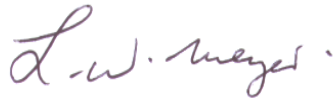
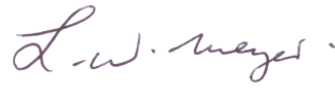


NWU-EMELTEN-REC

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

North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Office (NWU-EMELTEN-REC)		Standard Operating Procedure	
Title	SOP for monitoring and amendment of approved research studies		
SOP no	SOP_EMELTEN_Ethics_1.6	Version no	4
Date of approval	22 September 2017	Revision date	22 September 2021
Email address	Ethics-EMELTEN@nwu.ac.za	Page no	Page 1 to 15

1 COMPILATION AND AUTHORISATION

Action	Designated person	Signature	Date
Compiled by: Prof Minrie Greeff and amended by Prof Lukas Meyer	Prof Lukas Meyer		6 December 2016
Revised and Checked by:	EMHS-Research Ethics Office: Prof Lukas Meyer		1 December 2018 4 September 2019
Approved by:	NWU-EMELTEN-REC Chair: Prof Lukas Meyer		
	Faculty Board: Faculty of Education Chair:		
	SCRE Chair:		

Authorised by:	Chair of NWU-EMELTEN-REC: Prof Lukas Meyer		
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2 DISTRIBUTION

Department/Unit	Name	Signature	Date
Chairperson on behalf of NWU-EMELTEN-REC	Prof Lukas Meyer		
Deputy Deans: Research and Innovation			
NWU-EMELTEN-REC Administrator	Mrs Villera le Roux		

3 DOCUMENT HISTORY

Date	Version no	Reason for revision
06/12/2016	1	Formulated the SOP
7 May 2018	2	Changing old NWU Logo to new NWU Logo
1 December 2018	3	Changing committee's name EMHS-REC to NWU-EMELTEN-REC
4 September 2019	4	Revision of document

4 PURPOSE OF THE SOP

The purpose of this SOP is to provide researchers, the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Office (NWU-EMELTEN-REO) and the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC) with guidelines on the monitoring of approved studies and amendments.

5 SCOPE

5.1. Monitoring

the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC) has the right to monitor the research they approve. The National Health Research Ethics Council (NHREC) see this monitoring role of RECs as very important. The South African National Standard:

RECs may recommend and adopt any *additional appropriate mechanism* for monitoring, including:

- random (announced and unannounced) inspection of research sites;
- monitoring of data and signed informed consent documentation;
- monitoring of recorded individual interviews/focus groups;
- inspection that researchers adhere to SOPs and other approved research procedures;

- inspection of the scoring of welfare monitoring sheets (human);

The frequency and type of monitoring should reflect the *degree* and the *extent* of risk of harm to participants (adults and children).

Researchers should provide comprehensive and appropriate information to the NWU-EMELTEN-REC to facilitate the monitoring process.

Informed consent documentation should indicate to participants that such monitoring may take place during the research process.

5.2. Amendments

Researchers should inform and obtain approval of the NWU-EMELTEN-REC for *any* amendment to a proposal, informed consent documentation or other documentation before implementation thereof.

6 ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/definition	Description
NWU-EMELTEN-REC	North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee
NWU-EMELTEN-REO	North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Office
NHREC	National Health Research Ethics Council
SCRE	Senate Committee for Research Ethics
Monitoring	The process of ensuring that research conduct runs according to the NWU-EMELTEN-REC approved proposal by submitting and reviewing monitoring reports. It is also a system of granting researchers permission to continue with their research for a <i>further year</i> .
Passive monitoring	The submission of a monitoring report to the NWU-EMELTEN-REC as set out as terms during the review process. <i>For NWU-EMELTEN-REC:</i> <ul style="list-style-type: none"> • Minimal risk studies – annual report. • Medium risk studies - six monthly reports. • High risk studies - three monthly reports. <p>or for children and adults incapable of giving consent:</p> <ul style="list-style-type: none"> • No more than minimal risk of harm – annual report. • Greater than minimal risk but provides the prospect of direct benefit/high probability of providing significant generalizable knowledge – six monthly report. <p>The review of this monitoring report by the NWU-EMELTEN-REC followed by permission granted to continue the study for a further year.</p>
Active monitoring	Any additional appropriate mechanism for monitoring during the research conduct that the NWU-EMELTEN-REC deems necessary: <ul style="list-style-type: none"> • random inspection of research sites; • monitoring of data and signed informed consent documentation; • monitoring of recorded individual interviews/focus groups; • inspection that researchers adhere to SOPs and other approved research procedures;

Amendment	<p>Any change to the proposal, informed consent documentation or other documents while the research is in progress. NWU-EMELTEN-REC approval prior to implementation of such changes is essential. Changes could be minor or extensive in nature:</p> <ul style="list-style-type: none"> • Minor changes refer to e.g. sample size, community entry etc. • Extensive changes refers to a change in the total methodology e.g. changing from individual interview to focus groups.
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7 RESPONSIBILITIES

7.1. NWU-EMELTEN-REC responsibilities

NWU-EMELTEN-REC should request regular, *at least annual*, reports from researchers on matters including but not limited to:

- progress to date, or outcome in the case of completed research;
- current enrolment numbers;
- whether participant follow-up is still active or completed;
- information concerning maintenance and security of records;
- evidence of compliance with the approved proposal;
- evidence of compliance with any conditions of approval;
- list of adverse events in the past 12 months;
- list of amendments made in the past 12 months;
- list of sub-studies (if applicable).

NWU-EMELTEN-REC should inform researchers in *writing* of concerns arising from such monitoring activities or request clarification if uncertainties arise (see monitoring feedback letter).

NWU-EMELTEN-REC should grant researchers *written permission* to continue with their studies for a further year (see monitoring feedback letter). The date when the next monitoring report is due should be indicated clearly on the monitoring feedback letter.

7.2. Researcher's responsibilities

Researchers should provide NWU-EMELTEN-REC with detailed monitoring reports (comprehensive and appropriate information) for all studies approved by the NWU-EMELTEN-REC on the dates indicated to researchers during the approval process.

Note: Monitoring reports should be provided for all NWU-EMELTEN-REC approved studies of researchers and post-graduate students which includes sub-studies.

Researchers should inform NWU-EMELTEN-REC of any *incidents/adverse events* that occur during the research process (see Incident Report Form).

Researchers should request *amendments* to the proposal, informed consent documentation or other documentation before changes are implemented (SOP_EMELTEN_Ethics_v1.4).

8 PROCEDURE/S

8.1. Monitoring

The NWU-EMELTEN-REC keeps a database of all *active research studies* in the Faculty of Education, as well as other Faculties to whom they have granted ethics approval.

Note: Studies are granted a *one year approval only*. This date is clearly indicated on the ethics approval certificate.

Two months before a study's approval expires the administrator responsible for monitoring in the NWU-EMELTEN-REC sends a reminder to the researcher and attaches a copy of a monitoring

report (see attached) to be completed within *one week* of receiving the reminder. The latter is to ensure that permission to continue can be processed within a six week period as well as ratified during an EMHS-REC meeting.

The researcher completes the monitoring report and sends it to the administrator at Ethics-EMELTEN-mon@nwu.ac.za

The administrator forwards the monitoring report to the chairperson for his/her decision on which two NWU-EMELTEN-REC members will act as independent reviewers.

The chairperson sends the reviewer names to the administrator.

The administrator sends the completed monitoring reports to the allocated NWU-EMELTEN-REC members for review who then have three working days to review the report and return their comments to the administrator.

The administrator compiles an integrated report from the two reviews for the chairperson who then reviews the feedback and notifies the administrator of the final decision.

The administrator sends a monitoring feedback letter to the researcher indicating that the study:

- needs clarification on certain aspects;
- is suspended until certain aspects are clarified or corrected;
- is terminated on request of the researcher or the NWU-EMELTEN-REC;
- is completed;
- can continue for a further year (indicating the date of when the next monitoring report is due).

If *clarification*, *suspension* or *termination* is the option chosen, this process is handled by the chairperson and the administrator:

- Clarification - the administrator sends a monitoring feedback letter to the researcher indicating which aspects need clarification. The researcher has to provide the administrator with the requested clarification for the chairperson's perusal. Once resolved the study can continue.
- Suspension (temporary stoppage) - the researcher is notified by the chairperson that the research is temporarily suspended. An urgent meeting is called with the Executive Committee of the NWU-EMELTEN-REC and the researcher to discuss the concerns of the NWU-EMELTEN-REC and to find immediate solutions. The NWU-EMELTEN-REC can make recommendations or impose specific conditions. Once resolved the study can continue (see 8.2).
- Termination (permanent stoppage) - if the researcher requested the termination of the study the monitoring feedback letter will confirm this. If the NWU-EMELTEN-REC terminates the study, this is done after due process has been followed (see 8.2).

The decisions are ratified during the next NWU-EMELTEN-REC meeting.

8.2. Suspension or termination of studies

Where circumstances indicate that a project is non-compliant with the approved proposal and interest of the participants are at risk of harm or impact on human wellbeing exceeds what has been approved or can be justified, the NWU-EMELTEN-REC may withdraw approval, after due process has been followed (see 8.1).

A clear process should be followed that permits swift but proper investigation and decision-making to ensure protection of participants. This should include interaction with the researcher and other interested parties to ensure a fair and transparent process.

If a decision is to withdraw approval, the NWU-EMELTEN-REC should inform the researcher and other interested parties, including the SCRE (see 8.1).

It should also recommend *remedial actions* where appropriate.

In the case of suspension, the researcher should comply with the recommendations and/or conditions imposed by the NWU-EMELTEN-REC.

8.3. Amendments

NWU-EMELTEN-REC requires that researchers immediately report anything that might warrant *reconsideration of ethical approval* of the proposal, informed consent documentation or other documentation including but not limited to:

- serious or unexpected adverse effects on participants (SOP_EMELTEN_Ethics_v1.3);
- proposed changes to the proposal (SOP_EMELTEN_Ethics_v1.4);
- proposed changes to the informed consent documentation;
- proposed changes to the monitoring sheets of human wellbeing;
- Unforeseen events that might affect continued ethical acceptability of the project.

Researchers must seek approval for the amendment (SOP_EMELTEN_Ethics_v1.4 – Amendment application process) from Ethics-EMELTEN-apply@nwu.ac.za (for studies with human participants) *before the change can be implemented* and the study continues.

Note: If the nature of the amendment is *extensive* prior approval of the Scientific Committee must first be sought and proof provided to the NWU-EMELTEN-REC during the application for the amendment process.

As soon as the NWU-EMELTEN-REC receives a request for an amendment, the administrator sends the request through to the chairperson of the NWU-EMELTEN-REC.

The chairperson handles it through the *expedited review process (unless amendments are significant, requiring full committee approval)* by allocating it to two reviewers who have three working days to give their feedback of the review.

The administrator sends the amendment request to the reviewers and on receipt sends their reviews to the chairperson who makes the final decision to approve the request.

The decision is ratified during the following NWU-EMELTEN-REC meeting.

9 REFERENCE DOCUMENTS

- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015).
- The Rules for the Management of research ethics at the North-West University, 2018.

10 ADDENDA

No	Document name
<u>1</u>	Monitoring report
<u>2</u>	Monitoring feedback letter
<u>3</u>	NWU-EMELTEN-REC: Incident report form when conducting research with human participants

ADDENDUM 1



NWU-EMELTEN-REC

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

NORTH-WEST UNIVERSITY EDUCATION, MANAGEMENT AND ECONOMIC SCIENCES, LAW, THEOLOGY, ENGINEERING AND NATURAL SCIENCES RESEARCH ETHICS COMMITTEE (NWU-EMELTEN-REC) ANNUAL MONITORING REPORT

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 Head/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 (provide details)	
Industry		International grant		Self	
				Yes	No
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 <i>provisional approval</i> 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 <i>have/have not</i> 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 primary 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 primary investigator due to adverse events/serious adverse events/incidents/other reasons. Please provide reasons for these withdrawals:			

<p>Number of participants lost to follow-up (if appropriate). Please explain why they were lost:</p>	
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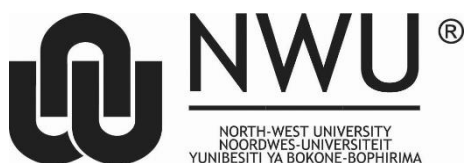
SECTION D: PROJECT AMENDMENTS AND STUDY STATUS			
10. Amendments	Yes	No	N/A
Has the study been amended or changed during the past year?			
Amendments	Date		

11. Status of study	Yes	No	N/A
Has the study been completed and does this serve as your final report?			
<p>Has this project been terminated?</p> <p>If so, please indicate the date, reason for termination and when the NWU-EMELTEN-REC was notified:</p>			
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.

ADDENDUM 2



Private Bag X6001, Potchefstroom
South Africa 2520

Tel: +2718 299-1111/2222
Web: <http://www.nwu.ac.za>

**North-West University Education
Management and Economic Sciences,
Law, Theology, Engineering and Natural
Sciences Research Ethics Office (NWU-
EMELTEN-REC)**

Tel: +2718 299 4707
Email: lukas.meyer@nwu.ac.za

FEEDBACK ON NWU-EMELTEN-REC ANNUAL MONITORING REPORT

Dear

FEEDBACK ON NWU-EMELTEN-REC MONITORING REPORT NWU-#####-##-A2

We would like to thank you for submitting the annual monitoring report for your project entitled, "xxx" to the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC) in a timely manner. Please find below the decision of the NWU-EMELTEN-REC regarding the continuation of your project.

Classification	Mark with X	Comment
<i>Clarification</i>		
<i>Completion (Final report)</i>		Should you view your project not as completed, please let us know
<i>Suspended</i>		
<i>Continuation</i>		Date of next monitoring report:
<i>Termination</i>		

Should you have any further queries, please feel free to contact Ms Villera le Roux at your earliest convenience (E-mail: Ethics-EMELTEN-mon@nwu.ac.za ; Tel: 018 299 4707).

We wish you well in your future research endeavours.

Yours sincerely

Prof LW Meyer
Chairperson: NWU-EMELTEN-REC

ADDENDUM 3



NWU-EMELTEN-REC

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NWU-EMELTEN-REC: INCIDENT REPORT FORM WHEN CONDUCTING RESEARCH WITH HUMAN PARTICIPANTS

Note: *An incident is seen as an unanticipated situation or issue that arises while conducting your research and that has no direct cause/effect due to an intervention.*

Please complete the form according to the following guidelines:

- Researchers need to complete Sections A to C.
- The Chairperson of the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC) will complete Section D.

SECTION A: GENERAL INFORMATION

1. Project Leader/Principle Investigator/Study leader Details					
Surname		Initials		Title	
School/ Research unit					
E-mail					
Telephone	Work		Cell		Fax
2. Student Details (if applicable)					
Surname		Initials		Title	
School/ Research unit					
E-mail					

Telephone	Work		Cell		Fax	
3. Details of approved research						
Title						
Ethics Approval Number						
Approval date				Expiry date		
Last submission of a monitoring report				Date:		

SECTION B: INCIDENT REPORT

Please describe the progress to date of the project (not more than 500 words):			
Please describe the incident that is being reported in detail (please ensure that you respond to what, where, who, how, when of the incident):			
Please describe the action that has been taken to date in detail in order to contain the incident:			
Please indicate a possible strategy/action plan for correcting the incident:			
Please indicate a possible strategy/action plan for ensuring that it will not occur again:			
	Yes	No	NA
If yes, please ensure that an amendment request is submitted to the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC) as soon as possible. Will this incident require that the proposal will have to be changed?			

SECTION C: SIGNATURE

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

SECTION D (for office use only):

14. North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC) report	Yes	No	NA
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Has the incident been satisfactorily reported?				
Has the incident been satisfactorily addressed?				
If yes, please explain the manner in which the incident was managed with the project leader/principle investigator/study leader and participant/s:				
NWU-EMELTEN-REC Chairperson		Signature		Date