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

NWU ETHICS APPLICATION FORM
THEOLOGY
(April 2016)

NB! PLEASE DO NOT DELETE ANY SECTIONS OF THIS FORM

CONFIDENTIAL!

NB! This document contains confidential information that is intended exclusively for the applicant(s), the non-Registered Committee of Faculty of Theology, Registered Research Ethics Committees (of the North-West University and the designated reviewers. Should this document or parts thereof come into your possession in error, you are requested to return it to the HREC without delay or destroy it. Unauthorised possession, reading, studying, copying or distribution of this material, or any other form of abuse, is illegal and punishable.

Instructions and recommended path for the completion of your application:

a. The research proposal forms the base document that is evaluated (by the Committee of Advanced Degrees of the Faculty of Theology) in conjunction with this application form. This application form gives the researcher the opportunity to expand on specific ethical issues required for approval.

b. All applicants complete § 1, 2, 3, 4, 5 and 7 (of all disciplines in Theology).

c. Select and complete the research-specific sub-sections from § 6 as applicable to the specific requirements of your study (utilise the table of contents).

d. Ensure that a proposal that has been approved by an appropriate Scientific/Research Proposal Committee is attached to the application form as well as proof of its approval according to the standardised template (see § 4.1).

e. Also attach an executive summary of the study (see § 4.1.1).

f. The applicants should ensure that a copy of the informed consent form for approval, that has been compiled according to the informed consent template and checklist supplied by the Faculty of Health Sciences Ethics Office for Research, Training and Support and Faculty of Theology (in Guidelines for Research Proposals), is submitted with the ethics application form.

g. Any questionnaires or interview schedules that will be used in the completion of the study have to be attached

h. Any advertisements that will be used in the study have to be attached

i. Attach any permission letters received from governing bodies.

j. Attach any contracts with collaborators/sponsors.

k. For applications of collaborative studies being conducted on more than one site, it is required that copies of the proposal and the informed consent forms from all centres involved in the study are included with the application.

l. Attach a 2-page narrative CV for each of the researchers involved in the study.

m. Liaise with the appropriate officials and colleagues mentioned in § 8, complete and sign a printed copy.

n. Submit scanned copies of the signed pages.

o. Include copies of proof of ethics training for all researchers involved in the study (not older than three years).

p. Submit the completed Ethics Application Form (with all the required attachments) via e-mail to. George.lotter@nwu.ac.za (Chairperson of CAD)

q. All required documentation (as previously outlined) should be attached separately to the aforementioned e-mail as indicated in point p.

r. Applicants must please ensure that all required finalised documents as indicated above are included with the application. **No additional attachments or version correction(s) will be accepted.** If this does occur and the application was incomplete then it will have to be resubmitted with the application form and all the required attachments which could mean that the application may miss the deadline for the closing of the agenda for the CAD meeting.

NWU Ethics Number

N	W	U	-	?	?	?	?	?	-	?	?	-	?	?

Campus

Faculty

Principle Investigator/Study Leader

Research entity

Study Title

Checklist for attachments for a Research Proposal:

Documents to Attach

Document		Tick if attached	Comment
1	Cover letter that indicates the title, researcher/s, the type of research ethics application, which documents are attached, and adds any explanations to clarify your application		
2	Executive summary of the project		
3	Proposal approved by a scientific/proposal committee		
4	An ethics application form to provide additional information not covered in the proposal		
5	Informed consent documentation and checklist (if collaborative study, informed consent from all the centers OR if an affiliated study, the original informed consent documentation of the original study)		
6	Advertisements or recruitment materials		
7	Questionnaire/s; interview schedule for interviews or focus groups		
8	Approval letter of the study by the scientific committee		
9	2-page narrative CVs of all the researchers in the project		
10	Proof of ethics training over the past three years for all the researchers in the project		
11	Permission letters from governing bodies to conduct the research		
12	Goodwill permission letters		

Table of Contents

1. SECTION 1: STUDY IDENTIFICATION

Provide the necessary descriptions below to identify this study application:

1.1 Full, descriptive title of the study

Type here

1.2 Name of the Study Leader/Primary investigator **NB!** Not the student's name

Type here

1.3 Name of the Student (if applicable)

Type here

1.4 Student number

Type here

1.5 Research entity e.g AUTHeR

Type here

1.6 Discipline e.g. Consumer sciences

Type here

1.7 Type of study

Type of study	
Single study	☐
Larger study	☐
Affiliated-study under a larger study	☐
Educational	☐
Other: Specify Type here	

1.8 In this study use is made of

Mark ALL options as “Yes” or “No” with X in the appropriate box – more than one option may be marked as “Yes”.

Description		**Yes**	**No**
Human participants (subjects)	Qualitative	☐	☐
	Quantitative	☐	☐
	Mixed method	☐	☐
	Other e.g. program evaluation	☐	☐
Filed privileged information (e.g. personal files) or stored data(e.g. data collected for another study)		☐	☐

1.9 Envisaged commencement and completion date of the study

More information
Here you can indicate the expected commencement and ending dates of the study, which may be anything from a day to a few years. The full expected duration of the study must be filled in below. Even if the expected duration of the study is uncertain, you can still make an estimate here and report the progress with the annual report. Ensure that the commencement date is at least a few weeks after the date of the HREC meeting at which your application is to be reviewed. The HREC will only grant ethics approval for a one year period. If the study should take longer, a monitoring report requesting permission for continuation must be submitted to the HREC two months before the expiry of the study.

Commencement Date	Completion Date
2 0 _ _ - _ _ - _ _ c c y y m m d d	2 0 _ _ - _ _ - _ _ c c y y m m d d

2. SECTION 2: STUDY CLASSIFICATION

Complete every option of all the questions in this section. This section is used to classify your study and select suitable reviewers.

2.1 Name of the Ethics Committee handling the application

Type here

2.2 Date of first application

Fill in below the date of the first submission of this ethics application

2 0 _ _ - _ _ - _ _
c c y y m m d d

2.3 Date of revised application (if applicable)

Fill in below the date of the submission of the revised ethics application

2 0 _ _ - _ _ - _ _
c c y y m m d d

2.4 Version number

Fill in the number of times this application has been submitted.

Version: _ _ _ _

2.5 Estimated risk level

Please indicate the estimated risk level of the research by using the two risk level tables indicated for adult human participants or children/incapacitated adults.

Estimated risk level for adult human participants	
Minimal risk	☐
Medium risk	☐
High risk	☐

Estimated risk level for children/incapacitated adults	
No more than minimal risk of harm (negligible risk)	☐
Greater than minimal risk but provides the prospect of direct benefit for the child/incapacitated adult	☐
Greater than minimal risk with no prospect of direct benefit to the child/incapacitated adult, but a high probability of providing generalizable knowledge	☐

2.6 Context of the Study

Mark ALL options as "Yes" or "No" with X in the appropriate box – more than one option may be "Yes".

Description		**Yes**	**No**
Scientific Research	Study falls within a research entity	☐	☐
	Study falls outside a research entity	☐	☐
	Study includes postgraduate students (e.g. masters or doctorate)	☐	☐
	Study includes contract work	☐	☐
Education and training (e.g. undergraduate practicals)	For staff of the North-West University	☐	☐
	For students (undergraduate or postgraduate learners)	☐	☐
	For other learners (not associated with University)	☐	☐

2.7 This study encompasses aspects that require additional ethical explanation

Mark ALL options as "Yes" or "No" with X in the appropriate box – more than one option may be "Yes". If a specific option is marked please complete the corresponding section in Section 6.

Description	**Yes**	**No**
Vulnerable participants	☐	☐
Measuring instruments and questionnaires that need psychometric interpretation	☐	☐
Any other aspect of potentially ethically sensitive nature (specify below)	☐	☐

Other aspects (specify)

Type here

2.8 For this study the following persons will be included in the study team

Fill in the number concerned with ALL options. Ensure that the participant numbers in this table correspond with the individuals indicated in Section 3.1, 3.2 and 3.3.

More information
*The **study leader** is generally viewed as the individual who takes the final responsibility for all aspects of the study e.g. study leader or principle investigator.*
*The **study supervisor** is generally the individual responsible for the day-to-day management of the study.*

Description		**Number**	
		Local	**Foreign**
Only for research studies	Study Leader (e.g. study leader/principle investigator)	0	0
	Study supervisor (day to day manager)	0	0
	Co-workers (researchers of the North-West University)	0	0
	Co-workers (researchers outside the North-West University)	0	0
	Co-workers (postgraduate students of the North-West University)	0	0
	Assistants/field workers	0	0
Only for education and training (e.g. undergraduate practicals)	Educator	0	0
	Co-workers (lecturers of the North-West University)	0	0
	Co-workers (lecturers outside the North-West University)	0	0
	Students (undergraduate learners of the North-West University)	0	0
	Students (postgraduate learners of the North-West University)	0	0
	Other learners (not associated with the North-West University)	0	0
	Assistants/field workers	0	0
Sponsors		0	0

Other members of the study team not mentioned above (specify)

Type here

I hereby declare that the above information in “Section 2: Study Classification” is complete and correct and that I did not withhold any information.

Yes	No
☐	☐

Remember to save your document regularly as you complete it!

3. SECTION 3: DETAIL OF STUDY LEADER/PRINCIPAL INVESTIGATOR, CO-WORKERS AND SUPERVISORS

3.1 Details of Study Leader/Principle investigator

More information
NB! Only NWU staff, or extraordinary professors in collaboration with staff of the North-West University, may register as Study Leaders/Principal Investigators. The Study Leader/Principal Investigator accepts final, overall responsibility for the total study.

Surname	Full Names	Title
Type here	Type here	Type here

NWU Campus	Faculty	Research entity/School
Type here	Type here	Type here

Position	University No.	Professional Registration (body & category)
Type here	Type here	Type here

Telephone			NWU-box or Postal Address
Work	Home	Cell	
Type here	Type here	Type here	Type here

E-mail Address
Type here

[PLEASE ATTACH THE TWO-PAGE NARRATIVE CV OF THE STUDY LEADER]

More information
NB! A 2-page CV in a narrative format, giving a brief overview of:

- *a researcher's qualifications*
- *career path to date*
- *specific research experience applicable to the present study (e.g. methodology or skills required)*
- *supervisory experience*
- *publication list (for the past 4 years)*

3.2 Details of Study Supervisor

Is the Study Leader also the study supervisor?
(Please mark with X in the appropriate box.)

More information
Where the Study Leader is not physically present or consistently available and where supervision of the research activities is necessary, a suitable researcher/lecturer may be designated as ***study supervisor****. The study supervisor is part of the study team.*

Yes	No
☐	☐

If “Yes”, this part can be left blank.
If “No” (i.e. if the Study Leader is not the Study Supervisor) give details below.

Surname	Full Names	Title
Type here	Type here	Type here

NWU Campus	Faculty	Research entity/School
Type here	Type here	Type here

Position	University no.	Professional Registration (body & category)
Type here	Type here	Type here

Telephone			NWU-box or Postal Address
Work	Home	Cell	
Type here	Type here	Type here	Type here

E-mail Address
Type here

[PLEASE ATTACH THE TWO-PAGE NARRATIVE CV OF THE STUDY SUPERVISOR]

More information
NB! A 2-page CV in a narrative format, giving a brief overview of:
- *a researcher’s qualifications*
- *career path to date*
- *specific research experience applicable to the present study (e.g. methodology or skills required)*
- *supervisory experience*
- *publication list (for the past 4 years) (if applicable)*

3.3 Other Members of the Study Team

Names, qualifications, professional registration and functions of all the other co-workers (researchers, postgraduate students in the case of a research study, or lecturers (in the case of training) and assistants/field workers who form part of the study team) should be indicated. The information given in this table should correspond with the number of team members given in Section 2.8 (Add extra rows to the table if required.)

Name	**Qualifications**	**Professional Registration**	**Association and/or Function**
Click and type here	Click and type here	Click and type here	Click and type here
Click and type here	Click and type here	Click and type here	Click and type here

Note: Type one name per row, or type “none” if there is no other team member.

[PLEASE ATTACH A TWO-PAGE NARRATIVE CV FOR ALL THE MENTIONED RESEARCH TEAM MEMBERS IN THIS SECTION]

More information
NB! A 2-page CV in a narrative format, giving a brief overview of:
- *a researcher’s qualifications*

- *career path to date*
- *specific research experience applicable to the present study (e.g. methodology or skills required)*
- *supervisory experience*
- *publication list (for the past 4 years)*

3.4 Conflict of Interests and Sponsors (if applicable)

3.4.1 Declare with full details any conflict of interests that any member of the study team or professional supervisor (see § 3.1, 3.2 and 3.3) might have.

More information
Examples of conflict of interest: financial, non-financial: intellectual, bias, overly optimistic promises of potential benefits, role of the researcher/s, desire of professional advancement, desire to make a scientific breakthrough, relationship with participants.

Name of Researcher	Complete description of the conflict and how it will be managed
Type name here, or type "Not applicable"	Type details here, or type "Not applicable"

Note: Type one name per row, or type "Not applicable" if there is no member of the study team or professional supervisor with a conflict of interest.

3.4.2 Give full details of all sponsors of the study.

Name of Sponsor	Contact Details	Affiliation & Contribution	Nature & Extent
Type name here, or type "Not applicable"	Type details here, or type "Not applicable"	Type details here, or type "Not applicable"	Type details here, or type "Not applicable"

Note: Type one name per row, or type "Not applicable" if there are no sponsors. Add extra rows to the table if required.

3.4.3 Is any participant in the study directly or indirectly involved with one or more of the sponsors or the researchers? Give full details.

Name of Participant	Association with Sponsor/Researcher
Type name here, or type "Not applicable"	Type details here, or type "Not applicable"

Note: Type one name per row, or type "Not applicable" if there are no such participants. Add extra rows to the table, if required.

3.4.4 Does any member of the study team receive any form of remuneration or other benefits from the sponsor(s), either directly or indirectly? Give full details.

Name of Team Member	Details
Type name here, or type "Not applicable"	Type details here, or type "Not applicable"

Note: Type one name per row, or type "Not applicable" if there are no such team members. Add extra rows to the table if required.

3.5 Collaborations (if applicable)

Declare with full details all collaboration agreements, e.g. with researchers or lecturers from another institution, national or international, who will be working on a defined section of the study.

More information
Your local team may collaborate with a team from a different national institution in South Africa or internationally, and thereby incorporate and benefit from their expertise and/or facilities. Typically, in such cases, functions and responsibilities differ for certain parts of the study. These functions and responsibilities must be fully described.

Name of Collaborator	National/International (Indicate which)	Full Description of functions and responsibilities
Type name here, or type "Not applicable"	Type name here, or type "Not applicable"	Type details here, or type "Not applicable"

Note: Type one name per row, or type "Not applicable" if there are no contractors. Add extra rows to table, if required.

3.6 Contractual Agreements (if applicable)

Declare with full details all contractual agreements (e.g. with team members, collaborators and sponsors) on the study. Please note: A copy of any contractual agreements must be submitted to the Health Research Ethics Committee, together with the submission of this application. Add extra rows to the table, if required.

More information
Sometimes there are contractual obligations with co-workers or organisations outside the University. These contractual obligations may e.g. place restrictions on certain aspects on the availability of raw data i.t.o. intellectual right of ownership. Particularly where foreign co-workers are involved, these contracts can get complex. Therefore you must indicate here what these contractual obligations encompass, whether the University approved and sanctioned it and declare and describe any other potential legal and ethical implications thereof.

Name of Contractor	Full Description of the agreement
Type name here, or type "Not applicable"	Type details here, or type "Not applicable"

Note: Type one name per row, or type "Not applicable" if there are no contractors. Add extra rows to the table, if required.

[PLEASE ATTACH ALL CONTRACTUAL AGREEMENTS]

3.7 Confidentiality

Note: Other people involved in the research that could pose a risk to confidentiality should sign confidentiality agreements e.g. transcribers and co-coder/s.

[PLEASE ATTACH ALL CONFIDENTIALITY AGREEMENTS (SEE CONFIDENTIALITY AGREEMENTS AS APPROVED BY THE LEGAL OFFICE OF THE NWU)]

3.8 Indemnity

Note: If people are involved in the research as part of the research team but are not as staff on the payroll of the university or by contract on the payroll of the university, they will not be covered by the insurance of the university and have to sign an indemnity form.

[PLEASE ATTACH ALL INDEMNITY FORMS (SEE INDEMNITY FORMS AS APPROVED BY THE LEGAL OFFICE)]

Remember to save your document regularly as you complete it!

4. SECTION 4: RESEARCH PROPOSAL AND SCIENTIFIC COMMITTEE APPROVAL

4.1 Executive summary and research proposal

4.1.1 Executive summary of the study

Provide an executive summary (maximum 150 words) of the study in the following format:

- brief problem statement (approx. 3 sentences)
- aims and objectives of the study
- study design and method

Type here

4.1.2 Proposal

Note: For each study a descriptive proposal has to be submitted and is used as the main document for evaluation. The proposal should reflect the ethics of the research throughout. Attach a proposal approved by the Scientific/Proposal Committee of your research entity.

[ATTACH THE RESEARCH PROPOSAL]

4.1.3 Scientific/Proposal Committee approval

This study should have been reviewed and approved by a Scientific/Proposal Committee.

More information
The proposal needs to be approved by a Scientific/Proposal Committee before it will be reviewed by the HREC. The HREC relies on the scientific expertise of this committee regarding the evaluation of the scientific merit and design of the study.

Yes	Details	
☐	Name of formal Scientific/Proposal Committee:	Type here
	Title, initials and surname of all of the members of Scientific/Proposal Committee present during the review.	Type here
	Date of approval:	Type here
No	Reason:	Type here
☐		

4.1.4 Letter confirming approval of protocol

The HREC has to have proof of confirmation of approval by the Scientific/Proposal Committee.

[ATTACH CONFIRMATION OF APPROVAL OF THE STUDY PROPOSAL BY THE SCIENTIFIC/PROPOSAL COMMITTEE ON THE MANDATED TEMPLATE.]

Remember to save your document regularly as you complete it!

5. SECTION 5: ADDITIONALLY REQUIRED INFORMATION ABOUT ETHICAL IMPLICATIONS OF THE RESEARCH NOT PROVIDED IN THE PROPOSAL

Note: The information contained in this section is *additional* to what is contained in the proposal.

5.1 What will be expected of participants during data gathering?

What will be expected of participants during data gathering e.g. a one hour interview, etc.

More information

Highlight what participants will be expected to do and what will be done to them, and how long it will take? This includes aspects such as procedures, methods of information gathering and what the probable associated experience of participants will be. Provide particular details on any step that might violate privacy e.g. sensitive questions. This section supports you in the completion of the section in the informed consent form entitled, "What will your responsibilities be?"

Type here

5.2 Risks and precautions

Name and explain *all the possible risks* for *all procedures* that the participants might experience during the research. Use the template at the back of the approved risk level descriptor document to guide you into identifying all the possible types of risk as well as the probability and magnitude of harm. By completing this section it will help you to answer the two sections on "Are there risks involved in your taking part in research?" and "What will happen in the unlikely event of some form of harm occurring as a direct result of your taking part in this research study?" in the informed consent form.

Risks (e.g. physical, psychological, social, legal, economic, dignitary and community) Identify all the possible risks.	**Precautions** (When describing these precautions be clear on how they will mitigate all the identified risks)
Type here	Type here

5.3 Benefits for participants

Describe 1) the potential *direct* benefits that the study might hold for the *individual participants*; or 2) the *indirect* benefits that the study holds for the *society at large* or for *the researchers and the organisations/institutions* they are working for, through the knowledge gained. By completing this section it will help you to answer the section on "Will you benefit from taking part in this research" in the informed consent form.

Direct benefits for participants	**Indirect benefits** for society at large or for the researchers/institution
Type here	Type here

5.4 Risk/benefit ratio analysis

The overall benefits should, in general, *always outweigh the risks*, for a study to be considered ethical. If this is not the case, there needs to be a *strong justification* for why research ethics approval should be given.

Benefit outweighs the risks	☐		
Risks outweigh the benefit	☐	Justify:	Type here

5.5 Facilities

Describe the place(s) and facilities in detail where the study will be implemented. This description is applicable to both institutions and the community. Also describe the availability of measures to handle emergencies in an applicable manner and how this will be executed.

Type here

5.6 Legal authorisation

Describe in detail *which bodies* must grant legal authorisation for this study (e.g. Department of Health, Department of Education, etc.). Mention *whether authorisation has already been obtained*, with reference to attached proof, or *how you will go about* getting authorisation before the study commences.
Conditional approval will be granted to obtain this authorisation but the study cannot commence before the HREC has received the final documents.

Type here

[PLEASE UPLOAD ALL DOCUMENTS INDICATING LEGAL AUTHORISATION]

5.7 Goodwill permission /consent

Describe in detail *what interest group representatives* must give permission for this study (e.g. community leaders, church leaders, tribal chiefs or other). Also mention *whether permission has already been obtained*, with reference to attached proof, or *how you will go about getting* permission before the study commences.
Conditional approval will be granted until proof of goodwill permission has be granted but the study cannot commence before the HREC has received the final documents.

Type here

[PLEASE UPLOAD ALL LETTERS OF GOODWILL PERMISSION]

5.8 Criteria for participant selection and recruitment

Describe in full which inclusion and exclusion criteria will be used to select participants and justify each of your choices. If you include one of the following in your exclusion/inclusion criteria, the need for it in the research has to be justified i.e. *race or ethnic origin, person's health or sex life, a person's inherited characteristics or biometric information*. Ensure that your exclusion criteria are not merely the opposite of the inclusion criteria.

Inclusion criteria	**Justification**
Type here	Type here

Exclusion criteria	Justification
Type here	Type here

5.9 Participant recruitment

Recruitment of human participants must take place within a specified time frame/schedule (i.e. specified starting and ending date) and cannot continue indefinitely. Explain how you will go about recruiting the participants.

More information
This process should take place in such a way that the participants do not feel intimidated by the process or implicitly "bribed", but decide absolutely voluntarily to participate. It should be fair and equitable. Include aspects of community entry e.g. advertisements, community advisory boards and the use of gatekeepers and mediators etc.

Type here

5.10 Informed consent (consent, permission, assent and dissent)

The focus in this section is on a detailed informed consent *process description*. According to law all participants must be fully informed about the implications and risks associated with participation in the study.

More information
How will you go about contacting them and explaining the study and accompanying implications to all participants? Ensure that participants are aware that participation in the research is voluntary and that they may withdraw from the study at any time. Where research is not carried out in participants' mother tongue, explain how you will go about conveying the information in an understandable manner. Where participants are not literate, a witness should be involved in obtaining informed consent. Be clear on who will obtain the informed consent (independent person) and how the researcher will be included to explain the research and answer questions. Discuss the role of the independent person. For your convenience you can use the template for informed consent as well as the accompanying checklist. Be clear on your description of the use of consent, permission, assent and dissent. For minors ensure that parental permission and child assent or adolescent consent (where applicable) is obtained for all participants.

Type here

[PLEASE UPLOAD YOUR INFORMED CONSENT FORM FOR APPROVAL AND THE INFORMED CONSENT CHECKLIST]

5.11 Incentives and/or remuneration of participants

Is any form of incentive and/or reimbursement offered to the participants?
If "Yes", describe it in full in terms of *what, how, where, when, how much, terms and conditions*, etc. Remember to work according to the TIE principle (**t**ime, **i**nconvenience, **e**xpenses e.g. transport and meals).
If no remuneration is offered, *justify why this is not the case* (Please mark with X in the relevant block and provide details).

Yes	No	Description
☐	☐	Type here

5.12 Announcement of study results to participants

Indicate *what, how, when and to whom* you will communicate the results of the study to the participants.

What?	Type here
How?	Type here
When?	Type here
To whom?	Type here

5.13 Privacy and Confidentiality

Explain how you will ensure both privacy and confidentiality throughout the research.

Privacy

Privacy is concerned with who has access to *personal information and records* about the participant as well as *privacy* during interviews/focus groups. Explain how privacy will be ensured in your study.

Type here

Confidentiality

Confidentiality ensures that *appropriate measures* will be implemented to *prevent disclosure of information* that might identify the participant either during the course of the research or afterwards e.g. anonymising data or pooling results. Explain how confidentiality will be ensured in your study.

Type here

5.14 Management, storage and destruction of data

Describe how you will manage the collected data as well as the storage thereof.

Data management

For management of data, indicate:

- what data will be stored
- how it will be stored
- how data in its various forms will be managed e.g. questionnaires, recorded interviews
- who will manage the data storage
- who will have access to the stored data
- how will data be regained from other research team members
- and if data sharing is to occur, how will this be managed?

Ensure that you refer to both *electronic* and *hard copy versions* of data.

Type here

Storage and destruction of data

Describe:

- where and how data will be stored
- for how long it will be stored

- who will be responsible for storage
- how it will be destroyed?

Ensure that you refer to both *electronic* and *hard copy versions* of data

Type here

5.15 Monitoring of research

Describe how you as the researcher will monitor:

- both the *implementation and progress* of the research
- compliance with the approved protocol
- the management of ethics throughout the research process
- the management of amendments during the execution of the research study, should they be needed
- how *incidents* and *adverse events/serious adverse events* (if applicable) will be reported.

Type here

5.16 Misleading of participants (if applicable)

Is use made of any form of misleading in the research, where the participants are not told the complete truth (e.g. psychotherapeutic interventions)?

More information
In the case of misleading participants, justification has to be provided that there is no alternative. When such an alternative exists, it should be provided to both the experimental and control group.

If "Yes":

- justify in full why it is necessary
- describe how the participants will be protected against potential negative consequences of the misleading information/action.
- when you will disclose and debrief
- describe how you will disclose to them that they were misled.

Yes	No
☐	☐

Justification	Precautionary measures
Type here	Type here
Disclosure	
When?	**How?**
Type here	Type here

5.17 Use of previously collected data (if applicable)

When your research study is making use of previously collected data, provide a comprehensive description of the following.

What was the purpose of the original collection?
Type here
What will your purpose be?
Type here

Give a description of how research integrity was ensured in the original study by referring to: • **how informed consent was obtained from participants** • **what they consented for** • **the circumstances under which the data were gathered** • **how the ethics of data collection was ensured?**
Type here
Give a detailed description of: • **how data storage was managed** • **where and how data were stored** • **for how long it was stored** • **who was responsible for storage** • **how it was ensured that no tampering occurred?**
Type here
Foreseeable risks for participants or researchers involved in using the previously collected data?

Risks	**Precautions**
Type here **Participants:** **Researchers:**	Type here

Will re-consent be necessary? **If "Yes" motivate:** • **why** • **for what** • **how this re-consent will be obtained.**

Yes	**No**		
☐	☐	**Why?**	Type here
		For what?	Type here
		How?	Type here

[ATTACH A LETTER FROM THE STUDY LEADER/PI GIVING PERMISSION FOR THE USE OF THE DATA]

[ATTACH THE ETHICAL APPROVAL OF THE ORIGINAL STUDY]

[ATTACH THE INFORMED CONSENT DOCUMENTATION FOR RE-CONSENT (IF APPLICABLE)]

5.18 Use of filed privileged information (if applicable)

Filed privileged information may be used for research purposes with the research ethics committee *waiving informed consent*. Give a detailed description of the process under the following headings.

The nature of the information to be used:
Type here
Process of obtaining permission/ethical approval for access:
Type here

Process of data collection:	
Type here	
Process of anonymization of the data:	
Type here	
Foreseeable risks for participants whose filed privileged information is being accessed:	
Risks	**Precautions**
Type here	Type here

5.19 Justifiability of statistical procedures

5.19.1 Statistical consultation

Indicate how you ensured the suitability of the statistical procedures to be used in this study e.g. consultation or proof of expertise.

Type here

5.19.2 Justification of sample size

Indicate how the sample size was determined e.g. power calculation or previously reported study designs.

Type here

5.19.3 Method of randomisation (if applicable)

If randomisation is to be used in this study, please indicate the manner by which randomisation will be assured.

Type here

5.19.4 Statistical methodology

Describe the means by which the statistical analyses will be conducted i.e. descriptive statistics, comparisons to be made, specific statistical tests to be used and the manner in which co-variance will be corrected for.

Type here

Remember to save your document regularly as you complete it!

6. SECTION 6: MATTERS THAT NECESSITATE ADDITIONAL INFORMATION

6.1 Sec 6A: Vulnerable participants

Please complete this section if your study includes *minors, adults with incapacities, persons in dependent relationships e.g. prisoners, students, persons with physical disabilities, collectivities and research-naïve communities.* (Mark ALL options as “Yes” or “No” with X in the appropriate box – more than one option may be “Yes”).

Description	Yes	No
Minors	☐	☐
Adults with incapacities	☐	☐
Persons in dependent relationships e.g. prisoners	☐	☐
Students	☐	☐
Persons with physical disabilities	☐	☐
Collectivities	☐	☐
Research-naïve communities	☐	☐
Other	☐	☐
Specify: Type here		

6.1.1 Description

Give a detailed description of the vulnerable group by referring to:

- who they are
- where they come from
- what makes them vulnerable.

Type here

6.1.2 Justification for inclusion

Explain the necessity for including this specific group of vulnerable people as human participants (subjects) indicating the *direct benefit to the participants themselves* or the *indirect benefit of an improved scientific understanding.*

Type here

6.1.3 Additional precautionary measures to reduce the risk of harm

Explain any additional precautionary measures you will take to reduce the possibility of harm.

Type here

6.2 Sec 6B: Measuring instruments and questionnaires that need psychometric interpretation

Please complete this section if any measuring instruments or validated questionnaires are used in this study that needs psychometric interpretation.
NB! Do not complete this section for any other types of questionnaires.

6.2.1 Name

Which psychometric measuring instruments and validated questionnaires will be used in the study?

Description
Type here

6.2.2 Information about the measuring instrument/questionnaire

Provide detailed information on the psychometric measuring instrument/questionnaire, so that the reviewers can evaluate the ethically justifiable use thereof.
NB! If more than one psychometric measuring instrument/questionnaire is used, select and copy the whole table and paste as many tables underneath as is necessary.

Psychometric measuring instrument/questionnaire

Approved Name	Normal Application
Type here	Type here

Reliability	Validity
Type here	Type here

Other Relevant Information
Type here

6.2.3 Validation for target group:

Is the measuring instrument validated for the target group (e.g. for South African circumstances)? Provide full details. Please mark with X in the appropriate box and provide details.

Yes	No	Details
☐	☐	Type here

Remember to save your document regularly as you complete it!

7. SECTION 7: OTHER ETHICS EVALUATIONS AND RISK INSURANCE

7.1 Sec 7a: Evaluation by other Research Ethics Committees

Please complete this section if this study has been or will be evaluated by any other research ethics committees, for example with multi-institutional studies. Provide information about all research ethics committees involved in the review and approval of this study.

Name of the Research Ethics Committee	**Date of Approval/In Process**	**Contact Number or E-mail address of the research ethics committee**	**Approval no.**
Type name here, or type “None”	Type details here	Type details here, or type “Not applicable”	Type details here, or type “Not applicable”
Type name here, or type “None”	Type details here	Type details here, or type “Not applicable”	Type details here, or type “Not applicable”
Type name here, or type “None”	Type details here	Type details here, or type “Not applicable”	Type details here, or type “Not applicable”

Remember to save your document regularly as you complete it!

7.2 Sec 7b: Risk Insurance

The North-West University has insurance at its disposal to cover the risk of claims against the University in case of damage to participants due to professional negligence – the maximum cover is currently R100 million per annum (all studies included). However, this is only available if studies are ethically approved and researchers have kept to the proposal.

7.2.1 Describe the potential risks to which the participants/researchers/assistants/field workers are going to be subject to in so far as complications may lead to summonses.

Type	**Risks**
Participants	
Researchers	
Assistants and/or field workers	
Others	

7.2.2 These potential risks are covered by:

North-West University	☐
Sponsor/s	☐
Other: Specify: Type here	☐

7.2.3 Is this insurance adequate (measured against the potential risks)?

Please mark with X in the appropriate box.

Yes	No	If “No”, indicate what will be done to ensure that there is sufficient coverage?
☐	☐	Type here

Remember to save your document regularly as you complete it!

8. SECTION 8: DECLARATIONS

Applications and declaration are filled in and signed by:
Sec 8a: Study Leader
Sec 8b: Statistical Consultant
Sec 8c: Research Director

The pages with declarations and signatures must be **scanned** with this form.

[SCAN ALL SIGNED DECLARATIONS]

Health Research Ethics Application

Study Leader (Title, Initials and Surname)	Study Title (see § 1.1)
Type here	Type here

NWU Ethics Number

N	W	U	-						-			-		

8.1 Sec 8a: Study Leader

Application and Declarations by Study Leader

I, the undersigned, hereby apply for approval of the research study as described in the preceding proposal and declare that:

8.1.1 The information in this application is, to the best of my knowledge, correct and that no ethical codes will be violated with the study;
8.1.2 I will make sure that the study is managed ethically justifiably from start to finish;
8.1.3 In the case of human participants;
8.1.3.1 I will put it clearly to all participants that participation (including assent) in any research study is absolutely voluntary and that no pressure, of whatever nature, will be placed on any potential participant to take part;
8.1.3.2 I will put it clearly to all participants that any participant may withdraw from the study at any time and may ask that his/her data no longer be used in the study, without stating reasons and without fear of any form of prejudice;
8.1.3.3 every participant who takes part in the study will receive the accompanying form for informed consent and it will be ensured that every participant understands the information (including the process and risks) fully;
8.1.3.4 every participant will sign the informed consent in writing before the study commences, or a witness will stand in on behalf of the participant when the participant is illiterate;
8.1.3.5 the written permission of the parent or legal guardians of all minor subjects will be obtained before the research commences;
8.1.3.6 any foreseeable risk is restricted to the minimum, any permanent damage is avoided as far as possible and that appropriate precautions and safety measures are in place;
8.1.3.7 confidentiality of all the information of all participants will be respected and ensured;
8.1.4 I and all co-workers/assistants/field workers are appropriately qualified, capable and legally competent to implement the proposed studies/procedures/interventions;

8.1.5 I will not deviate from the approved proposal and that I understand approval for the study will be cancelled if I deviate from the proposal without the approval of the Health Research Ethics Committee;
8.1.6 the study is scientifically justifiable;
8.1.7 where necessary, all contracts, permits and the applicable documents of relevance will be obtained before the research commences;
8.1.8 I will ensure that all data are stored safely and remain in the possession of the North-West University;
8.1.9 I will report in writing any incidents or adverse events/serious adverse events that occur during the study without delay to the Health Research Ethics Committee;
8.1.10 I undertake to respect intellectual property rights throughout and to avoid any form of plagiarism;
8.1.11 I will obtain permission for amendments to the protocol and report annually (or more often for medium and high risk studies) to the Health Research Ethics Committee on the prescribed monitoring report concerning progress of the study;
8.1.12 I will notify the Health Research Ethics Committee should the study be terminated.

Name (Title, Full Names & Surname)	Qualifications
Type here	Type here
	2 0 _ _ - _ _ - _ _ c c y y m m d d
Signature	Date

Remember to save your document regularly as you complete it!

Study Leader (Title, Initials & Surname)	Study Title (see § 1.1)
Type here	Type here

NWU Ethics Number

N	W	U	-						-			-		

8.2 Sec 8b: Statistical Consultant (If applicable)

The statistician of the Statistical Consultation Service of the North-West University completes this section (where applicable).

8.2.1 Have you ascertained that the statistical analyses to be used in this study is justifiable according to your judgement?

Please mark with X in the appropriate box and provide details.

Yes	No	Remarks
☐	☐	Type here

Name (Title, Full Names & Surname)	Qualifications
Type here	Type here

	2 0 _ _ - _ _ - _ _ c c y y m m d d
Signature	Date

Remember to save your document regularly as you complete it!

Study Leader (Title, Initials & Surname)	Study Title (see § 1.1)
Type here	Type here

NWU Ethics Number

N	W	U	-						-			-		

8.3 Sec 8c: Research Director (School director if Education request)

I, the undersigned, hereby declare that the above study has been reviewed by a Scientific/Proposal Committee and may proceed to the Health Research Ethics Committee and that the Study Leader/Researcher has enough physical facilities, equipment and money at his/her disposal to implement and complete the study.

8.3.1 Research Director:

The director of the research entity signs here.

Name (Title, Full Names & Surname)	Capacity
Type here	Type here

	2	0			-			-		
	c	c	y	y		m	m		d	d
Signature	Date									

Remember to save your document regularly as you complete it!

Credits

Compiled by the Faculty of Health Sciences Ethics Office for Research, Training and Support