

NWU ETHICS APPLICATION FORM THEOLOGY¹

**Application for Ethics Approval for a Systematic Review / Literature Study
(June 2018)**

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 (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 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 ethics 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, 6 and 7.
- c. 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).
- d. Also attach an executive summary of the study (see § 4.1.1).
- e. Include a narrative CV for each of the researchers involved in the study.
- f. Liaise with the appropriate officials and colleagues mentioned in § 7, complete and sign a printed copy.
- g. Submit the scanned copies of the signed pages.
- h. Include copies of proof of ethics training for all researchers involved in the study (not older than three years).
- i. All 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 all of the documents attached which could mean that the application may not be considered for the applicable meeting date.

¹ The Faculty of Health Sciences Ethics Office is acknowledge for the use of their document with adjustment for the use in the Faculty of Theology at the North-West University.

NWU Ethics Number

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Campus
 Principle Investigator/Study Leader
 Study Title

Faculty
 Research entity

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 that adds any explanations to clarify your application		
2	Executive summary of the project (150 words only)		
3	Proposal approved by a scientific/proposal committee		
4	A systematic review ethics application form		
5	Approval letter of the study by the scientific committee		
6	2-page narrative CVs of all the researchers in the project		
7	Proof of ethics training over the past three years for all the researchers in the project		
8	Signed NWU code of conduct for researchers for each team member		
9	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		
10	Checklist of attachments		

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1 SECTION 1: STUDY IDENTIFICATION

Provide the necessary descriptions below to identify this study application:

1.1 Full, descriptive title of the study (title to be registered)

Type here

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

More information

NB! Only NWU staff, or extraordinary staff 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.

Type here

1.3 Name of the Student (if applicable)

Type here

1.4 Student number

Type here

1.5 Research entity: e.g Unit for Reformational Theology and the Development of the SA Society (URT); Ancient Texts: Text, Context, and Reception (AT)

Type here

1.6 Research focus: e.g Ancient Texts: Text, Context and Reception; Bibliological Perspectives; Ecclesiological Perspectives; Ecumenical Perspectives; Missiological Perspectives; Moral Development of the Society; Practical-Theological Perspectives; Public Practical Theology and Civil Society

Type here

1.7 Discipline e.g. Ancient Languages; Dogmatology; Ecclesiology; Missiology; New Testament; Old Testament; Practical Theology

Type here

1.8 Envisaged commencement and completion date of the study

More information

On the ethics application form the applicant can 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. The Research Ethics Committee of the Faculty of Theology (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 the Research Ethics Committee of the Faculty of Theology (REC-FT).

Commencement Date	Completion Date																																								
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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 Ethics Committee handling 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 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 application for the community in general by using the risk level table indicated.

Estimated risk level of the results for the community in general	
No/Low risk	<input type="checkbox"/>
Minimal risk	<input type="checkbox"/>
Medium risk	<input type="checkbox"/>

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	<input type="checkbox"/>	<input type="checkbox"/>
	Study falls outside a research entity	<input type="checkbox"/>	<input type="checkbox"/>

	Study includes postgraduate students (e.g. masters or doctorate)	<input type="checkbox"/>	<input type="checkbox"/>
	Study includes contract work	<input type="checkbox"/>	<input type="checkbox"/>

2.7 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 and 3.2.

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
	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	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
<input type="checkbox"/>	<input type="checkbox"/>

Remember to save your document regularly as you complete it!

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

3.1 Details of Study Leader/Principle investigator

Name and details of the Study Leader/Principal Investigator.

More information
NB! Only NWU staff, or extraordinary staff 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
Work	Home	Cell	Address		
Type here	Type here	Type here	Type here		

E-mail Address
Type here

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

<p><i>More information</i> NB! A 2-page CV in a narrative format, giving a brief overview of:</p> <ul style="list-style-type: none"> • 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 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 and assistants 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 2.7 (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

(Type one name per row, or type "none" if there is no other team member)

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

<p><i>More information</i> NB! A 2-page CV in a narrative format, giving a brief overview of:</p> <ul style="list-style-type: none"> • 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)

3.3 Conflict of Interests

Declare with full details any conflict of interests that any member of the study team might have.

More information

Examples: 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. Add extra rows to the table, if required.

3.4 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 the table, if required.

[PLEASE ATTACH ALL CONTRACTUAL AGREEMENTS]

Remember to save your document regularly as you complete it!

4 SECTION 4: RESEARCH PROPOSAL AND SCIENTIFIC COMMITTEE APPROVAL

4.1 Research proposal

4.1.1 Executive summary of the study

Provide an executive summary (150 words max) 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

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”)

More information
 The proposal needs to be approved by a Scientific/Proposal Committee before it will be reviewed by the Research Ethics Committee of the Faculty of Theology (REC-FT). The REC-FT relies on the scientific expertise of this committee regarding the evaluation of the scientific merit and design of the study.

Yes	Details	
<input type="checkbox"/>	Name of formal Scientific/Proposal Committee:	Select
	Title, initials and surname of all the members of Scientific/Proposal Committee present during the review.	Type here
	Date of approval:	Type here
No	Reason: Type here	
<input type="checkbox"/>		

4.1.4 Letter confirming approval of protocol

The *Research Ethics Committee of the Faculty of Theology (REC-FT)* 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 SYSTEMATIC REVIEW / LITERATURE STUDY

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

5.1 Please describe the study characteristics according to the PICOS (participants, interventions, comparisons, outcomes and study design) assessment:

More information
 The PICOS assessment highlights the core strategy and purpose of the systematic review to be undertaken by defining exactly the parameters to be followed. The “**participants**” aspect indicates the study populations that will be investigated i.e. which population groups will be included in the analysis? The “**intervention**” aspect highlights the specific therapeutic strategy that is being investigated e.g. a new medication or psychological intervention. The “**comparisons**” aspect defines the alternative therapeutic strategy that the intervention is being compared to, in order to determine if the intervention has greater efficacy e.g. the current standard of care or a placebo. The “**outcomes**” aspect refers to the actual variable that is being measured in the analysis to determine the efficacy of the intervention e.g. weight loss over time or reduced cholesterol levels. The “**study design**” aspect highlights the types of studies that are to be included in the systematic review e.g. randomised control trials or epidemiological studies. For each aspect that is indicated in the table, please give an explanation for the choice of the specific aspect e.g. the black South African population is being investigated due to

the increased probability of side-effects and non-efficacy of standard pharmaceutical agents in the treatment of hypertension in this population.

Aspect	Decision	Explanation
Participants	Type here	Type here
Interventions	Type here	Type here
Comparisons	Type here	Type here
Outcomes	Type here	Type here
Study design	Type here	Type here

5.2 Rationale for the specific methodology of the review / study

As applicable to your study, with reference to available alternatives (if applicable), motivate your choice of the specific systematic review procedures/techniques/methods/approaches being undertaken to achieve your study's aims.

More information

It must be clear to the evaluators that you have chosen a meaningful/best study design to achieve your study aims. Particularly where alternative review procedures/techniques/methods/approaches exist to what you used in the study, it is important to motivate your alternative choice.

Type here

5.3 Search strategy

Please indicate the reasoning behind the specific search strategy being implemented with specific reference to the:

- databases to be investigated,
- motivation for the databases being used,
- time period being investigated,
- languages to be investigated,
- specific search string to be used and
- curation strategy to be implemented i.e. the manner in which objectivity will be ensured during the search phase.

Type here

5.4 Criteria for article selection

Describe in full which inclusion and exclusion criteria will be used to select the manuscripts to be included in the systematic review and motivate (justification).

More information

Include also criteria for evaluating that the research undertaken in the manuscripts being chosen for review was ethical e.g. indication of ethics committee review, obtaining written informed consent etc.

Inclusion criteria	Justification
Type here	Type here
Exclusion criteria	Justification
Type here	Type here

5.5 Risk of bias and trustworthiness

Please explain the procedures that will be implemented in order to ensure that bias is limited in the process of the systematic review and that the articles and information sources being used for the review will be trustworthy. If a meta-analysis or meta-synthesis is being

performed, please indicate the summary measures that will be used to evaluate inter-study bias.

Type here

5.6 Benefits for participants

Describe the potential *indirect* benefits (risk/benefit analysis) 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.

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

5.7 Synthesis of results

Discuss the process by which the results will be determined from this analysis by highlighting the reasons for the use of the methodology indicated e.g. the use of a data synthesis table. If a meta-analysis or meta-synthesis is being performed, please indicate and justify the statistical procedures that will be implemented as well as the software to be used.

Type here

5.8 Expertise, skills and legal competencies

What expertise is needed to implement the systematic review? Do the study leader/researcher(s)/assistants/fieldworkers have at their disposal the necessary expertise to implement the techniques concerned? If not and as applicable, explain how the necessary training will be provided before the study commences.

Study leader	Researchers/Assistants/Fieldworkers
Type here	Type here

5.9 Monitoring of research

Describe how you as the researcher will monitor both the implementation and the progress of the research, compliance with the approved protocol, the management of ethics throughout the research process, as well as the need for amendments during the execution of the research study.

Type here

Remember to save your document regularly as you complete it!

6 SECTION 6: OTHER RESEARCH ETHICS EVALUATIONS

6.1 Evaluation by other Research Ethics Committees

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

Name of Research Ethics Committee	Date of Approval/In process	Contact or E-mail address of the research ethics committee	Number	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 details here, or type "Not applicable"
Type name here, or	Type details here	Type details here, or	Type details here, or	Type details here, or

type "None"

type "Not applicable"

type "Not applicable"

Remember to save your document regularly as you complete it!

7 SECTION 7: DECLARATIONS

Applications and declaration are filled in and signed by:

Sec 7a: Study Leader

Sec 7b: Research Director

The pages with declarations and signatures must be uploaded with this form.

[PLEASE UPLOAD ALL SIGNED DECLARATIONS]

NWU Ethics Application

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

NWU Ethics Number

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7.1 Sec 7a: 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:

- 7.1.1 The information in this application is, to the best of my knowledge, correct and that no ethical codes will be violated with the study;
- 7.1.2 I will make sure that the study is managed ethically justifiably from start to finish;
- 7.1.3 I and all co-workers/assistants/field workers are appropriately qualified, capable and legally competent to implement the proposed studies/procedures/interventions;
- 7.1.4 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 *Research Ethics Committee of the Faculty of Theology (REC-FT)*;
- 7.1.5 the study is scientifically justifiable;
- 7.1.6 I undertake to respect intellectual property rights throughout and to avoid any form of plagiarism;
- 7.1.7 I will report in writing any incidents or adverse events/serious adverse events that occur during the study without delay to the *Research Ethics Committee of the Faculty of Theology (REC-FT)*;
- 7.1.8 I will notify the *Research Ethics Committee of the Faculty of Theology (REC-FT)* should the study be terminated.

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

Signature	Date																			
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NWU Ethics Application

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

NWU Ethics Number

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7.2 Sec 7b: Research Director

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.

7.2.1 Research Director:

The director of the research entity signs here.

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

Signature	Date																			
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Remember to save your document regularly as you complete it!

Credits:

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.

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