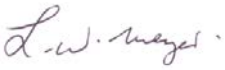
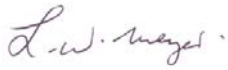
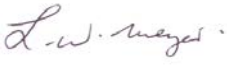
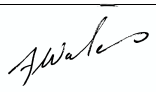
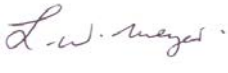
NWU-EMELTEN-REC

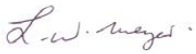
The Faculty of Health Sciences Ethics Office of the North-West University is acknowledged for the use of their document with minor adjustments made by the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU-EMELTEN-REC).

NWU-EMELTEN ReSEARCH ETHICS OFFICE (NWU-EMELTEN-REO)	**Standard Operating Procedure**		
Title	SOP for the research ethics approval application process		
SOP no	SOP_EMELTEN_Ethics_1.4	**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 35

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:	NWU-EMELTEN- Research Ethics Office Prof Lukas Meyer		1 December 2018 4 September 2019
Approved by:	NWU-EMELTEN-REC: Chair: Prof Lukas Meyer		9 March 2020
	Faculty Board: Faculty of Education: Chair: Prof Lloyd Conley		15 April 2020
	SCRE Chair:		27 August 2020
Authorised by:	Chair of NWU-EMELTEN-REC: Prof Lukas Meyer		28 August 2020

2 DISTRIBUTION

Department/Unit	Name	Signature	Date
Chairperson on behalf of NWU-EMELTEN-REC	Prof Lukas Meyer		28 August 2020
Deputy Dean: Research and Innovation			
NWU-EMLTEN-REC: Administrator	Mrs Villera le Roux		31 August 2020

3 DOCUMENT HISTORY

Date	Version no	Reason for revision
6 December 2016	1	Compiling of SOP
7 May 2018	2	Changing old NWU Logo to new 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 with a clear systematic procedure to follow when applying for one of the five options for ethics approval:

4.1 A first time application for a *single study* or a *larger study* (See 6 for definitions)

4.2 A *sub-study application* (Master or Doctoral student) under an approved *larger* study

4.3 An application for an *amendment* to an approved study

4.4 *Monitoring report* or a request for an *extension* of an approved study

5 SCOPE

This SOP is intended for all researchers and postgraduate students of the NWU who plan to conduct studies of a non-health related focus where vulnerable human participants are involved and/or the possibility of medium to high risk of potential harm to human participants exist. It covers the full application process to obtain research ethics approval before research is conducted, permission for amendments and the monitoring process during research.

6 ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/definition	Description
NWU-EMELTEN-REC	North-West University Education, Management and Economic Sciences, Law, Thelogly, Engineering and Natural Sciences Research Ethics Committee
NWU-EMELTEN-REO	North-West University Education, Management and Economic Sciences, Law, Thelogly, Engineering and Natural Sciences Research Ethics Office
NWU	North-West University
Single Study	A study consisting of one or more researchers not intending to involve Masters or Doctoral students, or for the purpose of a single Masters or Doctoral study. or A single study could also be *affiliated* to *another study* not approved as a larger study by using the other study's previously collected data but using a specific

	methodology for obtaining results. The methodology is not specified in the original *other study*. The project leader of the other study must give permission for the use of the data and specify its use. The study could either: 1) fulfill one of the previously stated objectives not yet achieved, or 2) work on secondary data analysis. or A study intending to run over several years, collecting data to be used with the described methodology focusing more on data collection. Follow up studies will use various methodologies to obtain results from the originally collected database.
Larger Study	A study planning to involve several Masters and Doctoral students and that clearly identify the objectives per student as well as the methodology to be used by each potential student. The extent of the data is more extensive in nature and can accommodate several students. The objective/s should indicate whether it is for a Masters or a Doctoral student. The inclusion of this type of study is to simplify the research ethics application process for future Masters and Doctoral students that will be working in this study.
Sub-study	A sub-study that has been identified as a potential Masters or Doctoral study in the objectives of an ethically approved larger study by covering a *specific stated objective/s* of the larger study and uses *identical methodology* or section/s of the methodology as the larger study. It could be that data have already been collected or are going to be collected. NB The sub-study can add **no new methodology** that was not covered in the larger study. If the latter is needed the larger study should be amended first.
Amendment	Any change made to the originally planned proposal and that happens while the study is being conducted. No change may be implemented without first obtaining the necessary approval of the NWU-EMELTEN-REC.
Monitoring	Monitoring refers to the process of observing quality and conduct of the research while in progress. *Passive monitoring* refers to the compulsory reporting required by NWU-EMELTEN-REC (minimum on an annual basis). *Active monitoring* refers to unannounced monitoring visits conducted by NWU-EMELTEN-REC to research sites or where data is stored. A study is approved on a year by year basis based on the submission and positive outcome of the review of the annual monitoring report and written confirmation that the study may continue for another year.
Extension	However, if a researcher requires extension for a study not falling in the mentioned monitoring time frame, extension can be requested by submitting a monitoring report to NWU-EMELTEN-REC and requesting extension.

7 RESPONSIBILITIES

The responsibility lies with the researcher (employee of the University) or study-leader to ensure that research ethical approval is obtained in time before a study is started and that the study is conducted according to the approved proposal. The study-leader remains the primary accountable person for the way in which the study obtained ethical approval and is conducted. The NWU-EMELTEN-REC and the NWU-EMELTEN-REC administrators communicate with the researcher or study-leader and not the student. The latter is the responsibility of the study-leader.

8 PROCEDURE/S

8.1 A first time application for a single study (including an affiliated study to another study with previously collected data) or a larger study with defined postgraduate student projects

Process:

Conceptualize the research study (Observing problems, reading literature, discussion etc.)

Develop the research proposal and applicable accompanying documentation and enter into negotiations with potential authorities to ensure that they will be open for the research to be conducted.

Download the necessary documents from the NWU-EMELTEN-REC webpage.....

Submit the proposal to the *scientific/proposal committee* in your research entity for scientific evaluation and approval.

Obtain a letter of approval by them that has to be attached to the application.

Once the proposal has been approved by the scientific/proposal committee submit the title registration request through the Faculty Research Office (this is a process that runs parallel to the research ethics application process).

Submit the completed ethics application to the:

- NWU-EMELTEN-REO administration for research involving humans (Ethics-EMELTEN-apply@nwu.ac.za)

Attach all the required documents *separately* to the NWU_EMELTEN-REC e-mail address (see attachment checklist below).

Attach a *covering letter* indicating:

- the title of the research
- the researcher/s
- the type of research ethics application
- which documents are attached to the application, and
- add any explanation you wish the to take note of in your application

Application sent by NWU-EMELTEN-REO administration (within three working days) to two or three independent reviewers (5 working days for review).

The application is discussed at the NWU-EMELTEN-REC meeting.

- Decision process
  - Aggregate individual views
  - Deliberation (debate)
  - Analogue (consensus)
  - Vote if necessary
- Decision
  - Approved
  - Approved with minimal/several changes

- Deferred (too many changes and further committee deliberation needed)
- Disapproved (have to go back to the drawing board)

Formal letter of decision of the NWU-EMELTNE-REC with attached independent reviewer reports are sent to the applicant (always the study leader or PI) as soon as possible (approximately three working days) after the meeting by the appropriate administrator.

Corrections are done by the applicant and are sent back as soon as possible to:

- the NWU-EMELTNE-REC administrator for research involving humans (note that the corresponding person for NWU-EMELTNE-REC now changes to Ethics-EMELTEN-process@nwu.ac.za if corrections are needed).

A rebuttal letter should be included indicating *what, how* and *where* in the documentation the corrections were addressed (Corrections should be highlighted in the various documents as well).

The *total set* of new documentation should be included as this will then be the set used for monitoring purposes as required by the NHREC.

The updated application is re-sent to the same independent reviewers for the review of the corrections (three working days).

Corrections are either approved by reviewers or further corrections are requested.

If additional corrections are requested they should be corrected (as previously indicated) and re-submitted by the applicant to:

- the NWU-EMELTEN-REC administration for research involving humans (note that the corresponding person for the NWU-EMELTNE-REC remains Ethics-EMELTEN-process@nwu.ac.za during this reviewing process).

If approved, a letter of approval is sent to the researcher/s by:

- the NWU-EMELTNE-REC administrator for research involving humans (Ethics-EMELTEN-apply@nwu.ac.za).

The letter will either indicate *final approval* or *conditional approval* (Conditional approval is given when there are certain processes that have to occur before final approval can be given e.g. approval of a study from the Department of Education (DoE) can only be applied for after the NWU-EMELTEN-REC gives approval however the NWU-EMELTNEN-REC cannot approve the study without receiving the permission letter from the DoE, therefore *conditional approval* is granted; or where interview schedules will be developed as the study unfolds. These conditions will be clearly stated).

Once the English version of the informed consent form has been finally approved, the applicants can have the form translated into the culturally relevant languages. This is to ensure that the applicants only have to translate the informed consent documentation once it has been approved.

If a project has been conditionally approved, any other outstanding documents e.g. permission letters from authorities (e.g. Department of Education) that could only be obtained after ethical approval was obtained, must be sent to the appropriate administration in the Ethics Office as soon as possible (if applicable).

If the *conditions associated with the approval are process-linked* e.g. development of an interview schedule for phase two of a project is based on the results obtained during phase one of the project, then the research

can continue until that point e.g. the end of phase one, where after the applicant must submit the required documentation for approval before the study can continue.

This documentation must be submitted to:

- the NWU-EMELTEN-REC administration for research involving humans (Ethics-EMELTEN-process@nwu.ac.za).

For research involving humans, the approved informed consent documentation as well as the translated versions of the informed consent documents must be brought to be *stamped* by the NWU-EMELTEN-REO before they are photocopied and used in the research (Contact Ms Marlize Bisschoff at 018 299 4707 for an appointment).

Research can begin as soon as the researcher has received the ethics approval letter.

The ethics approval letter is only issued by the NWU-EMELTEN-REC once all conditions are met.

If needed, send any future amendments of the proposal or the rest of the documentation to the appropriate administration:

- the NWU-EMELTEN-REC administration for research involving humans (Ethics-EMELTEN-apply@nwu.ac.za)

(See Section 3 (amendments) for the process)

For ***minimal risk studies*** *involving humans*, an ***annual monitoring report*** must be submitted for the duration of the study *at least two months before expiry* and annually until it has been completed. For ***medium risk studies***, **a monitoring report must be submitted *six monthly and for high risk studies a monitoring report must be submitted every three months*** for the duration of the study. Ensure that the monitoring report submitted for the end of the annual term, is submitted *at least two months before expiry* of the ethics approval of the project (See Section 4 (monitoring reports) for the process). Ensure that the monitoring report submitted for the end of the annual term, is submitted *at least two months before expiry of the ethics approval of the project.*

Note: Only one year ethics approval of projects may be granted due to legal requirements.

It must be indicated in the monitoring report whether the study is *completed or not*. If the study is completed, the monitoring report acts as a *final report*. If the study is not complete, the monitoring report acts as a request to *extend the study*.

NB If a study is terminated immediately notify the appropriate administration.

Research dissemination/publication.

Checklist for attachments for a single study research ethics approval applications to the NWU-EMELTEN-REC:

	Document	Tick if attached	Comment
NWU-EMELTNE-REC Administration:			
1	Application cover sheet with progress report		
2	Checklist of attachments		
3	Feedback Letter to applicant		
4	Reviewer reports		
Ethics Applications submission:			
5	Cover letter that indicates: • The title, • The researcher/s, • The type of research ethics application, • Documents attached • Discipline and or entity the study belongs • Explanations to clarify your application		
6	Executive summary of the project (150 words only)		
7	Proposal approved by a scientific/proposal committee		
8	Ethics application form to provide additional information not covered in the proposal.		
9	Recruitment and Enrolment • Advertising materials • recruitment materials		
10	Budget: • Reimbursements • Inducements for participants • Costs for participants		
11	Informed consent documentation • Informed consent form • Checklist (if collaborative study, informed consent from all the centres OR if an affiliated study, the original informed consent documentation of the original study)		
12	Questionnaire/s: Interview schedules for interviews or focus groups		
13	Risk-Benefit Assessment • Safety reviews		
14	Scientific/ Research Committee evaluation: • Approval letter • Extracts from the minutes of meeting		
15	2-page narrative CVs of all the researchers in the project		
	Document	**Tick if attached**	**Comment**
16	Proof of ethics training over the past three years for all the researchers in the project		
17	Permission letters to conduct the research: • Governing bodies • Parents (if applicable) • Guardians (if applicable) •		
18	Goodwill permission letters		
19	Any other applicable documentation: • Memorandum of Understanding • Contracts with collaborators • Permits etc.		

20	Signed NWU code of conduct for researchers for each team member		
21	Declarations by the: • Project leader, • Statistical consultation services, • Director of the research entity		
22	Ethics review checklist		
If applicable:			
23	Confidentiality agreement		
24	Indemnity form and Insurance Certificate		
25	Permission from the project leader if a study is done as an affiliated study under another study or a sub-study under a larger study		
26	Signed statistical review form		
27	Form A for delegated ministerial consent in the case of greater than minimal risk research in children with no prospect of direct benefit to them		
28	Permission letter of the chairperson of the NWU-EMELTNE-REC if the study is an affiliated study or sub-study under a larger study falling on another campus than that where the student is registered		
29	Additional information documents		

8.2 A research ethics approval application for a sub-study under an approved larger study

Process:

Conceptualize the sub-study and how it will fall within the approved larger study (Observing the specific problems, reading focused literature, discussion etc.).

Enter into negotiations with the project leader of the larger study, to ensure that he/she will be open for the sub-study to be conducted under the larger study.

Develop the research proposal for the sub-study and get the applicable accompanying documentation ready.

Submit the proposal to the *scientific/proposal committee* in your entity for scientific evaluation and approval.

Obtain a letter of approval by them that has to be attached to the application.

Once the proposal has been approved by the scientific/proposal committee submit the title registration request through the Faculty Research Office (this is a process that runs parallel to the research ethics application process).

Download the necessary documents from the NWU-EMELTNE-REO webpage: .....

Submit the new sub-study proposal and the additional required documentation to:

- NWU-EMELTNE-REC administration for research involving humans (Ethics-EMELTEN-apply@nwu.ac.za).

Attach all the required documents *separately* to the e-mail (see attached checklist below)

Attach a covering letter indicating:

- the title of the research
- the researcher/s
- the type of research ethics application
- which documents are attached to the application, and
- add any explanation you wish the NWU-EMELTNE-REC to take note of in your application

Application sent by administration (three working days) to two or three independent reviewers (5 working days for review).

The application is discussed at the NWU-EMELTEN-REC meeting. Decision process:

- Aggregate individual views
- Deliberation (debate)
- Analogue (consensus)
- Vote if necessary

- Decision
  - Approved
  - Approved with minimal/several changes
  - Deferred (too many changes and further committee deliberation needed)
  - Disapproved (have to go back to the drawing board)

Formal letter of decision of the NWU-EMELTNE-REC with attached independent reviewer reports are sent to the applicant (always the study leader or PI) as soon as possible (approximately three working days) after the meeting by the appropriate administrator.

Corrections are done by the applicant and are sent back as soon as possible to:

- the NWU-EMELTNE-REC administration for research involving humans (note that the corresponding person for NWU-EMELTNE-REC now changes to Ethics-EMELTEN-process@nwu.ac.zaif corrections are needed).

A rebuttal letter should be included indicating *what, how* and *where* in the documentation the corrections were addressed (Corrections should be highlighted in the various documents as well).

The *total set* of new documentation should be included as this will then be the set used for monitoring purposes as required by the NHREC.

The updated applications are re-sent to the same independent reviewers for the review of the corrections (three working days).

Corrections are either approved by reviewers or further corrections are requested.

If additional corrections are requested they should be corrected (as previously indicated) and re-submitted by the applicant to:

- the NWU-EMELTNE-REC administration for research involving humans (note that the corresponding person for the NWU-EMELTNE-REC remains Ethics-EMELTEN-process@nwu.ac.za during this reviewing process).

If approved a letter of approval is sent to the researcher/s by:

- the NWU-EMELTNE-REC administration for research involving humans (Ethics-EMELTEN-apply@nwu.ac.za)

The letter will either indicate *final approval* or *conditional approval* (Conditional approval is given when there are certain processes that have to occur before final approval can be given e.g. approval of a study from the Department of Education (DoE) can only be applied for after the NWU-EMELTNE-REC gives approval however the NWU-EMELTNE-REC cannot approve the study without receiving the permission letter from the DoE, therefore *conditional approval* is granted. These conditions are clearly stated).

Once the English version of the informed consent form has been finally approved, the applicants can have the form translated into the culturally relevant languages. This is to ensure that the applicants only have to translate the informed consent documentation once it has been approved.

If a project has been conditionally approved, send any other outstanding documents e.g. permission letters from authorities (e.g. Department of Education) that could only be obtained after ethical approval was obtained, to the appropriate administration in the NWU-EMELTNE-REO as soon as possible (if applicable).

If the *conditions associated with the approval are process-linked* e.g. development of an interview schedule for phase two of a project is based on the results obtained during phase one of the project, then the research can continue until that point e.g. the end of phase one, where after the applicant must submit the required documentation for approval before the study can continue.

This documentation must be submitted to:

- the NWU-EMELTEN-REC administration for research involving humans (Ethics-EMELTEN-process@nwu.ac.za).

For research involving humans, the approved informed consent documentation as well as the translated versions of the informed consent documents must be brought to be *stamped* by the NWU-EMELTNE-REO before they are photocopied and used in the research (contact Ms Marlize Bisschoff at 018 299 4707 for an appointment).

Research can begin as soon as the researcher has received the ethics approval letter.

The ethics certificate is only issued by the Institutional Office once all conditions are met.

If needed, send any future amendments of the proposal or the rest of the documentation to the appropriate administraton:

- the NWU-EMELTNE-REC administration for research involving humans (Ethics-EMELTEN-apply@nwu.ac.za)

(See Section 3 (amendments) for the process)

For ***minimal risk studies involving humans***, an ***annual monitoring report*** must be submitted for the duration of the study *at least two months before expiry* and annually until it has been completed. For ***medium risk studies***, ***a monitoring report must be submitted six monthly and for high risk studies a monitoring report must be submitted every three months*** for the duration of the study. Ensure that the monitoring report

submitted for the end of the annual term, is submitted *at least two months before expiry of the ethics approval of the project* (See Section 4 (monitoring reports) for the process). Ensure that the monitoring report submitted for the end of the annual term, is submitted *at least two months before expiry of the ethics approval of the project.*

Note: Only one year ethics approval of projects may be granted due to legal requirements.

It must be indicated in the monitoring report whether the study is *completed or not*. If the study is completed, the monitoring report acts as a *final report*. If the study is not complete, the monitoring report acts as a request to *extend the study*.

NB If a study is terminated immediately notify the appropriate administration.

Research dissemination/publication.

Checklist for attachments for a sub-study under a larger study research ethics approval applications to the NWU-EMELTNE-REC:

	Document	Tick if attached	Comment
1	Have the data already been gathered or is it in a process of longitudinal gathering or part of an intervention?	If *yes*: If *no*:	Continue Make sure the larger study truly qualifies as a larger study by completing the attached evaluation form.
2	Is the study clearly stated as an objective in the larger study	If *yes*: If *no*:	Continue Make sure the larger study truly qualifies as a larger study by completing the attached evaluation form.
3	Cover letter that indicates: • Title of the larger study • Title of the sub-study • Student information • Study-leader/s • What the sub-study is about and how it fits into the larger study; the objective/s it intends to fulfil from the original study • What documents are attached • Detailed description of any outstanding issues of the larger study identified during the evaluation of the larger project (see evaluation form below) done by the project leader and how it will be addressed (Note: *This should be handled as a separate amendment to the larger study if it involves changes that will still take place in future and should be done before the sub-study is submitted for ethics approval*).		
4	Executive summary of the sub-study (150 word only)		
5	Original proposal of the larger study		
6	Original informed consent documentation of the larger study		
7	Copy of the ethics approval letter of the larger study		

8	Letter from the project leader clearly indicating *which objective/s will be covered* as a sub-study under the larger project, as well as clearly specifying *what part of the previously collected data can be used* and *for what*		
9	Approval letter of the sub-study by the scientific/proposal committee		
10	New proposal of the sub-study		
11	2-page narrative CVs of all the researchers in the sub-study		
12	Proof of ethics training over the past three years for all the researchers involved in the sub-study		
13	Signed NWU code of conduct for researchers for each team member		
14	Signed statistical consultation form		
15	**Submitted as hard or scanned copies:** Printed and signed pages of the ethics application form for the declarations by the project leader, statistical consultation services, director of the research entity		
16	Checklist of attachments		
	If applicable:		
17	Confidentiality agreement		
18	Indemnity form		
19	Form A for delegated ministerial consent in the case of greater than minimal risk research in children with no prospect of direct benefit to them		
21	Permission letter of the chair of the NWU-EMELTEN-REC if the study is an affiliated study or sub-study under a larger study falling on another campus than that where the student is registered		
22	Evaluation form to see if the larger study qualifies as a larger study, completed by the project leader		

8.3 Application for an amendment to an approved study

Process:

Decide what the required amendments are for the present study (*It might be that amendments require speedy approval*).

Review and update the proposal and any other study documentation and indicate clearly where the possible changes have been made in order to amend the existing study (using yellow highlight).

Formulate a clear and systematic cover letter guiding the appropriate ethics committee e.g. NWU-EMELTNE-REC for research involving humans, through the amendments that have been made:

- the title of the research
- the researcher/s
- that it is an amendment request
- the nature of the amendment (Indicating what changes have been made and where)
- which documents are attached to the application, and
- add any explanation to clarify your application

Submit the amended ethics application either to the:

- NWU-EMELTNE-REC administration for research involving humans (Ethics-EMELTEN-apply@nwu.ac.za).

Attach all the required documents separately to the e-mail (see document checklist below).

Application sent by administration (within three days) to two to three independent reviewers (3 working days for review).

The application is handled as expedited (changes not of a large nature) or discussed at the next appropriate Education Ethics Committee meeting (if large changes are made) e.g. research involving humans at the NWU-EMELTNE-REC meeting if of a larger nature.

- Decision process
  - Aggregate individual views
  - Deliberation (debate)
  - Analogue (consensus)
  - Vote if necessary
- Decision
  - Approved
  - Approved with minimal/several changes
  - Deferred (too many changes and further committee deliberation needed)
  - Disapproved (have to go back to the drawing board)

Formal letter of decision of the REC with feedback is sent to the applicant (always the study leader or PI) as soon as possible (approximately three working days) after the meeting by the appropriate administration or sooner if expedited.

Corrections are done by the applicant and are sent back to:

- the NWU-EMELTNE-REC administration for research involving humans (note that the corresponding person for NWU-EMELTNE-REC now changes to Ethics-EMELTEN-process@nwu.ac.za).

A rebuttal letter should be included indicating *what*, *how* and *where* in the documentation the corrections were addressed (Corrections should be highlighted in the various documents as well).

The *total set* of new documentation should be included as this will then be the set used for monitoring purposes as required by the NHREC.

The updated application is re-sent to the same independent reviewers for the review of the corrections (three working days).

Corrections are either approved by reviewers or further corrections are requested.

If additional corrections are requested they should be corrected (as previously indicated) and re-submitted by the applicants to:

- the NWU-EMELTNE-REC administration for research involving humans (note that the corresponding person for the NWU-EMELTNE-REC remains Ethics-EMELTEN-process@nwu.ac.za during this reviewing process).

If approved a letter of approval is sent to the researcher/s by:

- the NWU-EMELTNE-REC administration for research involving humans (Ethics-EMELTEN-apply@nwu.ac.za)

Research can continue with the amended approach and documentation as soon as the researcher has received the ethics approval letter from the appropriate REC for the amendments.

If needed, send any future amendments of the proposal or the rest of the documentation to the appropriate administration:

- the NWU-EMELTNE-REC administration for research involving humans (Ethics-EMELTEN-apply@nwu.ac.za)

Checklist for attachments for an amendment to a study to the NWU-EMELTNE-REC:

	Document	Tick if attached	Comment
1	Cover letter that indicates the title, researcher/s, the nature of the amendment, and what has been changed within the various attached documents (NB highlighted)		
2	Adjusted proposal with highlighted changes		
3	Adjusted documentation with highlighted changes (if applicable)		

8.4 Monitoring report/or request for extension of the study

A compulsory annual (in the case of minimal risk studies) and six monthly (in the case of mediumrisk studies) and three monthly (in the case of high risk studies) monitoring report of approved projects is required. This should be submitted at least *two months before the expiry date* of the study. The monitoring report requests a clear indication of the status of the study:

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

If the study has not been completed an *extension* will automatically be granted for the project if the monitoring report is approved.

Note: Should you require an extension for the study at a time which does not fall within the required monitoring report period you can use the same process to request for an extension by completing the monitoring report. A cover letter should clearly indicate that this is what you require.

Monitoring report process:

For minimal risk studies, an annual monitoring report must be submitted for the duration of the study until it has been completed. For medium risk studies, a monitoring report must be submitted six monthly for the

duration of the study and for high risk studies a monitoing report must be submitted every three months for the duration of the study.

Two months before the end of the ethics approval period indicated for the different risk level studies, the researcher needs to complete a monitoring report. To download the necessary documents from the NWU-EMELTNE-REO webpage go to:

Complete the monitoring report ensuring that all appropriate sections are completed.

It must be indicated in the monitoring report whether the study is *completed or not*. If the study is completed, the monitoring report acts as a *final report*. If the study is not complete, the monitoring report acts as a *request to extend the study*.

Submit your completed monitoring report to Ethics-EMELTEN-mon@nwu.ac.za(indicate your choice of option in the report).

The monitoring report is sent (within three working days) to two independent reviewers (5 days to review).

Feedback from the monitoring reports is consolidated and discussed at the appropriate Ethics Committee meeting e.g. research involving humans at the NWU-EMELTEN-REC meeting.

- Decision
  - Clarification
  - Completion
  - Suspended
  - Continuation
  - Termination

A formal letter of decision is sent to applicants as soon as possible by the administration.

If any clarification or feedback is requested, the applicants should send the required information within a week to Ethics-EMELTEN-mon@nwu.ac.za.

Clarifications are sent back to the same independent reviewers.

Clarifications are either approved by reviewers or further clarification is requested.

If additional clarification is requested, it should be corrected (as indicated) and re-submitted within a week by the applicant to Ethics-EMELTEN-mon@nwu.ac.za.

A letter will be sent to the applicant stating the status of the research. If it is a continuation, it will state the date for the next monitoring report.

The decision is ratified at the next NWU-EMELTEN-REC meeting

The researcher can continue with the research as soon as he/she has received the letter indicating continuation.

NB Notify the administration at Ethics-EMELTEN-mon@nwu.ac.za as soon as possible if the study is terminated unexpectedly.

Note: Extension request not falling in the monitoring report cycle:

If a researcher wants to extend an approved research project at any other time other than the compulsory monitoring times i.e. annually for minimal risk studies, six monthly for a medium risk study and three montly for a high risk study, the researcher can do so by submitting the same monitoring report with a very clear cover letter indicating that extension is requested that falls outside the monitoring cycle.

9 REFERENCE DOCUMENTS

- The National Health Act, No 61 of 2003.
- Regulations Relating to Research with Human Participants, 19 September 2014.
- Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015)
- Risk level descriptors for human participants and environmental impact
- The Rules for the Management of research ethics at the North-West University, 2018.

10 ADDENDA

No	Document name
1	Informed consent template
2.	Informed consent checklist
3	Indemnity form
4.	EMELTEN-REC Reviewer report
5.	Ethics approval letter template
	See all the documents referred to in the checklists and find it on the NWU-EMELTEN-REC webpage:.....

ADDENDUM 1

NWU®
NORTH-WEST UNIVERSITY
NOORDWES-UNIVERSITEIT
YUNIBESITI YA BOKONE-BOPHIRIMA

Private Bag X1290, Potchefstroom
South Africa 2520

Tel: +2718 299-1111/2222
Fax: +2718 299-4910
Web: http://www.nwu.ac.za

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).

NWU-EMELTEN-REC Stamp

INFORMED CONSENT DOCUMENTATION FOR.....

TITLE OF THE RESEARCH STUDY:

ETHICS REFERENCE NUMBERS:

PRINCIPAL INVESTIGATOR:

POST GRADUATE STUDENT:

ADDRESS:

CONTACT NUMBER:

You are being invited to take part in a **research study** that forms part of my/our..... Please take some time to read the information presented here, which will explain the details of this study. Please ask the researcher or person explaining the research to you any questions about any part of this study that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research is about and how you might be involved. Also, your participation is **entirely voluntary** and you are free to say no to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part now.

This study has been approved by the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee (NWU.....) and will be conducted according to the ethical guidelines and principles of Ethics in Health Research: Principles, Processes and Structures (DoH, 2015) and other international ethical guidelines applicable to this study. It might be necessary for

Commented [MG1]: Add for whom and what. Be specific who your participant will be and what they will be doing so that this informed consent form will be identifiable e.g. young pregnant women being interviewed

Commented [MG2]: Type in the title of your study

Commented [MG3]: Type in your ethics allocated number

Commented [MG4]: Type in the name of the researcher or the study-leader

Commented [N5]: Type in the student's name if applicable

Commented [MG6]: Type in the address of the primary investigator

Commented [MG7]: Contact number of the primary investigator

Commented [MG8]: Say what studies or what research study is being undertaken. If Masters or Doctoral study do not write "my" but "a" Masters or Doctoral study as you have indicated both the study leader and the student

Commented [MG9]: Type your ethics approval number in

the research ethics committee members or other relevant people to inspect the research records.

What is this research study all about?

- *We plan to ……..:*
- *This study will be conducted .....and will be done by experienced health researchers trained in ..... X participants will be included in this study.*

Why have you been invited to participate?

- *You have been invited to be part of this research because you are ……..*
- *You will unfortunately not be able to take part in this research if …….*

What will be expected of you?

- *You will be expected to*

Will you gain anything from taking part in this research?

- The gains for you if you take part in this study will be……../There will be no direct gains for you in the study.
- The other gains of the study is for ……..

Are there risks involved in you taking part in this research and what will be done to prevent them?

- The risks to you in this study are……. but will be limited by……..
- There are more gains for you in joining this study than there are risks.

How will we protect your confidentiality and who will see your data?

- *Anonymity of your data will be protected by..... Your privacy will be respected by …….. Your results will be kept confidential by …….. Only the researchers and.....will be able to look at your data. Data will be kept safe by locking hard copies in locked cupboards in the researcher's office and for electronic data it will be password protected. (As soon as data has been transcribed it will be deleted from the recorders.) Data will be stored for ..... years.*

What will happen with the data or samples?

- *The findings of this study will only be used for this study/will be used in future……..*

How will you know about the results of this research?

- We will give you the results of this research when …… by……..
- You will be informed of any new relevant findings by……..

Commented [N10]: Describe the objectives of your research in simple language. Please do not use the scientific language of your proposal.

Commented [MG11]: Where? When? E.g. in Potchefstroom in a private venue of your choice.

Commented [MG12]: Say what the experience is in e.g. interviewing? It is important that the participant see that the researchers are experienced.

Commented [MG13]: Replace with your planned number of participants

Commented [MG14]: Tell them why you have selected them to be part of the study. State the inclusion criteria in simple language

Commented [N15]: State your exclusion criteria in simple language

Commented [MG16]: Give a detail description of *what* will be expected of the participant, *how long, how often, when* etc. e.g an interview of 30 minutes with 6 questions once in two weeks' time/in June or with the possibility of a follow up interview. If your participant will be expected to be involved in several activities, they all have to be mentioned here in detail with the what is expected of them for each activity/procedure etc.

Commented [N17]: Give the direct benefit to the participant here or tell him/her that there is no direct gain for them

Commented [N18]: Tell them who else will gain and what these people will gain e.g. their community at large about….or researchers by gaining new knowledge about ….. etc.

Commented [N19]: It is important to note here that it is here you will add the section of bodily harm and insurance should it be applicable to the study.

Commented [MG20]: State each risk and immediately follow up with what precautionary measures will be taken by you to limit the risk. You could even bring in a table with the risk in the one column and the precautionary measure in the other column

Commented [N21]: Adjust this line if the risks are more to the participant in a medium of high risk study

Commented [MG22]: Explain how this will be ensured in this study and what will be done to protect it. Mention if it is only partial and what will be done from your side

Commented [N23]: Describe how you will ensure privacy while obtaining their information

Commented [N24]: Describe how you will ensure confidentiality once you have obtained the information and when you disseminate it

Commented [MG25]: Say who will have access to the data. If an agreement of confidentiality is signed with someone mention it

Commented [MG26]: Only add this if you have recorded data

Commented [MG27]: Put in the time you will store it

Commented [128]: Indicate whether this data/samples will only be used for this study or will it be used again for further studies or collaborative studies. If you are going to use it again indicate *for what* and *related to what*. Ensure them that for any furthers studies it will always first be approved by the HREC that will stand in on their behalf. How will the data/samples be handled. Where will it be stored and analysed e.g. SA or overseas. Please ensure you cover this in detail to protect yourself during future use.

Commented [N29]: Tell the participant when you will share the findings with them and how you will share it with them.

Commented [N30]: Tell them how you will do this

Will you be paid to take part in this study and are there any costs for you?

This study is funded by……

Yes, you will be paid an amount of …. when you…. /No you will not be paid to take part in the study because …..

Travel expenses will be paid for those participants who have to travel to the site...../You had no travel expenses and do not to be refunded for traveling.

Refreshments/a meal will be served when.....

There will thus be no costs involved for you, if you do take part in this study.

Is there anything else that you should know or do?

- You can contact ..... at ..... if you have any further questions or have any problems.
- You can also contact the North-West University Education, Management and Economic Sciences, Law, Theology, Engineering and Natural Sciences Research Ethics Committee via Mrs Marlize Bisschoff at 018 299 4707 or marlize.bisschoff@nwu.ac.za if you have any concerns that were not answered about the research or if you have complaints about the research.
- You will receive a copy of this information and consent form for your own purposes.

Commented [N31]: Adjust this section as it is applicable to your study. Please take the TIE principle into consideration. (T=time; I=inconveniences; E=expenses)

Commented [N32]: Mention if this study is funded or not. If funded by whom.

Commented [MG33]: Researchers details

Commented [WU34]: Where can the person contact the researcher

Declaration by participant

By signing below, I …….. agree to take part in the research study titled:……

I declare that:

- I have read this information/it was explained to me by a trusted person in a language with which I am fluent and comfortable.
- The research was clearly explained to me.
- I have had a chance to ask questions to both the person getting the consent from me, as well as the researcher and all my questions have been answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be handled in a negative way if I do so.
- I may be asked to leave the study before it has finished, if the researcher feels it is in the best interest, or if I do not follow the study plan, as agreed to.

Signed at (*place*) ……..…….. on (*date*) ……..…….. 20....

…….. ……..

Signature of participant Signature of witness

Declaration by person obtaining consent

I *(name)* …….. declare that:

- I clearly and in detail explained the information in this document to

  ……

- I did/did not use an interpreter.
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above

Commented [N35]: Name and surname of participant

Commented [MG36]: Add tile of the study

Commented [WU37]: Witnesses are only added in the case of illiterate participants who then bring along a trusted person to sign on their behalf. The participant can draw a cross or make a finger print.

- I gave him/her time to discuss it with others if he/she wished to do so.

Signed at (*place*) .....…….. on (*date*) ……..…….. 20....

.....
Signature of person obtaining consent

Declaration by researcher

I *(name)* ……..…….. declare that:

- I explained the information in this document to …….. **or** I had it explained by …….. who I trained for this purpose.
- I did/did not use an interpreter
- I encouraged him/her to ask questions and took adequate time to answer them or I was available should he/she want to ask any further questions.
- The informed consent was obtained by an independent person.
- I am satisfied that he/she adequately understands all aspects of the research, as described above.
- I am satisfied that he/she had time to discuss it with others if he/she wished to do so.

Commented [N38]: Please adjust this sentence according to your process followed

Commented [N39]: Please adjust this sentence according to your process followed

Signed at (*place*) .....…….. on (*date*) ……..…….. 20....

.....
Signature of researcher

ADDENDUM 2

NWU-EMELTEN-REC

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INFORMED CONSENT CHECKLIST FOR NWU-EMELTEN-REC

Here are just a few pointers when preparing your informed consent documentation

The text in the informed consent:

The text:

- is in plain language and appropriate to the participant's level of understanding, clear and direct
- is free of jargon and unexplained acronyms
- is clear and explains technical terminology e.g. randomisation
- is translated into other languages as appropriate to the context

  (***The translation has to reach the NWU-EMELTEN-REC within one week after the final informed consent document was approved in English***)
- conforms to the proposal
- the readability level is on grade 8 level
- the language and translation is appropriate

Examples of readability tests:

- Flesh Readability Formula (Flesh, 1948)
- Fry Readability Scale (Fry, 1968)
- Flesh-Kincaid Readability Scale (See Paasche-Orlow MK, Taylor HA, Brancati FL) – informed consent should be at the 8th-grade level (USA)

TICK LIST FOR YOUR CONVENIENCE:

These are important aspects that should be included in the informed consent documentation as expected by the National Health Research Ethics Council (2014):

Make a tick in each block. If not applicable indicate N/A

Item	Yes	No	N/A
The informed consent document is official and on the letterhead of the NWU			
The information should explain:			
• that the person is being asked to participate in the research			

• who the researchers are and the nature of their expertise (qualifications)			
• what the research is about (purpose and nature)			
• the choice whether to participate is voluntary			
• the refusal to participate will not be penalised			
• that choosing to participate can be reversed, i.e. the person may decide to terminate participation at any time without explanation or prejudice			
• that a participant is free at any time to withdraw consent without having to face negative consequences			
• a description of the procedures to which the subject will be subjected			
• the expected duration of participation			
• the nature of the researcher's responsibilities			
• the total number of participants that will be involved in the research			
• the anticipated risks of harm or discomforts			
• If risk of bodily harm how this will be covered by insurance			
• how these risks or discomforts will be managed			
• the potential benefits, if any, for participants themselves (direct) and for others after the research (indirect)			
• the extent to which privacy and confidentiality is possible			
• what will happen to the findings or samples - only for this study or further studies - If further studies for what and related to what - further studies will be approved by a REC on their behalf - how the data/samples will be used - where will it be stored and analysed - permission that it can be done overseas if that is the intension			
• whether there will be any financial implications e.g. out of pocket costs like travel			
• whether there will be any remuneration			
• identify the funder, where applicable and any potential conflict of interest			
• how the person will be informed of findings and when			
• their right to be informed of relevant new findings and how this will be done			
• that sponsors of the research and regulatory authorities (NWU-EMELTEN-REC) may inspect research records			
• that the research has been approved by a registered NWU-EMELTEN-REC (include identifying details)			
• that queries about the research may be directed to the researcher concerned (include contact details)			
Item	**Yes**	**No**	**N/A**
• that queries and complaints about being a research participant may be directed to the NWU-EMELTEN-REC concerned (include contact details)			
Only add if applicable			
• that the research may be terminated early in particular circumstances			
• the consequences of withdrawal			

What the NWU-EMELTEN-REC will look for in the proposal:

- The process of obtaining informed consent is described in full

- The principle of *respect* for persons was followed, that it is *voluntary*, and based on *information* that allows an *informed choice*
- Environment where process of consent is conducted

  - private, confidential and safe
- Assessment of capacity to consent

  - age
  - legally informed consent
  - decisional impaired persons
  - legally authorized representation
  - literacy
- Assessment of participant's comprehension
- Presentation of all mentioned *elements* of IC and the *process* that will be followed
- Whether gatekeepers/mediators are involved and their roles in this process
- Time to talk to researcher to ask questions
- Documentation of IC (language level, language offered in)
- Use of delayed consent procedure

  - time to think
  - time to discuss with family/friends etc.
- Who is going to obtain the consent (independent person)
- Ongoing consent/re-consent if necessary due to the nature of the research

Developed by: Prof Minrie Greeff

ADDENDUM 3

NWU-EMELTEN-REC

INDEMNITY FORM

I, the undersigned

_____

identity number: _____,

hereby indemnify the North-West University ("NWU") and/or any of its office-bearers and staff (temporary or permanent) against any liability in respect of personal losses and/or damages suffered by me or any other person arising from or resulting as a consequence of my participation in the research entitled _____ (the "Research"), and hereby hold harmless the NWU against above-mentioned liability.

I confirm that I voluntarily consent to participate in the Research, and that I was in no way forced or coerced by the NWU to participate in the Research, and that the waiver and release shall apply to any claims that may arise during and/or after the Research.

I declare that I am aware of the risks involved in the Research, as explained to me, and of the implications of this waiver and release, and agree that this document shall also be binding upon my executor, curator or other assigns.

Signature _____

Date _____

ADDENDUM 4

NWU-EMELTEN-REC

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REVIEWER REPORT

Title of the study	
Ethics Application nr.	**NWU-**
Applicant's Name	
Reviewer Code	
Date of Review	

	Element	Yes No NA	Comment
1	Is the title appropriate to the content of the research?		
2	Has the research proposal been evaluated by a scientific/research proposal committee?		
3	Is the study relevant and of value? • Responsive • Contributes to knowledge • Worth doing		
4	Does the study show scientific integrity? • Knowledge of relevant literature • Sound and valid design and methodology • Was open to peer review and scrutiny • The ethical implications of the design and method clearly stated • Rationale of methodology		
5	Are the aims and/or objectives achievable and will it produce outcomes?		
6	Is the selection of the study population fair and just? • Method clear and complete • Fair distribution of burden and likelihood of benefit • No groups are deprived of an opportunity		

7	Are the inclusion and exclusion criteria clearly stated, appropriate and justified? • Rationale for the planned number reasonable • Rationale for inclusion and exclusion criteria clear and reasonable • Inclusion of vulnerable participants is justified		
8	Is the process of recruitment and enrolment clear and in detail? • Recruitment strategies neutral • Recruitment method (including screening) clear • Roles of gatekeepers and mediators clear • Recruitment materials appropriate (e.g. advertisement) • Done by an independent person • Location, context and timing appropriate and privacy and confidentiality protected • Participants not over researched		
9	Has a risk-benefit ratio analyses been done? • Risks identified • Precautions mentioned • Direct and indirect benefit stated • Risk benefit ratio analyses favourable		
10	Will the participants be appropriately reimbursement? • Time • Inconvenience • Expenses • No coercion or undue influence		
11	Is the participant's privacy and confidentiality protected? • Personal information and records protected • Identity protected		
12	Is the process of obtaining informed consent/permission/assent clear? • Informed and voluntary • Written and verbal • Obtained by an independent person • Confirmed by the researcher • Sufficient time given to consult and make an informed decision before signing • Can withdraw • Without coercion, undue influence or inappropriate incentives • Understandable and valid informed consent form • Need for translation		
13	Are the researchers professionally competent? • Academic qualifications suitable • Scientific and technical competence adequate • Proof of research competence (education, knowledge and experience) • Appropriate skills • Mentoring		

14	Is respect for participants clear throughout? • Dignity • Voluntary • Safety • Well-being • Interest of the participant		
15	Are the facilities where the research will be conducted appropriate and suitably resourced?		
16	Is data-collection well managed? • What data is being collected? • Why is the data being collected? • What will happen to the data? • How long will data be retained? • Will the data identify the participant? • Will it be shared with others and why? • Will it leave the country?		
17	Is the process of sample storage clear (if applicable)? • For how long? • Where will it be stored? • Is there informed consent for the analyses? • Who will manage it? • Will it be shared with others and why? • Will it leave the country?		
18	Was a statistician included or consulted/proof of expertise?		
19	Are all the additional legal documents/requirements applicable, included and correctly completed? • What is the current status thereof? • To what extent has it been operationalized? ▪ International contractual agreements/sub agreements ▪ National contractual agreements/sub agreements ▪ Collaboration agreements (other universities, individuals etc.) ▪ Written permission (National/provincial Departments, hospitals, clinics, universities etc.) ▪ Written goodwill permission (Traditional leaders, managers etc.) ▪ Confidentiality agreements (fieldworkers, mediators, participating clinicians or professionals etc.) ▪ Export/import permits ▪ Sponsorship agreements ▪ Service agreements (with sponsors, other entities etc.)		
20	Is the researcher and project covered by insurance?		
21	Is it clear how results will be disseminated? • How will participants be informed? • Is there a sure dissemination plan? • Will it be done in an ethical manner?		
22	Is conflict of interest clearly stated and how it will be handled?		

23	Is the process of data management and storage clear? • How will electronic data and hard copies be stored? • How will audio and video data be stored? • Who will store the data? • Who will have access? • How will the data be protected? • For how long will data be stored? • How will it finally be disposed of?		
24	Are there clear monitoring and safety measures in place?		
25	Is it a realistic time schedule?		
26	Has a budget been included and has it been stated how it will be covered?		
27	Specifically for secondary use of data or samples (if applicable): • Is there a permission letter from the project head stating what can be done? • Is the documentation of the original study included (e.g. proposal, ethics certificate etc.)? • Does the sub-study match the larger study? • Was permission given in the signed informed consent for the planned sub-study? • Is it clear that the initial data set or samples were collected in an ethical manner? • Is it clear how data/sample integrity was ensured through safe storage? • Has a clear methodology been presented on how the data/samples will be used in the present sub-study?		

Recommendation for status of the application

Approved	
Approved with minimal changes	
Approved with several changes	
Deferred	
Disapproved	

Recommendation for potential risk level of the application in the case of adult participants

No risk	
Minimal risk	
Medium risk	
High risk	

Recommendation for potential risk level of the application in case of children or incapacitated adults

No risk	
No more that minimal risk of harm	
Greater than minimal risk but provides prospect of direct benefit	

Greater that minimal risk with no prospect of direct benefit	

_____

Reviewer signature

_____

Date

ADDENDUM 5

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, Enigeering and Natural Sciences Research Ethics Office (NWU-EMELTEN-REC)
Tel: +2718 299 4707
Email: lukas.meyer@nwu.ac.za

Date

Prof/Dr/Ms /Mr
Address

ETHICS APPROVAL NOTIFICATION TEMPLATE

Dear Prof/Dr/Ms / Mr

APPROVAL NOTIFICATION OF YOUR APPLICATION BY THE NWU-EMELTEN-REC

Ethics number: NWU-

Kindly use the ethics reference number provided above in all correspondence or documents submitted to the NWU-EMELTEN-REC

Study title:……..

Study leader/supervisor: ……..

Student: …….

Application type: Larger study/Single study/Sub-study

Risk level: ……..

You are kindly informed that your application was reviewed at the meeting held on ……of the NWU-EMELTEN-REC and was approved/conditionally approved (see conditions at end of letter) on ……

The commencement date for this study is ……..dependent on fulfilling the conditions indicated below. Continuation of the study is dependent on receipt of the annual (or as otherwise stipulated) monitoring report and the concomitant issuing of a letter of continuation up to a maximum period of three years when extension will be facilitated during the monitoring process.

After ethical review:

Translation of the informed consent document to the languages applicable to the study participants should be submitted to the NWU-EMELTEN-REC (if applicable).

The NWU-EMELTEN-REC requires immediate reporting of any aspects that warrants a change of ethical approval. Any amendments, extensions or other modifications to the proposal or other associated documentation must be submitted to the NWU-EMELTEN-REC prior to implementing these changes. Any adverse/unexpected/unforeseen events or incidents must be reported on either an adverse event report form or incident report form.

A monitoring report should be submitted within one year of approval of this study (or as otherwise stipulated) and before the year has expired, to ensure timely renewal of the study. A final report must be provided at completion of the study or the NWU-EMELTEN-REC must be notified if the study is temporarily suspended or terminated. The monitoring report template is obtainable from the NWU-EMELTEN-REC Office at Ethics-EMELTEN-mon@nwu.ac.za. Annually a number of studies may be randomly selected for an external audit.

Please note that the NWU-EMELTEN-REC has the prerogative and authority to ask further questions, seek additional information, require further modification or monitor the conduct of your research or the informed consent process.

Please note that for any research at governmental or private institutions, permission must still be obtained from relevant authorities and provided to the NWU-EMELTEN-REC Office. Ethics approval is required BEFORE approval can be obtained from these authorities. The NWU-EMELTEN-REC complies with the South African National Health Act 61 (2003), the Regulations on Research with Human Participants (2014), the Ethics in Health Research: Principles, Structures and Processes (2015), the Belmont Report and the Declaration of Helsinki (2013).

We wish you the best as you conduct your research. If you have any questions or need further assistance, please contact the NWU-EMELTEN-REC Office at Ethics-EMELTEN-apply@nwu.ac.za

Conditions of approval (if applicable):

1. ….

Yours sincerely

Prof LW Meyer

NWU-EMELTEN-REC Chairperson

_____