

FACULTY OF
THEOLOGY

MANUAL FOR M- & D-STUDENTS IN WRITING

A RESEARCH PROPOSAL

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INTRODUCTION:

Students must prepare a research proposal outlining their proposed area of study as part of their master's or doctoral studies. This will be done under the guidance of a supervisor whose profile and research interests match your own¹.

A research proposal is also “a document that outlines how you *propose to undertake your research studies*”, and it is a project-planning document which “embodies your thinking about the study as you envisage it at the beginning of the project” (Mouton, 2001:45). The greatest value of a proposal is that it can be used to keep your research project on course by means of your specific focus. A well-written proposal will ensure that your research progresses at a reasonable pace, without too many ‘detours’. Remember: a research proposal has to convince a panel of research experts that you are capable of planning independent research.

In the writing of a research proposal, students show their ability to progress from an education-orientated project to a goal-orientated project.

Maree (2009:5) proposes the following three initial steps prior to writing a research proposal:

1. select a focus that states your purpose;
2. identify primary and secondary research questions; and
3. write a preliminary literature review.

The route for the development and completion of the research proposal (RP) for master's and PhD students is as follows:

Exploratory discussions with a potential supervisor.



Formal allocation of supervisor by the research director.



Supervisor. Finalisation of the RP under the guidance of the supervisor.



Subject Group. Submission of RP to subject group for approval.



Project Proposal Committee (PPC). Submission of revised RP to PPC.



Committee for Advanced Degrees (CAD). Final submission to and approval of the RP by the CAD.



Registration of the title by the Faculty Administrative Manager.



Approval of the RP by the Executive Committee of the Faculty of Theology

¹ The research director is ultimately responsible for assigning a supervisor to each student

1 GUIDELINES FOR THE RESEARCH PROPOSAL

Title page

Surname and initials:

Degree registered for:

Student number:

Contact number:

E-mail address:

Supervisor:

Co-supervisor/assistant supervisor (if any):

Synopsis of the subdivisions of a research proposal:

1. Proposed title and key words
2. Abstract
3. Background and problem statement/rationale
4. Preliminary literature study
5. Research problem, aim and objectives
6. Central theoretical argument
7. Research design/Methodology
8. Concept clarification, if applicable
9. Ethical considerations, if applicable
10. Provisional classification of chapters
11. References
12. Proposed research schedule/Time frame
13. Schematic presentation

Herewith some guidelines for each of the subdivisions.

1.1 Proposed title

The title must be appropriate and concise, and have impact (preferably not longer than 12 words). Omit superfluous phrases such as “an investigation into”. If it must be longer than 12 words, give a short main title with a longer subtitle². Be careful not to incorporate a conclusion into the title.

Give five to ten key words which describe the theme. These words should be suitable for database searches on the internet to allow easy identification of the content and focus of your work (Bak, 2004).

If **abortion** has to be **evaluated from a theological-ethical point of view**, the title could be:
A theological-ethical evaluation of abortion.

1.2 Abstract

Write an abstract of no more than 150 words. Writing an abstract before the research proposal will not only focus your thoughts on the structure of the proposal, but also enable you to summarise the major components of the research proposal.

² If some of the terms used in the title are not explained in the “problem statement”, a short explanation should be given here, but only as a provisional explanation and not a final definition; that should come later.

1.3 Background and problem statement

1.3.1 Background

Outline the background to the problem in one or two paragraphs, or describe why you became interested in the problem. A description of the background helps to position your research area in the broad subject area through the contextualisation of your topic. Identify the most important literature you will be using. Explain why the focus is important and relevant. Maree (2009:13) suggests the 'funnel' technique, i.e. work from a general approach and gradually narrow down the focus of the orientation to highlight specific aspects.

1.3.2 Problem statement

State the theme of the investigation and put it into perspective by using the information gleaned from literature in the field of research. Indicate the specific gap or *lacuna* in current knowledge on the subject, or indicate the area where a new contribution could be made.

Corroborate your choice by means of evaluative (not enumerative) reference to recent research (problems, disparities, unanswered questions or niches for creative development). It must be clear that the problem is at present unsolved or that there is a need or a possibility for new or meaningful development. Explain why it is necessary to investigate the problem or to find an answer to the research question - in other words, demonstrate the pertinence of the research.

It is important that the research questions the proposed investigation aims to answer are explicitly formulated (this can also be done under a separate heading). Also indicate to what extent or in what respect the proposed research will contribute to solving the research questions and to developing or expanding knowledge about the research question in the specific professional field. Vithal & Jansen (2004) list the following four criteria for the formulation of research questions:

Research questions are –

1. directly linked to the problem statement;
2. connected logically to one another, i.e. the second research question can be answered only once the first question has been answered, etc.;
3. linked conceptually through key terms that appear in each question; and
4. self-explanatory and apparent to outside readers, and able to stand alone as researchable questions.

Conclude this section by formulating the specific overarching research question, followed by other questions on subdivisions of the problem. Each subdivision must eventually become a heading (or chapter) in the research report.

If **abortion** has to be **evaluated from a theological-ethical point of view**, the problem statement could be:

*The "pro-choice" group states that abortion on request is necessary when the woman experiences the pregnancy as unwanted (*****, 19**.**. Refer here to a source from the pro-choice group). On the other hand, the "pro-life" group asserts that abortion on request is tantamount to murder and a violation of the human rights of the unborn child, and must/should therefore be prohibited (*****, 19**.**. Refer here to a source from the pro-life group).*

*The problem is even bigger. There are high-ranking Christians (like Kuitert, 19**.**. Refer here to one of his works where he states his viewpoint) who maintain that abortion on request is admissible from a Christian-ethical point of view. There are also, however, Christian scholars (like Douma, Velema and others. Refer here to one of each scholar's works where he states his viewpoint) who assert on Christian ethical grounds that abortion on request is unacceptable.*

*In the light of so many opposing viewpoints, the question is: **How should one evaluate abortion on request from a Scriptural point of view?** This is the problem which this study will research.*

Questions arising from this problem:

- * *What are the arguments of the pro-choice group, and how should one evaluate them?*
- * *What are the arguments of the pro-life group, and how should one evaluate them?*
- * *What is the evidence of Scripture on the different facets of abortion?*
- * *How should one evaluate abortion on request in the light of Scripture?*

The golden rule for formulating a research problem is that you must be able to state it in ONE sentence!

1.4 Aim and Objectives

Set out the central aim and objectives that guide your research. Which hypothesis or argument are you trying to explore? (Consult the postgraduate manual of the University

at: http://www.nwu.ac.za/library/documents/manualpostgrad_a.pdf).

1.4.1 Aim

Formulate the main aim of the research project; it must correlate with the main research problem.

The **theological ethical-evaluation of abortion** as an example:

The main aim of this study is to make a theological-ethical evaluation of abortion on request, i.e. evaluate it from a Scriptural point of view.

1.4.2 Objectives

Formulate the individual objectives which need to be reached in order to achieve the aim. These individual objectives must correlate with the subdivisions of the problem as mentioned in the last paragraph of 1.3.2.

The **theological-ethical evaluation of abortion** as an example:

The specific objectives of the study are to:

- * *study and evaluate the arguments of the pro-choice group;*
- * *study and evaluate the arguments of the pro-life group;*
- * *locate scriptural evidence on the different facets of abortion;*
- * *evaluate abortion on request in the light of Scripture.*

These four objectives correlate with the individual questions which arose from the "Problem statement" and constitute the headings or chapters of the research report (assignment, article, [mini] dissertation).

1.5 Central theoretical argument

Briefly state your expectations for the results of your research. It can also be called the "basic hypothesis". In Theology, however, it is better to speak of the "central theoretical argument".

The **theological-ethical evaluation of abortion** as an example:

The central theoretical argument of this study is that abortion on request is unacceptable in the light of Scripture.

1.6 Methodology

1.6.1 Introduction

1.

Under this heading you must clearly indicate which method you will adopt in your research to find answers to each of the questions you set in the problem statement: what information you will need, how you will collect it, and how you are going to analyse it. You must refer to an authoritative definition and/or application of the specific method. This must be indicated in broad outline only at this point.

You must also clearly state the theological tradition from which you approach your research.

The **theological-ethical evaluation of abortion** as an example:

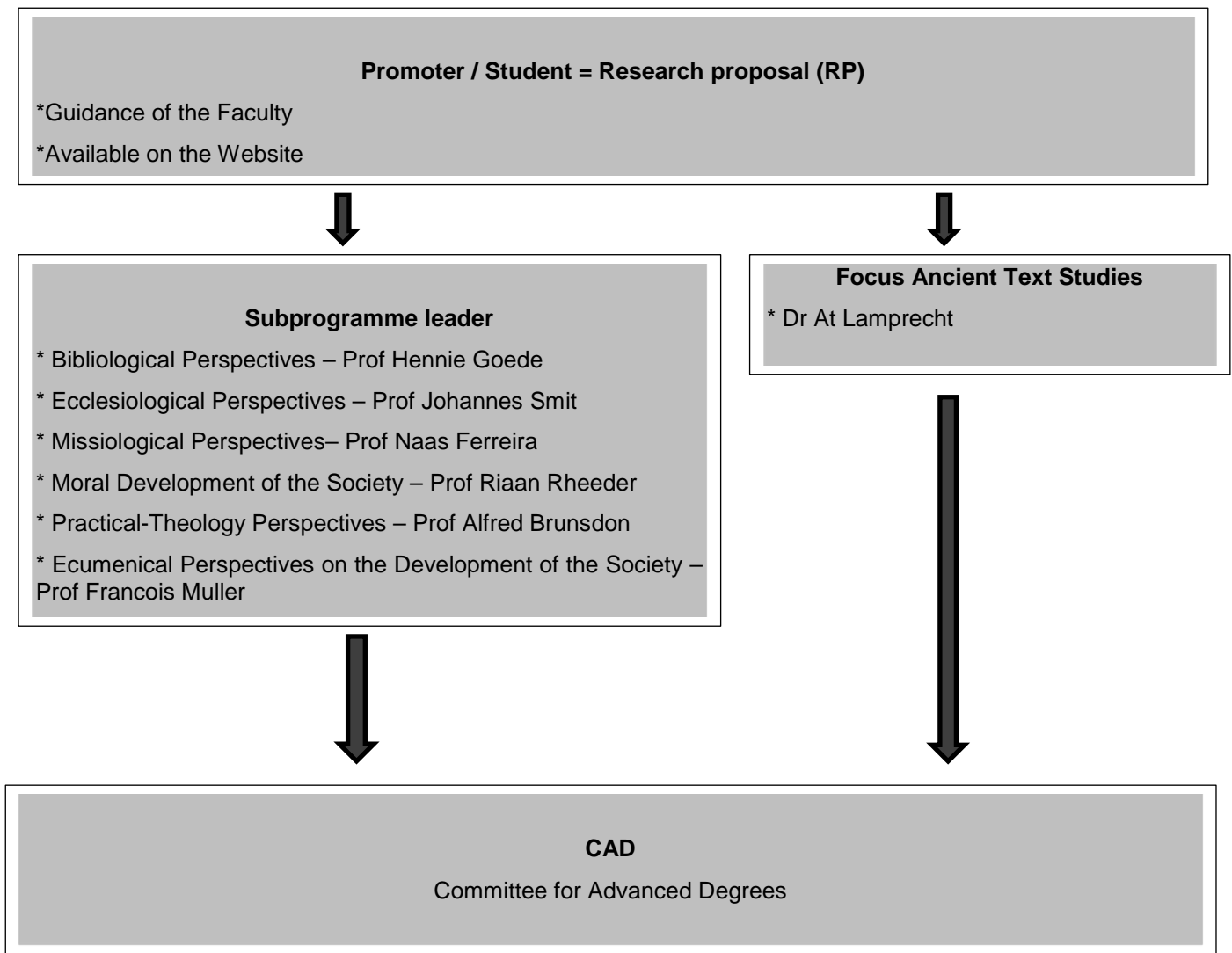
This theological-ethical study is done from the perspective of the Reformed tradition.

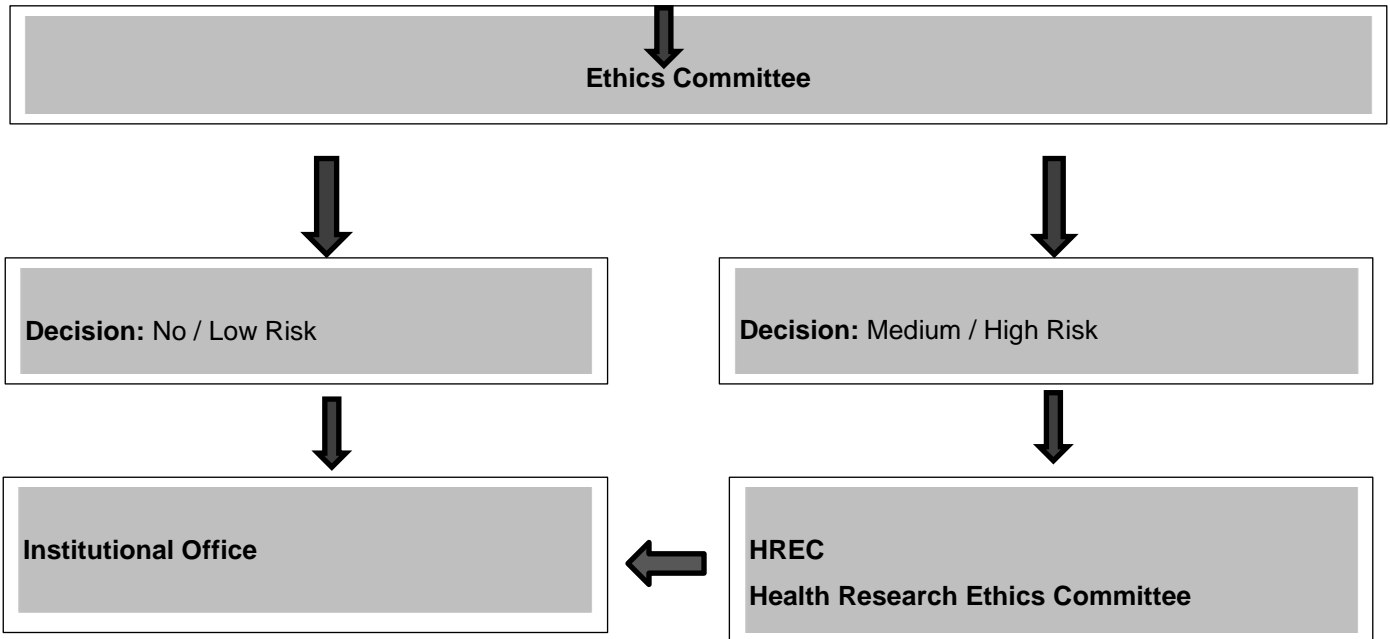
The following methods are used to answer the various research questions:

- * *in order to study and evaluate the arguments of the pro-choice group, a literature analysis is to be conducted to determine and evaluate past and present viewpoints. [It is necessary to indicate which resources you will be using or perhaps a few examples];*
- * *in order to study and evaluate the arguments of the pro-life group, a literature analysis is to be conducted to determine and evaluate past and present viewpoints. [It is necessary to indicate which sources you will be using or perhaps a few representative examples];*
- * *in order to locate scriptural evidence about the different facets of abortion, the applicable parts of Scripture are identified and exegeses are made of them. The method for exegesis is the grammatico-historical method [and here you refer to a source which defines this method]. The hermeneutical rules, according to which Scripture is interpreted, are those formulated by [and then you might refer to the 1997 publication by Prof Christi Coetzee, for instance];*
- * *in order to evaluate abortion on request in the light of Scripture, the collected data are selected and categorised through analysis, interpretation and synthesis.*

1.6.2 Diagram

Standard Operational Process of the Faculty of Theology for 2016





1.6.3 Guidelines for scientific aspects of RP (CAD)

The value and benefits of research are vitally dependent on the integrity of research. While there may be national and disciplinary differences in the way research is organized and conducted, there are also principles and professional responsibilities that are fundamental to the integrity of research wherever it is undertaken. The study's design and methodology are vital for the integrity of the research, regardless of the discipline. Sound design and methodology are likely to result in reliable and valid data and outcomes that address the research objectives.³

WHAT THE SCIENTIFIC COMMITTEE LOOKS FOR IN A PROPOSAL (as relevant to a particular study):

Element	Yes/No/NA	Comments
Is the evaluation of the relevant literature thorough? <ul style="list-style-type: none"> • Is it comprehensive? • Is applicable literature used? • Does it cover the grounding theory and paradigm? • Will the study add to the body of knowledge? • Were the search engines used sufficient and relevant? • Have new references been used? 		

³ Scientific and ethical guidelines in this document to which students must adhere are found in the following national and international documents and religious sources:

- Ethics in Health Research Principles, Processes and Structures (http://www0.sun.ac.za/research/assets/files/Integrity_and_Ethics/DoH%202015%20Ethics%20in%20Health%20Research%20-%20Principles,%20Processes%20and%20Structures%202nd%20Ed.pdf).
- The Singapore Statement on Research Integrity (www.singaporestatement.org).
- The Universal Declaration of Bioethics and Human Rights (<http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights>).
- Revelation in the Word of God.

<p>Is the scientific question important and novel (making use of the FINER principle)?</p> <ul style="list-style-type: none"> • Is it Feasible? • Is it Interesting? • Is it Novel? • Is it Ethical? • Is it Relevant? 		
<p>Is the title appropriate for the study?</p>		
<p>Have core concepts been identified?</p>		
<p>Are there clearly formulated aims and/or objectives?</p> <ul style="list-style-type: none"> • Do they link to the stated questions? 		
<p>Is there a clearly described setting/context?</p>		
<p>Is the research design feasible?</p> <ul style="list-style-type: none"> • Has the correct choice of research design been implemented? • Is it worth doing? • Is it possible to do? • Are there an adequate number of participants to reach the aims? • Is it affordable in terms of time and money? • Is the scope manageable? 		
<p>Is the methodology correct?</p> <ul style="list-style-type: none"> • Does it match the questions? • Is it the most appropriate methodology? • Does the student demonstrate knowledge of the methodology? • Is it clear and systematic? • Has the manner of obtaining data been described? • Has trustworthiness/validity and reliability been addressed? • Will the study result in reliable and valid data? 		
<p>Has the correct choice of sampling been made and has it been clearly described?</p> <ul style="list-style-type: none"> • Has the recruitment process been described? 		
<p>Are the inclusion/exclusion criteria appropriate?</p> <ul style="list-style-type: none"> • Are the criteria clearly stated? • Are the chosen criteria realistic? • Are the correct participants involved? • If the researcher wants to generalise the findings, does the sample match the population? • If the researcher wants to contextualise the findings, are the “expert” participants 		

included?		
<p>Will the enrolment criteria/sample size be met (if applicable)?</p> <ul style="list-style-type: none"> • Will the researcher meet the enrolment goals? • Does the researcher really understand saturation in qualitative research? 		
Is the informed consent process clear?		
<p>Is the analysis (statistical and/or qualitative) appropriate?⁴</p> <ul style="list-style-type: none"> • If quantitative, was a statistician consulted? • Is a report from a statistician included or proof of expertise indicated? • Do the researchers indicate knowledge regarding the method of analysis? 		
Is it clear how data will be stored?		
<p>Do the researchers have the qualifications and expertise to undertake the study?</p> <ul style="list-style-type: none"> • Does the expertise of the researcher match the study? • Do the CVs provide the necessary information? • Is it clear what role each researcher will play? • Is proof of previous experience in the methodology to be followed in the present study, provided? • How many studies has the researcher been involved in? • How many students has the researcher supervised? 		
<p>Are the necessary facilities available for the study?</p> <ul style="list-style-type: none"> • What is available? • Is it sufficient? 		
<p>Is there a need for a Data Safety Monitoring Board or DSMB (if applicable)?</p> <ul style="list-style-type: none"> • Does the proposed DSMB consist of appropriate supervisory individuals? • If it is a medium to high risk study, have adverse event (AE) and serious adverse event (SAE) reports been compiled to submit to the HREC and DSMB? • Is there sufficient information regarding the outcome of the study? (This is required for the DSMB). 		
<p>Is a research safety plan included?</p> <ul style="list-style-type: none"> • Is there an incident report structure in place? 		

⁴ Video discussing qualitative and quantitative research methodology: <https://www.youtube.com/watch?v=2X-QSU6-hPU> (only a brief overview).

<ul style="list-style-type: none"> • Is there a description of a clear process to be followed in case of an incident? 		
<p>Is there a data-management plan?</p> <ul style="list-style-type: none"> • What data will be stored? • How will data be stored? • Who will manage the data storage? • Who will have access to the data? • How will data-sharing be managed? • To whom will incidents be reported? 		
<p>Is there a clear monitoring plan?</p> <ul style="list-style-type: none"> • How will research be monitored? • How will ethical aspects be monitored? • How will progress be reported? • Is there a plan for amendments? 		
<p>Is there a clear dissemination plan?</p> <ul style="list-style-type: none"> • When will findings be communicated? • To whom will findings be communicated? • How will it be communicated? • Is the sustainability of the project considered (when applicable)? 		
<p>Has conflict of interest been declared, e.g. financial, intellectual, bias, overly optimistic promises of potential benefits, roles of the researchers, desire for professional advancement/fame, desire to make a breakthrough?</p>		
<p>Have all the necessary contracts been initiated if applicable?</p>		
<p>Have the ethical aspects been addressed in the proposal/protocol?</p>		
<p>Is a bibliography/reference list included?</p>		
<p>Has a realistic timeframe been included?</p>		
<p>Has an achievable and realistic budget been included?</p>		
<p>Has the potential risk level been identified?</p>		

1.6.4 Guidelines for ethical aspects of RP (Ethics committee)

To ensure that researchers treat the people of South Africa fairly and respectfully and that all research conducted in the country stands up to ethical scrutiny, research is conducted in accordance with the highest ethical norms and standards.⁵

WHAT THE ETHICS COMMITTEE WILL LOOK FOR IN THE PROPOSAL (where relevant for particular study):

⁵ Video material discussing Research Ethics: <https://www.youtube.com/watch?v=Zbj7nlbAuMQ>; <https://www.youtube.com/watch?v=zxQ6k6sz-QU> (only a brief overview).

Element	Yes/No/NA	Comment
Is the title appropriate to the content of the research?		
Has the research proposal been evaluated by a scientific/research proposal committee?		
<p>Is the study relevant and of value?</p> <ul style="list-style-type: none"> • Responsive • Contributes to knowledge • Worth doing 		
<p>Does the study show scientific integrity?</p> <ul style="list-style-type: none"> • Knowledge of relevant literature • Sound and valid design and methodology • Was open to peer review and scrutiny • The ethical implications of the design and method clearly stated • Rationale of methodology 		
Are the aims and/or objectives achievable and will it produce outcomes?		
<p>Is the selection of the study population fair and just?</p> <ul style="list-style-type: none"> • Method clear and complete • Fair distribution of burden and likelihood of benefit • No groups are deprived of an opportunity 		
<p>Are the inclusion and exclusion criteria clearly stated, appropriate, and justified?</p> <ul style="list-style-type: none"> • Rationale for the planned number reasonable • Rationale for inclusion and exclusion criteria clear and reasonable • Inclusion of vulnerable participants is justified 		
<p>Is the process of recruitment clear and detailed?</p> <ul style="list-style-type: none"> • Recruitment strategies neutral • Recruitment method (including screening) clear • Roles of gatekeepers and mediators clear • Recruitment materials appropriate (e.g. advertisement) • Done by an independent person • Location, context and timing appropriate and privacy and confidentiality protected • Participants not over-researched 		
<p>Has a risk-benefit ratio analysis been done?</p> <ul style="list-style-type: none"> • Risks identified • Precautions mentioned • Direct and indirect benefit stated • Risk-benefit ratio analysis favourable 		

<p>Will the participants be appropriately reimbursed?</p> <ul style="list-style-type: none"> • Time • Inconvenience • Expenses • No coercion or undue influence 		
<p>Is the participant's privacy and confidentiality protected?</p> <ul style="list-style-type: none"> • Personal information and records protected • Identity protected 		
<p>Is the process of obtaining informed consent/permission/assent clear?</p> <ul style="list-style-type: none"> • Informed and voluntary • Written and verbal • Obtained by an independent person • Confirmed by the researcher • Sufficient time given to consult and make an informed decision before signing • Can withdraw • Without coercion, undue influence or inappropriate incentives • Understandable and valid informed consent form • Need for translation 		
<p>Are the researchers professionally competent?</p> <ul style="list-style-type: none"> • Academic qualifications suitable • Scientific and technical competence adequate • Proof of research competence (education, knowledge and experience) • Appropriate skills • Mentoring 		
<p>Is respect for participants clear throughout?</p> <ul style="list-style-type: none"> • Dignity • Voluntary • Safety • Wellbeing • Interest of the participant 		
<p>Are the facilities where the research will be conducted appropriate and suitably resourced?</p>		
<p>Is data-collection well managed?</p> <ul style="list-style-type: none"> • What data is being collected? • Why is the data being collected? • What will happen to the data? • How long will data be retained? 		

<ul style="list-style-type: none"> • Will the data identify the participant? • Will it be shared with others and why? • Will it leave the country? 		
<p>Is the process of sample storage clear (if applicable)?</p> <ul style="list-style-type: none"> • For how long? • Where will it be stored? • Is there informed consent for the analyses? • Who will manage it? • Will it be shared with others and why? • Will it leave the country? 		
<p>Was a statistician included or consulted/proof of expertise?</p>		
<p>Are all the additional legal documents/requirements applicable included and correctly completed?</p> <ul style="list-style-type: none"> • What is the current status thereof? • To what extent has it been operationalised? ▪ International contractual agreements/subagreements ▪ National contractual agreements/subagreements ▪ Collaboration agreements (other universities, individuals etc.) ▪ Written permission (national/provincial departments, hospitals, clinics, universities etc.) ▪ Written goodwill permission (traditional leaders, managers etc.) ▪ Confidentiality agreements (fieldworkers, mediators, participating clinicians or professionals etc.) ▪ Export/import permits ▪ Sponsorship agreements ▪ Service agreements (with sponsors, other entities etc.) 		
<p>Are the researcher and project covered by insurance?</p>		
<p>Is it clear how results will be disseminated?</p> <ul style="list-style-type: none"> • How will participants be informed? • Is there a sure dissemination plan? • Will it be done in an ethical manner? 		
<p>Is conflict of interest clearly stated and how it will be handled?</p>		
<p>Is the process of data management and storage clear?</p> <ul style="list-style-type: none"> • How will electronic data and hard copies be stored? • How will audio and video data be stored? 		

<ul style="list-style-type: none"> • Who will store the data? • Who will have access? • How will the data be protected? • For how long will data be stored? • How will it finally be disposed of? 		
Are there clear monitoring and safety measures in place?		
Is it a realistic time schedule?		
Has a budget been included and have details of how it will be covered provided?		
<p>Specifically for secondary use of data or samples (if applicable):</p> <ul style="list-style-type: none"> • Is there a permission letter from the project head stating what can be done? • Is the documentation of the original study included (e.g. proposal, ethics certificate etc.)? • Does the substudy match the umbrella study? • Was permission for the planned substudy provided in the signed informed consent? • Is it clear that the initial data set of samples were collected in an ethical manner? • Is it clear how data/sample integrity was ensured through safe storage? • Has a clear methodology for use of the data/samples in the present substudy been provided? 		

1.6.5 Guidelines for aspects of informed consent (where relevant for particular study)

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

The text in the informed consent:

The text:

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

(The translation has to reach the HREC within one week after the final informed consent document was approved in English)

- conforms to the proposal;
- the readability level is grade 8;
- the language and translation is appropriate.

Examples of readability tests:

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

TICK LIST FOR YOUR CONVENIENCE:

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

Item	Yes	No	N/A
The informed consent document is official and on the letterhead of the NWU			
<i>The information should explain:</i>			
• that the person is being asked to participate in the research			
• who the researchers are and the nature of their expertise (qualifications)			
• what the research is about (purpose and nature)			
• the choice whether to participate is voluntary			
• the refusal to participate will not be penalised			
• that choosing to participate can be reversed, i.e. the person may decide to terminate participation at any time without explanation or prejudice			
• that a participant is free at any time to withdraw consent without having to face negative consequences			
• the expected duration of participation			
• a description of the procedures to which the subject will be subjected			
• the nature of the participant's responsibilities			
• the nature of the researcher's responsibilities			
• the total number of participants that will be involved in the research			
• the anticipated risks of harm or discomforts			
• how these risks or discomforts will be managed			
• the potential benefits, if any, for participants themselves (direct) and for others after the research (indirect)			
• the extent to which confidentiality is possible			
• whether there will be any financial implications e.g. out-of-pocket costs, like travel			
• whether there will be any remuneration			
• identify the funder where applicable and any potential conflict of interest			
• their right to be informed of relevant new findings and how this will be done			
• that sponsors of the research and regulatory authorities (HREC) may inspect research records			
• that the research has been approved by a registered HREC (include identifying details)			
• that queries about the research may be directed to the researcher concerned (include contact details)			
• that queries and complaints about being a research participant may be directed to the HREC concerned (include contact details)			
<i>Only add if applicable</i>			
• that the research may be terminated early in particular circumstances			
• the consequences of withdrawal			
<i>In addition to the above, where clinical trials is intended, the information should explain:</i>			
• the procedure and the activities that will take place, including whether any is experimental, innovative or novel in humans			
• that research is separate from clinical care for the illness or condition that the person may have			
• whether research-related injuries will be treated and remedied at the cost of the sponsor			
• explanation as to whether compensation will be given for research-			

related injuries			
• the contact details of the person to contact in the event of a research-related injury			
• the alternative procedures or treatment available			
• the approximate number of participants			
• the possibility of randomisation and the implications			
• the meaning and implications of placebo			
• the difference between experimental and control groups			

What the REC will look for in the proposal:

- The process of obtaining informed consent (IC) is described in full
- The principle of *respect* for persons were followed, that it is *voluntary*, and based on *information* that allows an *informed choice*
- Environment where process of consent is conducted
 - private, confidential and safe
- Assessment of capacity to consent
 - age
 - legally informed consent
 - decisionally impaired persons
 - legal/authorized representation
 - literacy
- Assessment of participant's comprehension
- Presentation of all mentioned *elements* of IC and the *process* that will be followed
- Whether gatekeepers/mediators are involved and their roles in this process
- Time to talk to researcher to ask questions
- Documentation of IC (language level, language offered in)
- Use of delayed consent procedure
 - time to think
 - time to discuss with family/friends etc.
- Who is going to obtain the consent (independent person)
- Ongoing consent/re-consent if necessary due to the nature of the research

1.6.6 Risk level Descriptors for Research (ethics committee)

A risk is seen as “the probability of harm occurring as a result of participation in research” and must assessed prior

to conducting research. A risk level descriptor (RLD) is the specification of the magnitude of the risk and the probability of such a risk occurring. It forms the basis of the Research Ethics Committee's (REC) decision-making regarding ethical clearance of research.

A risk-benefit ratio analysis should precede the research.

The potential risk of harm should be outweighed by the likelihood of benefit – it should be a favorable ratio.

Both *magnitude* and *seriousness* of harm should be assessed.

If any harm (physical, psychological, legal, social or financial) is possible, it should be justified.

This document is not only concerned with harm to the participants themselves, but also to the researchers, community or societal interests.

1.6.6.1 Researchers with a conflict of interest (declared) increase the risk level of the research

1.6.6.2 RISK LEVELS FOR HEALTH AND HEALTH-RELATED RESEARCH

Risk Category	Definition	Explanation and/or Examples
No risk	No contact with human participants	<ul style="list-style-type: none"> • Certain systematic reviews • Review of literature available in the public domain.
Minimal, low or negligible risk	<p>The probability, magnitude or seriousness of harm or discomfort anticipated in the research is negligible and not greater than that ordinarily encountered in daily life ("Daily life" as a benchmark should be that of daily life experienced by the average person living in a safe "first world" country).</p> <p>Research in which the only foreseeable risk is one of minimal discomfort or inconvenience.</p>	<ul style="list-style-type: none"> • Market research surveys. • Research in which the investigation of largely uncontroversial topics is undertaken through interviews, surveys and participant observation. • The research will collect information that would generally not be regarded as sensitive, such as opinions rather than personal information. • Document analysis. • Interviews with officials and practitioners in their official capacity e.g. consultation with a practicing attorney who specializes in mineral law to understand how applications for mining rights are done. • Bio-physical research involving previously collected or collection of human blood through finger prick, sputum or urine. • The participants are adults and not considered to be a vulnerable research population (Children are generally considered to be a vulnerable research population. Some projects with children can be evaluated as "low risk"). • Use of anonymized data from medical schemes database is a power differential. <p>- Focus groups with the potential of loss of anonymity.</p>

		<ul style="list-style-type: none"> • Psycho-social intervention studies • The intervention can cause physical or psychological harm. • Research involving collection of more than human blood (through needle prick), sputum or urine samples. • The information needs to be collected with personal identifiers (name, student number, etc.). • The research participants may come from a vulnerable or marginalised group, such as those with disabilities, people living with HIV or other chronic disease, the economically disadvantaged, etc. • Use of patient information in existing health systems • Use of laboratory test of patients in existing health systems
<p>High Risk</p>	<p>Research in which there is a real and foreseeable risk of harm and discomfort, and which may lead to serious adverse consequences if not managed in a responsible manner.</p>	<p>One or more of the following apply:</p> <ul style="list-style-type: none"> • The intervention can cause serious physical or psychological adverse consequences. • Pharmaceutical drug research. • Research involving highly sensitive topics and/or very vulnerable and marginalized communities e.g. people with multiple vulnerabilities. • Research involving the deception of the participants. • Research investigating illegal activities: e.g. involving participants who are illegal immigrants or engaged in illegal activities. • Collection of biological samples through invasive techniques. • By agreeing to participate in the research participants will be placed at a real risk of harm. • The researcher may be placed at risk of breaking the law by carrying out certain activities, e.g. research investigating gang activities and possession of illegal firearms. • The research may reveal information that requires action on the part of the researcher or an institution (private or public) that could place the participant or others at risk, e.g. research involving child victims of physical or sexual abuse, victims of domestic violence, etc. • Review of privileged literature/documentation. e.g. privileged records of a company's annual meetings with a high level of sensitivity.

1.6.6.3 RISK LEVELS FOR RESEARCH WITH CHILDREN

- Minors are all persons under 18 years of age.
- The research is not contrary to the **best interest** of the minor.
- **Greater than minimal risk** of harm should represent no more than a **minor increase** over minimal risk.
 - **ABSOLUTE RESTRICTIONS:** No biological materials that are not naturally replaceable may be taken from a minor without ministerial permission.
 - This is also true for gametes from a minor or fetal biological material without ministerial permission except for umbilical cord progenitor cells.

Risk Category	Definition	Explanation and/or Examples
No more than minimal risk of harm (negligible risk) (Category 1)	The probability or magnitude of harm or discomfort anticipated in the research is negligible and not greater than that ordinarily	<ul style="list-style-type: none"> • Children are generally considered to be a vulnerable research population. • Selected projects with children can be evaluated as “low risk”.
Greater than minimal risk but provides the prospect of direct benefit to the child (Category 2)	<p>Research in which there is a potential risk of harm or discomfort, but where appropriate steps can be taken to mitigate or reduce overall risk. Should the steps not be taken there is a real and foreseeable risk of harm and discomfort, which may lead to adverse consequences if not managed in a responsible manner.</p> <p>There is a direct benefit to the child.</p>	<ul style="list-style-type: none"> • Research with children to obtain information from them but which leads to their own benefit. <p>One or more of the following apply:</p> <ul style="list-style-type: none"> • The research topic is considered “sensitive”. • Information gathered is on opinions or attitudes and is personal in nature or is a combination of these aspects. • The information needs to be collected with personal identifiers (name, student number, etc.). • The child may come from a vulnerable or marginalised group, such as those with disabilities, people living with HIV or other chronic diseases, the economically disadvantaged, etc. • The research may reveal information that requires action on the part of the researcher that could place the child or others at risk, e.g. research involving child victims of physical or sexual abuse, victims of domestic violence, etc. • Involves face-to-face contact with participants e.g. interviews and focus groups. • Research to obtain information from children but of no benefit to the child.

<p>Greater than minimal risk with no prospect of direct benefit to the child but has a high probability of providing significant generalisable knowledge (Category 3)</p>	<p>Research in which there is a potential risk of harm or discomfort, but where appropriate steps can be taken to mitigate or reduce overall risk. Should the steps not be taken there is a real and foreseeable risk of harm and discomfort, which may lead to adverse consequences if not managed in a responsible manner.</p> <p>There is no benefit to the child.</p>	<p>One or more of the following apply:</p> <ul style="list-style-type: none"> • The research topic is considered “sensitive”. • Information gathered is on opinion or attitude and personal in nature, or is a combination of these. • The information needs to be collected with personal identifiers (name, student number, etc.). • The child may further come from a vulnerable or marginalised group, such as those with disabilities, people living with HIV or other chronic diseases, the economically disadvantaged, etc. • The research may reveal information that requires action on the part of the researcher that could place the participant or others at risk, e.g. research involving child victims of physical or sexual abuse, victims of domestic violence, etc. • Involves face-to-face contact with participants e.g. interviews and focus groups.
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1.6.6.4 RISK LEVELS FOR ADULTS INCAPABLE OF GIVING ADEQUATE INFORMED CONSENT

The research to be undertaken, including observational research, is not contrary to the best interest of the individual.

The research, including observational research, places the incapacitated adult at no more than minimal risk.

The greater than minimal risk must represent no more than a minor increase over minimal risk.

No biological materials may be taken from mentally ill persons without ministerial permission.

Risk Category	Definition	Explanation and/or Examples
<p>No more than minimal risk of harm (negligible risk)</p>	<p>The probability or magnitude of harm or discomfort anticipated in the research is negligible and not greater than that ordinarily encountered in daily life (“Daily life” as a benchmark should be that of daily life experienced by the average person living in a safe “first world” country).</p> <p>Research in which the only foreseeable risk is one of minimal discomfort or inconvenience.</p>	

<p>Greater than minimal risk but provides the prospect of direct benefit for the incapacitated adult</p>	<p>Research in which there is a potential risk of harm or discomfort, but where appropriate steps can be taken to mitigate or reduce overall risk. Should the steps not be taken there is a real and foreseeable risk of harm and discomfort, which may lead to adverse consequences if not managed in a responsible manner.</p> <p>There is a direct benefit to the incapacitated adult.</p>	
<p>Greater than minimal risk with no prospect of direct benefit to the incapacitated adult, but a high probability of providing generalisable knowledge</p>	<p>Research in which there is a potential risk of harm or discomfort, but where appropriate steps can be taken to mitigate or reduce overall risk. Should the steps not be taken there is a real and foreseeable risk of harm and discomfort, which may lead to adverse consequences if not managed in a responsible manner.</p> <p>There is no benefit to the incapacitated adult.</p>	

1.6.6.5 RISK LEVELS FOR HUMANITIES

Risk Category	Definition	Explanation and/or Examples
<p>No risk</p>	<p>No contact with human participants</p>	<ul style="list-style-type: none"> • Certain systematic reviews • Review of literature available in the public domain. • Studies based on theory analysis and theory development
<p>Minimal and/or low risk</p>	<p>The probability or magnitude of harm or discomfort anticipated in the research is negligible and not greater than that ordinarily encountered in daily life ("Daily life" as a benchmark should be that of daily life experienced by the average person living in a safe "first world" country).</p> <p>Research in which the only foreseeable risk is one of minimal discomfort or inconvenience.</p>	<ul style="list-style-type: none"> • Market research surveys • Research in which the investigation of largely uncontroversial topics is undertaken through interviews, surveys and participant observation. • The participants are adults and not considered to be a vulnerable research population (as discussed above). • The research will collect information that would generally not be regarded as sensitive, such as opinions/perceptions rather than personal information.

<p>Medium risk</p>	<p>Research in which there is a potential risk of harm or discomfort, but where appropriate steps can be taken to mitigate or reduce overall risk.</p>	<p>One or more of the following apply:</p> <ul style="list-style-type: none"> • The research topic is considered “sensitive”. • Information gathered is personal, rather than opinions or attitudes, or is a combination of these. • The information needs to be collected with personal identifiers (name, student number, etc.). • The research participants may come from a vulnerable or marginalised group, such as those with disabilities, people living with HIV or other chronic disease, the economically disadvantaged, etc. Involves face-to-face contact with participants through: <ul style="list-style-type: none"> - interviews dealing with personal sensitive information or within a power differential - focus groups with the potential of loss of anonymity.
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1.7 Concept clarification

Indicate how you interpret certain important concepts in literature on the field of study. Explain the interpretation of concepts, or formulate a working definition within the framework of your research.

1.8 Provisional classification of headings/chapters

Chapter 1 (or Heading 1) is the *Introduction*, which in fact is the research proposal you initially wrote.

List of tables

List of appendices

Definition of key terms

1. Introduction
2. Literature review
3. Research design and methodology
4. Presentation of findings
5. Conclusion and recommendations

References

Appendices

The classification of headings must correlate with the questions which arose from the problem statement, and which again occurred in “aims and objectives” and “methodology”.

The **theological-ethical evaluation of abortion** as an example:

1. *Introduction;*
2. *Arguments of the pro-choice group, and an evaluation thereof;*
3. *Arguments of the pro-life group, and an evaluation thereof;*
4. *The evidence of Scripture on the different facets of abortion, and an interpretation of this evidence;*
5. *Summary and conclusion: an evaluation of abortion on request in the light of Scripture.*

1.9 References

Mention **only** the sources explicitly referred to in the proposal.

Use the following as reference guide (available on the NWU website):

- Van der Walt, E.J. 2006. *Quoting Sources: Scientific Skills Series*. Potchefstroom: North-West University.
- References:
- BAK, N. 2004. *Completing your thesis: a practical guide*. Pretoria: Van Schaik.
- MAREE, K. & VAN DER WESTHUIZEN, C. 2009. *Head start in designing research proposals in the social sciences*. Pretoria: Juta.
- MOUTON, J. 2001. *How to succeed in your master's and doctoral studies*. Pretoria: Van Schaik.
- VITHAL, R. & JANSEN, J. 2004. *Designing your first research proposal*. Cape Town: Juta.

1.10 Proposed research schedule

Plan realistically! Incorporate some leeway for yourself. You need not produce a detailed time schedule, but it is helpful to provide a summary of what you are planning to do and when. Include dates of proposed meetings with your supervisor concerning draft chapters, etc.

1.11 Schematic presentation

After the outline of your research schedule, a schematic presentation must be provided that displays the correlation between your central research question, aim, objectives, and methodology:

Research question	Aim and objectives	Research method
How should one evaluate abortion on request from a Scriptural point of view?	The main aim of this study is to make a theological-ethical evaluation of abortion on request, i.e. evaluate it from a Scriptural point of view.	This theological-ethical study is conducted from the perspective of the Reformed Tradition.
What are the arguments of the pro-choice group, and how should one evaluate them?	To study and evaluate the arguments of the pro-choice group.	In order to study and evaluate the arguments of the pro-choice group, a literature analysis is conducted to determine and evaluate past and present viewpoints.
What are the arguments of the pro-life group, and how should one evaluate them?	To study and evaluate the arguments of the pro-life group.	In order to study and evaluate the arguments of the pro-life group, a literature analysis is conducted to determine and evaluate past and present viewpoints.
What is the evidence of Scripture on the different facets of abortion?	To locate scriptural evidence on the different facets of abortion.	In order to locate scriptural evidence about the different facets of abortion, the applicable parts of Scripture are identified and exegeses of them are made. The method for exegesis is the historic-grammatical method.
How should one evaluate abortion on request in the light of Scripture?	To evaluate abortion on request in the light of Scripture.	In order to evaluate abortion on request in the light of Scripture, collected data are selected and categorised through analysis, interpretation and synthesis.

Your supervisor will provide you with an example of a well-constructed RP in your particular field of study (i.e. Ethics, Dogmatics, New Testament, etc.).

IN CONCLUSION

Take care with the preparation of your research proposal, as the committee that evaluates your proposal will decide whether or not you are capable of planning a research project of this nature.

Go through the following checklist before submitting your proposal:

- Check spelling and grammar carefully.
- Make sure the format of the proposal complies with the requirements of the Faculty of Theology (available from the office of the research director). [Typeface: Arial or Times Roman; Font size: 11; Line spacing: 1 ½].
- Make sure all the information is correct (for example the name of the qualification).
- Use precise and simple language (see Mouton, 2001: 58-59).