository	☐
To nominate a person who will act as the data manager and who be ultimately responsible for the deidentification, security, sharing and destruction of data, namely _____	☐

Database Research Investigator Declaration_v01   *Page **2** of **4***
Effective date: March 2022
Faculty of Health Sciences, University of the Free State

4. DECLARATIONS AND SIGNATURES

Note: This application will not be processed unless all the required declarations and signatures are completed.

4.1 Applicant

My signature confirms that:

 i. Information in this application is true and accurate.
 ii. I will begin the research only after written HSREC approval is obtained.
 iii. I accept full responsibility for the protection of participants' rights and welfare.
 iv. I will manage the data according to all ethical, regulatory and legal requirements stipulated in the HSREC's Standard Operating Procedures.
 v. I will provide an annual progress reports to the HSREC or as requested, including a final closing report at the close of the database/registry/repository.
 vi. I will notify the HSREC in writing if any change to the data collection process is proposed and await approval before proceeding with the proposed change except when urgently necessary to protect participants' safety.
 vii. I will notify the HSREC in writing immediately if any adverse event or unanticipated problem occurs related to the database/registry/repository.
 viii. I will not share or use any data in this database/registry/repository with any person/organization/body without HSREC approval.
 ix. I will allow an audit of my database/registry/repository if requested by the HSREC or any other ethical body.
 x. I have the time, training, experience and resources to participate in this database/registry/repository.
 xi. I acknowledge and concur with all the points under the PROTECTION of PARTICIPANT PERSONAL INFORMATION as above.

Signature of applicant		Date	
Print name			

Note: The applicant and all collaborators are all are jointly responsible for the ethical conduct of this database/registry/repository.

4.3 DATA MANAGER.	☐ N/A

My signature(s) confirm that:

 i. Information in this application is true and accurate.
 ii. I will begin collecting data upon HSREC approval.
 iii. I will adhere to the data management and data sharing plan as outlined in the application.
 iv. I will not share or use any data in this database/registry/repository with any person/organization/body without HSREC approval.
 v. I accept full responsibility for management of sharing of any data/specimen or other research material held in the database/registry/repository always considering the protection of participants' rights and welfare.
 vi. I will manage the data in this database/registry/repository according to all ethical, regulatory and legal requirements as stipulated in the HSREC's Standard Operating Procedures.
 vii. I acknowledge and concur with all the points under the PROTECTION of PARTICIPANT PERSONAL INFORMATION as above.

Name		Signature		Date	

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4.4 COLLABORATOR(s)	☐ N/A

My/our signature(s) confirm that:

   i. Information in this application is true and accurate.
  ii. I will begin the research only after written HSREC approval is obtained.
 iii. I accept full responsibility for the protection of participants' rights and welfare.
 iv. I will manage the data according to all ethical, regulatory and legal requirements stipulated in the HSREC's Standard Operating Procedures.
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  x. I have the time, training, experience and resources to participate in this database/registry/repository.
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Name		Signature		Date	
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Database Research Investigator Declaration_v01   *Page **4** of **4***
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