



University of Fort Hare
Together in Excellence

Health Research Ethics Committee

UFH HREC – University of Fort Hare Faculty Human Research Ethics Committee

(REC-100118-054)

MONITORING REPORT

Version: January 2022

CONFIDENTIAL! This document contains confidential information that is intended strictly and exclusively for the applicant and UFH HREC. Should this document or parts thereof erroneously come in to your possession, you are requested to destroy it or to return it to UFH HREC immediately. .

Please complete the form according to the following guidelines:

- All researchers need to complete Sections A and E.
- Section B is only completed if the research project is *quantitative* in nature.
- Section C is only completed if the research project is *qualitative* in nature.
- Section D is only completed if the researchers are making use of *previously collected biological samples or data*.

SUMMARY OF STUDY

Title of the study	Click or tap here to enter text.
Ethics Application number:	Click or tap here to enter text.
Project Leader/Principal Investigator	Click or tap here to enter text.
Student Details (Initials & Surname):	Click or tap here to enter text.

SECTION A: GENERAL INFORMATION AND PROGRESS

1. Study Supervisor details (if applicable)

Surname	Click or tap here to enter text.	Initials	Click or tap here to enter text.	Title	Click or tap here to enter text.
Department	Click or tap here to enter text.				
E-mail	Click or tap here to enter text.				
Telephone	Work	Click or tap here to enter text.	Cell	Click or tap here to enter text. Click or tap here to enter text.	

2. Student Details (if applicable)

Surname	Click or tap here to enter	Initials	Click or tap here to	Title	Click or tap here
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	text.		enter text.		to enter text.
Department	Click or tap here to enter text.				
E-mail	Click or tap here to enter text.				
3. Details of approved proposal/protocol					
Title	Click or tap here to enter text.				
Ethics Approval Number	Click or tap here to enter text.	Risk level	Click or tap here to enter text.		
Approval date	Click or tap here to enter text.	Expiry date	Click or tap here to enter text.		
Are there any sub-studies/affiliated studies linked to this project?		Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
If YES, please indicate titles of the sub-study/affiliated study below and mark whether a report has been submitted.					
Titles of sub-studies/affiliated studies		Students/researchers included		Report in? (Please attach)	
				Yes	No
Title of sub-study/affiliated study.		Students/researchers included		<input type="checkbox"/>	<input type="checkbox"/>
Title of sub-study/affiliated study.		Students/researchers included		<input type="checkbox"/>	<input type="checkbox"/>
Title of sub-study/affiliated study.		Students/researchers included		<input type="checkbox"/>	<input type="checkbox"/>

4. Funding details (Where do you receive your funding from? Please mark with an X)					
Internal	<input type="checkbox"/>	National (NRF/MRC)	<input type="checkbox"/>	NIH/US Gov	<input type="checkbox"/>
Industry	<input type="checkbox"/>	International grant	<input type="checkbox"/>	Self	<input type="checkbox"/>
				Yes	No
Were you able to fund your project as initially intended?				<input type="checkbox"/>	<input type="checkbox"/>
If not, please indicate here in what way it has changed:				<input type="checkbox"/>	<input type="checkbox"/>

5. Summary of progress to date	
Shortly describe the overall progress to date of the project (500 words): Click or tap here to enter text.	
Please describe any ethical issues (both minor and/or major) that may have arisen during the past year (500 words): Click or tap here to enter text. Click or tap here to enter text.	
Describe the research monitoring approach you followed:	

Click or tap here to enter text. Click or tap here to enter text.			
	Yes	No	N/A
<p>Has the level of risk to the participants changed during the past year? If yes, please explain here (new level, reason, how UFH HREC was notified): Click or tap here to enter text.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Has any new conflict of interest occurred during the past year? If yes, please explain here: Click or tap here to enter text.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>Have the research records produced (both hard and soft copies) been correctly maintained and secured as stated in the application? Please explain your system here: Click or tap here to enter text.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>If the UFH HREC has provided <i>provisional approval</i> for your project, have you fulfilled the conditions of the provisional approval. Please give greater detail regarding the manner in which you <i>have/have not</i> adhered to the conditions of provisional approval provided by the ethics committee: Click or tap here to enter text. Click or tap here to enter text.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. Adverse events/Serious adverse events/Incidents (if applicable)	Yes	No	N/A
<p>Have there been any adverse events/serious adverse events/incidents in the project during the past year? Please give the following for each of the adverse events/serious adverse events/incidents that occurred: the date, a narrative overview, how it was managed and how the UFH HREC was notified. 1) Click or tap here to enter text. 2) Click or tap here to enter text. 3) Click or tap here to enter text.</p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<p>If a data safety monitoring board was part of your planned research have they evaluated the adverse events/serious adverse events/incidents? <i>If yes, please attach a copy of the report.</i></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7. External monitoring (if applicable)	Yes	No	N/A
<p>Has the study been externally monitored or audited e.g. SAHPRA, FDA? If yes, please indicate the name of the agency: Click or tap here to enter text. <i>Please attach a copy of the report.</i></p>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SECTION B: QUANTITATIVE STUDIES

8. Enrolment of participants	
Total number of participants planned to be included in the project.	Insert
Actual number of participants enrolled in the project.	Insert
Number of participants that withdrew from the project out of own choice. Please provide reasons here for participants' withdrawal: Click or tap here to enter text.	Insert
Number of participants withdrawn by primary investigator, due to adverse events/serious adverse events/incidents/other reasons. Please provide reasons here for these withdrawals: Click or tap here to enter text.	Insert
Number of participants lost to follow-up (if appropriate). Please explain here why they were lost: Click or tap here to enter text.	Insert

SECTION C: QUALITATIVE ANALYSES

9. Methods used			
How many participants have been enrolled to date?	Click or tap here to enter text. Click or tap here to enter text.		
	Yes	No	N/A
Has data saturation been reached in this project?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Please give an overview of the methodology used to determine the indicated data saturation: Click or tap here to enter text. Click or tap here to enter text.			
Number of participants that withdrew from the project out of own choice. Please provide reasons for participants' withdrawal:	Click or tap here to enter text. Click or tap here to enter text.		
Number of participants withdrawn by the primary investigator due to adverse events/serious adverse events/incidents/other reasons. Please provide reasons for these withdrawals: One companion did not stay with the birthing woman throughout childbirth. One companion did not stay with the birthing woman throughout childbirth.	Click or tap here to enter text. Click or tap here to enter text.		
Number of participants lost to follow-up (if appropriate). Please explain why they were lost: Click or tap here to enter text.	Click or tap here to enter text. Click or tap here to enter text.		

SECTION D: USE OF PREVIOUSLY COLLECTED BIOLOGICAL SAMPLES OR DATA

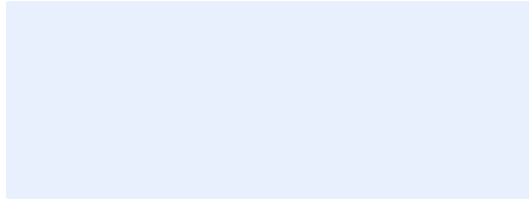
10. Biological sample analysis	
Total number of previously collected samples that were planned to be used.	Insert
How many actual samples have been examined?	Insert

11. Databases	Yes	No	N/A
Was the database you received anonymised? Describe the process: Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Was the database you received password protected?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

SECTION E: PROJECT AMENDMENTS AND STUDY STATUS

12. Amendments	Yes	No	N/A
Has the study been amended or changed during the past year?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Amendments	Date		
Click or tap here to enter text.	Click or tap to enter a date.		
Click or tap here to enter text.	Click or tap to enter a date.		

13. Status of study	Yes	No	N/A
Has the study been completed and does this serve as your final report?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has this project been terminated? If so, please indicate the date, reason for termination and when the UFH HREC was notified: Click or tap here to enter text.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the project have to continue in the following year?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

14. Signature			
By signing this document, I certify that the information provided is accurate and complete.			
Signature by the primary investigator		Date	Click or tap to enter a date.

Some sections of this document have been adapted from similar HREC documentation of the North West University, University of Stellenbosch and the University of the Cape Town.

