NWU-EMELTEN-REC MONITORING REPORT

The Faculty of Health Sciences Ethics Office of the North-West University is acknowledged for the use of their document with minor adjustments by the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC).

Please complete the form according to the following guidelines:

- *All researchers* need to complete Sections A and D.
- 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.

SUMMARY OF STUDY	
Title of the study	
Ethics Application number:	**NWU-**
Project Leader/Principal Investigator/Study Leader:	
Student Details (Initials & Surname):	

SECTION A: GENERAL INFORMATION AND PROGRESS

1. Project Head/Principal Investigator/Study leader Details

Surname		**Initials**		**Title**	
Department					
E-mail					
Telephone	**Work**		**Cell**		

2. Student Details

Surname		**Initials**		**Title**	
Department					
E-mail					

3. Details of approved proposal/protocol						
Title						
Ethics Approval Number			**Risk level**			
Approval date			**Expiry date**			
Are there any sub-studies/affiliated studies linked to this project?	**Yes**		**If yes, please indicate titles of the sub-study/affiliated study below and mark whether a report has been submitted.**			
	No					
Titles of sub-studies/affiliated studies			**Students/researchers included**		**Report in? (Please attach)**	
					Yes	**No**

4. Funding details (Where do you receive your funding from? Please mark with an X)					
Internal		**National (NRF)**		**Other (Please explain)**	
Industry		**International grant**		**Self**	

	Yes	**No**	**N/A**
Were you able to fund your project as initially intended? **If not, please indicate here in what way it has changed:**			

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

	Yes	**No**	**N/A**
Has the level of risk to the participants changed during the past year? **If yes, please explain here (new level, reason, how the NWU-EMELTEN-REC was notified):**			

Has any new conflict of interest occurred during the past year? **If yes, please explain here:**			
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:**			
If the NWU-EMELTEN-REC, has provided *provisional approval* for your project, have you fulfilled the conditions of the provisional approval e.g. approval from the Department of Health, goodwill permission from the school principal etc. and provided the NWU-EMELTEN-REC with these? **Please give greater detail regarding the manner in which you *have/have not* adhered to the conditions of provisional approval provided by the ethics committee:**			

6. Adverse events/Serious adverse events/Incidents (if applicable)	**Yes**	**No**	**N/A**
Has 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: the date, a narrative overview, how it was managed and how the NWU-EMELTEN-REC was notified.** 1) 2) 3)			
If a data safety monitoring board was part of your planned research have they evaluated the adverse events/serious adverse events/incidents? **If yes, please attach a copy of the report.**			

7. External monitoring (if applicable)	**Yes**	**No**	**N/A**
Has the study been externally monitored or audited? **If yes, please indicate the name of the agency:** **Please attach a copy of the report.**			

SECTION B: QUANTITATIVE STUDIES	
8. Enrolment of participants	
Total number of participants planned to be included in the project.	
Actual number of participants enrolled in the project.	

Number of participants that withdrew from the project out of own choice. **Please provide reasons here for participants' withdrawal:**	
Number of participants withdrawn by principal investigator due to adverse events/serious adverse events/incidents/other reasons. **Please provide reasons here for these withdrawals:**	
Number of participants lost to follow-up (if appropriate). **Please explain here why they were lost:**	

SECTION C: QUALITATIVE STUDIES

9. Methods used

How many participants have been enrolled to date?	

	Yes	No	N/A
Has data saturation been reached in this project?			
Please give an overview of the methodology used to determine the indicated data saturation:			
Number of participants that withdrew from the project out of own choice. **Please provide reasons for participants' withdrawal:**			
Number of participants withdrawn by the principal investigator due to adverse events/serious adverse events/incidents/other reasons. **Please provide reasons for these withdrawals:**			
Number of participants lost to follow-up (if appropriate). **Please explain why they were lost:**			

SECTION D: PROJECT AMENDMENTS AND STUDY STATUS

10. Amendments	Yes	No	N/A
Has the study been amended or changed during the past year?			

Amendments	Date

11. Status of study	Yes	No	N/A
Has the study been completed and does this serve as your final report?			
Has this project been terminated? **If so, please indicate the date, reason for termination and when the NWU-EMELTEN-REC was notified:**			
Does the project have to continue in the following year?			

12. Signature			
By signing this document, I certify that the information provided is accurate and complete.			
Signature by the principal investigator		**Date**	

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

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