

NWU ETHICS APPLICATION FORM
**THEOLOGY[[1]](#footnote-1)**

***(January 2022)***

**THE INFORMATION IN THIS FORM IS CONFIDENTIAL!**

This document contains confidential information that is intended exclusively for the applicant(s), the non-Registered Committee of Faculty of Theology (TREC), 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 TREC 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 the application**:

Applicants must please ensure that all required finalised documents are included for the application. If the application is incomplete, 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 ethics meeting.

1. Research proposal: The research proposal forms the main document that is evaluated (by the Committee of Advanced Degrees of the Faculty of Theology) in conjunction with this ethics application form. This application form gives the researcher the opportunity to expand on specific ethical issues required for approval. Ensure that the research proposal has been approved by the relevant scientific / research proposal committee and attach proof of its approval.
2. Ethics application form:
	1. Make sure you complete sections 1, 2, 3, 4, 5 and 7 of this form.
	2. Section 6 must be completed if the study involves vulnerable participants, and/or psychometric interpretation.
	3. Liaise with the appropriate officials and colleagues (mentioned in section 8) to complete and sign the application form. If this form cannot be electronically signed, print the relevant pages and submit the scanned signed pages with this application form.
	4. For applications of collaborative studies being conducted on more than one site, it is required that copies of the research proposal and the informed consent forms from all centres involved in the study are included with the application.
3. Attach the following additional documents:
	1. Informed consent letters: Applicants must use the informed consent template 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

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* 1. Questionnaires or interview schedules
	2. Narrative CV for all participating researchers
	3. Proof of ethics training for all participating researchers
	4. Code of conduct for all participating researchers
	5. Permission letters from relevant governing bodies
	6. Contracts with collaborators or sponsors
	7. Signed statistical consultation form (if applicable)
	8. Confidentiality undertaking (if applicable)
	9. Indemnity form (if applicable)
	10. Advertisements (If applicable)

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **NWU Ethics Number**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
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|  |
| Campus |  | Faculty |  |
| Principle Investigator/Study Leader | Type here | Research entity |  |
| Study Title | Type here |

1. Section 1: STUDY identification

* 1. Full, descriptive title of the study (title to be registered)

|  |
| --- |
| Type here |

* 1. Name of the study leader / primary investigator (Not the student's name)

Only NWU staff members or extraordinary staff members, in collaboration with staff members of the NWU, may register as study leaders / principal investigators, as they have to accept final, overall responsibility for the total study.

|  |
| --- |
| Type here |

* 1. Name of the Student

|  |
| --- |
| Type here |

* 1. Student number

|  |
| --- |
| Type here |

* 1. Research entity

|  |
| --- |
|  |

* 1. Research focus

|  |
| --- |
|  |

* 1. Discipline

|  |
| --- |
|  |

1.8T Type of study

|  |
| --- |
| **Type of study** |
| Single study | **[ ]**  |
| Larger study | **[ ]**  |
| Affiliated-study under a larger study | **[ ]**  |
| Other (specify):       | **[ ]**  |

1.9I Methodology that will be followed

|  |  |  |
| --- | --- | --- |
| **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) | **[ ]**  | **[ ]**  |

1.10i Envisaged commencement and completion date of the study

Indicate the expected commencement and ending dates of the study, which may be anything from a day to a few years (depending on a M or PhD study). The full expected duration of the study should be filled in. Even if the expected duration of the study is uncertain, the applicant can still make an estimate duration and report the progress of the study with the annual monitoring report. REC-FT could grant ethics approval for a day to a few years’ period (depending on the nature and duration of the study). If the study should take longer, the annual monitoring report requesting permission for continuation should be submitted to REC-FT.

|  |  |
| --- | --- |
| Commencement Date (Please update) | Completion Date (Please update) |
| Click or tap to enter a date. | Click or tap to enter a date. |

1. Section 2: Study Classification
	1. Name of the ethics committee handling this application

|  |
| --- |
| REC-FT |

* 1. Date of first application

|  |
| --- |
| Click or tap to enter a date. |

* 1. Date of revised application (if applicable)

|  |
| --- |
| Click or tap to enter a date. |

* 1. Version number

|  |
| --- |
| Version:  |

* 1. 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.

Studies conducted within the risk level descriptors (RLD) are discipline-specific (scope of practise) within a broader national and international environment with a distinct reflection on the risk benefit analysis[[2]](#footnote-2). It forms the basis of all research ethics committees’ (RECs’) decision-making regarding ethical clearance of research. The research ethics committee of the Faculty of Theology (REC-FT) refer health related research on humans with a medium or high risk level and vulnerable participants to one of the two National Health Research Ethics Council (NHREC) registered RECs of the NWU, one of which focuses on research on humans that is health related research (Health Research Ethics Committee – HREC), and the other one on research on humans that is not health related research (Education, Management, Humanities and Social Sciences Research Ethics Committee - EMHS-REC)

|  |
| --- |
| **Estimated risk level for adult human participants** |
| No/Low risk | **[ ]**  |
| 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 | **[ ]**  |

* 1. Context of the Study

|  |  |  |
| --- | --- | --- |
| **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) | **[ ]**  | **[ ]**  |

* 1. Additional ethical considerations linked with section 6 of this form

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|  |  |  |
| --- | --- | --- |
| **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)

|  |
| --- |
|  |

* 1. Persons 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.

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** |
| Study Leader (e.g. study leader/principle investigator) |  |  |
| Study supervisor (day to day manager) |  |  |
| Co-workers (researchers of the North-West University) |  |  |
| Co-workers (researchers outside the North-West University) |  |  |
| Co-workers (postgraduate students of the North-West University) |  |  |
| Assistants/field workers |  |  |

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 |
| **[ ]**  | **[ ]**  |

1. Section 3: Detail of Study Leader / Principal investigator, Co‑workers and supervisors
	1. Details of study leader / principle investigator

Only NWU staff members or extraordinary staff members, in collaboration with staff members of the NWU, may register as study leaders / principal investigators, as they have to accept 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 NARRATIVE CV OF THE STUDY LEADER, which indicates researcher’s qualifications, career path to date, specific research experience applicable to the present study (e.g. methodology or skills required), supervisory experience, and publication list (for the past 4 years)]

* 1. Details of study supervisor

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.

|  |  |  |
| --- | --- | --- |
| 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 NARRATIVE CV OF THE STUDY SUPERVISOR, which indicates researcher’s qualifications, career path to date, specific research experience applicable to the present study (e.g. methodology or skills required), supervisory experience, and publication list (for the past 4 years)]

**3.3 Other Members of the Study Team**

|  |  |  |
| --- | --- | --- |
| **Name** | **Qualifications** | **Association and/or Function** |
| Type here | Type here | Type here |
| Type here | Type here | Type here |

[Please attach **CV of other co-workers** (researchers, postgraduate students in the case of a research study and assistants who form part of the study team)]

* 1. Conflict of interests and sponsors (if applicable)

Declare with full details any conflict of interests that any member of the study team might have. For example, financial, intellectual, bias, role of the researcher/s, desire of professional advancement, relationship with participant.

|  |  |
| --- | --- |
| **Name of Researcher** | **Complete description of the conflict and how it will be managed** |
| Type here | Type here |

Note: Type one name per row, or type “none” if there is no conflict of interest

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Sponsor** | **Contact Details** | **Affiliation & Contribution** | **Nature & Extent** |
| Type here | Type here | Type here | Type here |

Note: Type one name per row, or type “none” if there is no sponsor

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 here | Type here |

 Note: Type one name per row and add more rows if necessary

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 here | Type here |

Note: Type one name per row and add more rows if necessary

* 1. Collaborations (if applicable)

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 here | Type here | Type here |

Note: Type one name per row and add more rows if necessary

* 1. Contractual Agreements (if applicable)

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 in terms of 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 here | Type here |

Note: Type one name per row and add more rows if necessary

[PLEASE ATTACH ALL CONTRACTUAL AGREEMENTS]

* 1. Confidentiality

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)]

* 1. Indemnity

If people are involved in the research as part of the research team, but are not as staff members 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)]

1. Section 4: Research proposal and scientific committee approval
	1. Research proposal

For each study a descriptive research proposal has to be submitted and is used as the main document for evaluation. The proposal should reflect the ethical considerations of the research throughout.

[ATTACH THE RESEARCH PROPOSAL]

**4.2 Scientific commitee**

The proposal must be approved by a scientific committee, before it can be reviewed by the REC-FT, as REC-FT relies on the scientific expertise of this committee regarding the evaluation of the scientific merit and design of the study.

Has this study been evaluated and approved by a Scientific/Proposal Committee? If “Yes”, provide details. If “No”, provide a reason. (Please mark with X in the relevant block and provide details if “Yes”)

|  |  |  |
| --- | --- | --- |
|  |  | **Details:** |
| **Yes[ ]**  |  | Name of formal Scientific Committee: |  |
|  | Date of approval: | Click or tap to enter a date. |
|  |  |  |
| **No** |  | Reason: | Type here |
| **[ ]**  |  |

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

1. Section 5: Additional required information about ethical implications of the research not provided in the proposal

The information contained in this part is *additional* to what is contained in the proposal. Make sure that all the relevant ethical implications are discussed in the proposal and give an indication of the page number where the information can be found in the proposal.

* 1. What will be expected of participants during data gathering?

Highlight what participants can be expected to do and what can 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 can 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?”

See point …… on page ……. of the proposal. If not discussed in the proposal, provide the information below.

|  |
| --- |
| Type here |

* 1. 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 sensitive characteristics 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.

See point …… on page ……. of the proposal. If not discussed in the proposal, provide the information below.

|  |  |
| --- | --- |
| **Inclusion criteria** | **Justification**  |
| Type here | Type here |
| **Exclusion criteria** | **Justification**  |
| Type here | Type here |

* 1. Participant recruitment

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

See point …… on page ……. of the proposal. If not discussed in the proposal, provide the information below.

|  |
| --- |
| Type here |

* 1. Informed consent (consent, permission, assent and dissent)

According to law all participants must be fully informed about the implications and risks associated with participation in the study. Describe: 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.

See point …… on page ……. of the proposal. If not discussed in the proposal, provide the information below.

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| Type here |

[PLEASE ATTACH YOUR INFORMED CONSENT FORM FOR APPROVAL]

* 1. 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.

See point …… on page ……. of the proposal. If not discussed in the proposal, provide the information below.

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

* 1. Benefits for participants

Describe first, the potential direct benefits that the study might hold for the individual participants; and second, 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.

See point …… on page ……. of the proposal. If not discussed in the proposal, provide the information below.

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

* 1. Risk/benefit ratio analysis

The overall benefits (risk/benefit analysis) 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.

See point …… on page ……. of the proposal. If not discussed in the proposal, provide the information below.

|  |  |
| --- | --- |
| Benefit outweighs the risks | **[ ]**  |
| Risks outweigh the benefit | **[ ]**  | Justify: | Type here |

* 1. Privacy and Confidentiality

See point …… on page ……. of the proposal. If not discussed in the proposal, provide the information below.

|  |
| --- |
| **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 |

* 1. 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.

See point …… on page ……. of the proposal. If not discussed in the proposal, provide the information below.

|  |
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| Type here |

* 1. 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 REC-FT has received the final documents.

See point …… on page ……. of the proposal. If not discussed in the proposal, provide the information below.

|  |
| --- |
| Type here |

[PLEASE ATTACH ALL DOCUMENTS INDICATING LEGAL AUTHORISATION]

* 1. Goodwill permission / consent (Gatekeeper 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 REC-FT has received the final documents.

See point …… on page ……. of the proposal. If not discussed in the proposal, provide the information below.

|  |
| --- |
| Type here |

[PLEASE ATTACH ALL LETTERS OF GOODWILL PERMISSION]

* 1. 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).

See point …… on page ……. of the proposal. If not discussed in the proposal, provide the information below.

|  |  |  |  |
| --- | --- | --- | --- |
| Yes | No |  | Description |
| **[ ]**  | **[ ]**  |  | Type here |

* 1. Management, storage and destruction of data, and monitoring of research

See point …… on page ……. of the proposal. If not discussed in the proposal, provide the information below

|  |
| --- |
| **Data management: storage and destruction**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, for how long will it be stored and how will it be destroyed? Ensure that you refer to both electronic and hard copy versions of data*.* |
| Type here |
| **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, and how *incidents* and *adverse events/serious adverse events* (if applicable) will be reported. |
| Type here |

* 1. 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** |
| **Participants:**Type here**Researchers:** Type here | 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 / PRINCIPLE INVESTIGATER 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)]

* 1. Justifiability of statistical procedures

See point …… on page ……. of the proposal. If not discussed in the proposal, provide the information below

* + 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 |

* + 1. Justification of sample size

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

|  |
| --- |
| Type here |

* + 1. Method of randomisation

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

|  |
| --- |
| Type here |

* + 1. 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 |

1. Section 6: Matters that Necessitate Additional Information

* 1. Sec 6A: Vulnerable participants

 Does your study include any of the following persons?

|  |  |  |
| --- | --- | --- |
| **Description** | **Yes** | **No** |
| Minors | **[ ]**  | **[ ]**  |
| Adults with incapacities | **[ ]**  | **[ ]**  |
| Persons in dependent relationships e.g. prisoners | **[ ]**  | **[ ]**  |
| Students | **[ ]**  | **[ ]**  |
| Persons with physical disabilities | **[ ]**  | **[ ]**  |
| Collectivises | **[ ]**  | **[ ]**  |
| Research-naïve communities | **[ ]**  | **[ ]**  |
| Other | **[ ]**  | **[ ]**  |
| Specify:  |

* + 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 |

* + 1. 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 |

* + 1. Additional precautionary measures to reduce the risk of harm

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

|  |
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| Type here |

* 1. 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.

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

|  |
| --- |
| **Description** |
| Type here |
| Approved Name | Normal Application |
| Type here | Type here |
| Reliability | Validity |
| Type here | Type here |
| Other Relevant Information  |
| Type here |

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 |

1. Section 7: Other Ethics Evaluations AND Risk Insurance

* 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 here | Type here | Type here | Type here |
| Type here | Type here | Type here | Type here |

* 1. 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.

Describe the potential risks

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

These potential risks are covered by:

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

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

|  |  |  |
| --- | --- | --- |
| Yes | No | If “No”, indicate what will be done to ensure that there is sufficient coverage? |
| **[ ]**  | **[ ]**  | Type here |

1. Section 8: Declarations

* 1. Sec 8a: Declaration by the study leader

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

* + 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;
		2. I will make sure that the study is managed ethically justifiably from start to finish;
		3. In the case of human participants;
* 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;
* 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;
* 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;
* 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;
* the written permission of the parent or legal guardians of all minor subjects will be obtained before the research commences;
* 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;
* confidentiality of all the information of all participants will be respected and ensured;
	+ 1. I and all co-workers/assistants/field workers are appropriately qualified, capable and legally competent to implement the proposed studies/procedures/interventions;
		2. I will not deviate from the approved proposal, and I understand approval for the study will be cancelled if I deviate from the proposal without the approval of REC-FT;
		3. The study is scientifically justifiable;
		4. Where necessary, all contracts, permits and the applicable documents of relevance will be obtained before the research commences;
		5. I will ensure that all data are stored safely and remain in the possession of the NWU;
		6. I will report in writing any incidents, adverse or serious adverse events that occur during the study without delay to REC-FT;
		7. I undertake to respect intellectual property rights throughout and to avoid any form of plagiarism;
		8. I will obtain permission for amendments to the protocol and report annually (or more often for medium and high risk studies) to REC-FTon the prescribed monitoring report concerning progress of the study;
		9. I will notify REC-FTshould the study be terminated for one or another reason.

|  |
| --- |
|  |
|  |  |
| Click or tap to enter a date. |
| Signature | Date |

* 1. Sec 8b: Declaration of statistical consultant (If applicable)

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

|  |  |  |  |
| --- | --- | --- | --- |
| Yes | No |  | Remarks |
| **[ ]**  | **[ ]**  |  | Type here |

|  |  |
| --- | --- |
| Name (Title, Full Names & Surname) | Qualifications |
| Type here | Type here |
|  |
|  |  |
| Click or tap to enter a date. |
| Signature | Date |

* 1. Sec 8c: Declaration of the 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 relevant 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.

|  |  |
| --- | --- |
| Name (Title, Full Names & Surname) | Capacity |
| Type here | Type here |
|  |
|  |  |
| Click or tap to enter a date. |
| Signature | Date |

|  |
| --- |
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1. The Faculty of Health Sciences Ethics Office is acknowledged for the use of their document with adjustment for the use in the Faculty of Theology at the North-West University. [↑](#footnote-ref-1)
2. Regulations relating to research on human subjects, Department of Health, Government Gazette #36508, 29 May 2013. [↑](#footnote-ref-2)