Faculty of Health Sciences Ethics Office for Research, Training and Support
[health-sciences.nwu.ac.za/healthethics](http://www.nwu.ac.za/healthethics)

|  |
| --- |
| **HREC** Health Research Ethics Committee *(REC-130913-037)***Ethics Application Form for a Systematic Review*****HREC 01-03a, version Nov 2016*** |
| **CONFIDENTIAL!** This document contains confidential information that is intended exclusively for the applicant(s), the Health Research Ethics Committee (HREC) of the Faculty of Health Sciences of the North-West University and the designated reviewers. Should this document or parts thereof come into your possession in error, you are requested to return it to the HREC without delay or destroy it. Unauthorised possession, reading, studying, copying or distribution of this material, or any other form of abuse, is illegal and punishable. |
| **NWU Ethics Number: *(issued upon 1st submission)*** | Click or tap here to enter text. |

**Instructions and recommended path for the completion of your application:**

1. The research proposal forms the base document that is evaluated in conjunction with this application form. This application form gives the researcher the opportunity to expand on specific ethical issues required for approval.
2. All applicants complete § 1, 2, 3, 4, 5, 6 and 7.
3. 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).
4. Also attach an executive summary of the study (see § 4.1.1).
5. Attach a 2-page narrative CV for each of the researchers involved in the study.
6. Liaise with the appropriate officials and colleagues mentioned in § 7, complete and sign a printed copy.
7. Submit the scanned copies of the signed pages.
8. Include copies of proof of ethics training for all researchers involved in the study (not older than three years).
9. Submit the completed Ethics Application Form (with the attached documentation) via e-mail to Ethics-HRECApply@nwu.ac.za .
10. 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.

|  |
| --- |
| NWU Ethics NumberNWU-?????-??-?? |
| Campus | Click here to enter text. | Faculty | Click here to enter text. |
| Principle Investigator/Study Leader | Click here to enter text. | Research entity | Click here to enter text. |
| Study Title | Click here to enter text. |

**Table of Contents**

[1 Section 1: Study identification 1](#_Toc468358079)

[1.1 Full, descriptive title of the study 1](#_Toc468358080)

[1.2 Name of the Study Leader/Primary investigator NB! Not the student's name 1](#_Toc468358081)

[1.3 Name of the Student (if applicable) 1](#_Toc468358082)

[1.4 Student number 1](#_Toc468358083)

[1.5 Research entity e.g AUTHeR 1](#_Toc468358084)

[1.6 Discipline e.g. Consumer sciences 1](#_Toc468358085)

[1.7 Envisaged commencement and completion date of the study 1](#_Toc468358086)

[2 Section 2: Study Classification 2](#_Toc468358087)

[2.1 Name of Ethics Committee handling application 2](#_Toc468358088)

[2.2 Dates of applications 2](#_Toc468358089)

[2.3 Version number 2](#_Toc468358090)

[2.4 Estimated risk level 2](#_Toc468358091)

[2.5 Context of the Study 2](#_Toc468358092)

[2.6 For this study the following persons will be included in the study team: 2](#_Toc468358093)

[3 Section 3: Detail of Study Leader/PRINCIPAL INVESTIGATOR AND Co-workers 4](#_Toc468358094)

[3.1 Details of Study Leader/Principle investigator 4](#_Toc468358095)

[3.2 Other Members of the Study Team 5](#_Toc468358096)

[3.3 Conflict of Interests 5](#_Toc468358097)

[3.4 Collaborations (if applicable) 5](#_Toc468358098)

[4 Section 4: Research proposal and scientific committee approval 6](#_Toc468358099)

[4.1 Research proposal 6](#_Toc468358100)

[5 Section 5: Additionally required information about ethical implications of the systematic REVIEW not provided in the proposal 7](#_Toc468358101)

[5.1 Please describe the study characteristics according to the PICOS (participants, interventions, comparisons, outcomes and study design) assessment: 7](#_Toc468358102)

[5.2 Rationale for the specific methodology of the review 8](#_Toc468358103)

[5.3 Search strategy 8](#_Toc468358104)

[5.4 Criteria for article selection 8](#_Toc468358105)

[5.5 Risk of bias and trustworthiness 8](#_Toc468358106)

[5.6 Benefits for participants 9](#_Toc468358107)

[5.7 Synthesis of results 9](#_Toc468358108)

[5.8 Expertise, skills and legal competencies 9](#_Toc468358109)

[5.9 Monitoring of research 9](#_Toc468358110)

[6 Section 6: Other research Ethics Evaluations 9](#_Toc468358111)

[6.1 Evaluation by other Research Ethics Committees 9](#_Toc468358112)

[7 Section 7: Declarations 10](#_Toc468358113)

[7.1 Sec 7a: Study Leader 10](#_Toc468358114)

[7.2 Sec 7b: Research Director 11](#_Toc468358115)

1. Section 1: Study identification

Provide the necessary descriptions below to identify this study application:

* 1. Full, descriptive title of the study

|  |
| --- |
| Click here to enter text. |

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

|  |
| --- |
| Click here to enter text. |

* 1. Name of the Student (if applicable)

|  |
| --- |
| Click here to enter text. |

* 1. Student number

|  |
| --- |
| Click here to enter text. |

* 1. Research entity e.g AUTHeR

|  |
| --- |
| Click here to enter text. |

* 1. Discipline e.g. Consumer sciences

|  |
| --- |
| Click here to enter text. |

* 1. Envisaged commencement and completion date of the study

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

|  |  |
| --- | --- |
| Commencement Date | Completion Date |
| Click here to enter a date. | Click here to enter a date. |

1. 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.

* 1. Name of Ethics Committee handling application

|  |
| --- |
| Click here to enter text. |

* 1. Dates of applications

Fill in below the date of the first submission and revised submission *(of applicable)* of this ethics application

|  |  |
| --- | --- |
| **Date of first application** | **Date of revise application** *(if applicable)* |
| Click here to enter a date. | Click here to enter a date. |

* 1. Version number

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

|  |  |
| --- | --- |
| Version | Choose |

* 1. 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 risk |[ ]
| Minimal risk |[ ]
| Medium risk |[ ]

* 1. Context of the Study

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

|  |  |  |
| --- | --- | --- |
| **Description** | **Yes** | **No** |
| Scientific Research  | Study falls within a research entity |[ ] [ ]
|  | Study falls outside a research entity |[ ] [ ]
|  | Study includes postgraduate students(e.g. masters or doctorate) |[ ] [ ]
|  | Study includes contract work |[ ] [ ]

* 1. 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 research 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)

|  |
| --- |
| Click here to enter text. |

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

|  |  |
| --- | --- |
| Yes | No |
|[ ] [ ]

|  |
| --- |
| Remember to save your document regularly as you complete it! |

1. Section 3: Detail of Study Leader/PRINCIPAL INVESTIGATOR AND Co-workers
	1. Details of Study Leader/Principle investigator

Name and details of the Study Leader/Principal Investigator.

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

|  |  |  |
| --- | --- | --- |
| Surname | Full Names | Title |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
|  |  |  |
| NWU Campus | Faculty | Research entity/School |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
|  |  |  |
| Position | University No. | Professional Registration (body & category) |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
|  |  |  |
| Telephone | NWU-box or Postal Address |
| Work | Home | Cell |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
|  |  |  |
| E-mail Address |
| Click here to enter text. |

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

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

* 1. 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 here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |

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

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

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

* 1. 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** |
| Click here to enter text. | Click here to enter text. |

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.

* 1. 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**  |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |

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

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| Remember to save your document regularly as you complete it! |

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

|  |
| --- |
| Click here to enter text. |

* + 1. 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]

* + 1. 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 HREC. The HREC relies on the expertise of a Scientific/Proposal committee regarding the evaluation of the scientific merit and design of the study.*  |

|  |  |  |
| --- | --- | --- |
| **Yes** |  | **Details** |
|[ ]   | Name of formal Scientific/Proposal Committee: | Click here to enter text. |
|  |  | Title, initials and surname of all the members of Scientific/Proposal Committee present during the review. | Click here to enter text. |
|  |  | Date of approval: | Click here to enter text. |
| **No** |  | Reason: | Click here to enter text. |
|[ ]   |  |  |

* + 1. Letter confirming approval of protocol

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

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

|  |
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| Remember to save your document regularly as you complete it! |

1. Section 5: Additionally required information about ethical implications of the systematic REVIEW not provided in the proposal

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

* 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 | Click here to enter text. | Click here to enter text. |
| Interventions | Click here to enter text. | Click here to enter text. |
| Comparisons | Click here to enter text. | Click here to enter text. |
| Outcomes | Click here to enter text. | Click here to enter text. |
| Study design | Click here to enter text. | Click here to enter text. |

* 1. Rationale for the specific methodology of the review

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/techni-ques/methods/approaches exist to what you used in the study, it is important to motivate your alternative choice.*  |

|  |
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| Click here to enter text. |

* 1. 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.

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| Click here to enter text. |

* 1. 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  |
| Click here to enter text. | Click here to enter text. |
| Exclusion criteria | Justification  |
| Click here to enter text. | Click here to enter text. |

* 1. 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.

|  |
| --- |
|  Click here to enter text. |

* 1. Benefits for participants

Describe the potential *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.

|  |
| --- |
| **Indirect benefits** for society at large or for the researchers/institution |
| Click here to enter text. |

* 1. 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.

|  |
| --- |
| Click here to enter text. |

* 1. 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** |
| Click here to enter text. | Click here to enter text. |

* 1. 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.

|  |
| --- |
| Click here to enter text. |

|  |
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| Remember to save your document regularly as you complete it! |

1. Section 6: Other research Ethics Evaluations

* 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 number or e-mail address of the research ethics committee** | **Approval no.** |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |

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| Remember to save your document regularly as you complete it! |

1. 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]

Health Research Ethics Application

|  |  |
| --- | --- |
| **Study Leader** (Title, Initials and Surname) | **Study Title**(see § 1.1) |
| Click here to enter text. | Click here to enter text. |

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

* 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:

* + 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. I and all co-workers/assistants/field workers are appropriately qualified, capable and legally competent to implement the proposed studies/procedures/interventions;
		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 Health Research Ethics Committee;
		5. the study is scientifically justifiable;
		6. I undertake to respect intellectual property rights throughout and to avoid any form of plagiarism;
		7. I will report annually to the Health Research Ethics Committee (or half-yearly as determined by the Health Research Ethics Committee) on the prescribed monitoring report concerning progress of the study;
		8. I will notify the Health Research Ethics Committee should the study be terminated.

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

NWU Ethics Application

|  |  |
| --- | --- |
| **Study Leader** (Title, Initials and Surname) | **Study Title**(see § 1.1) |
| Click here to enter text. | Click here to enter text. |

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

* 1. 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.

* + 1. Research Director:

The director of the research entity signs here.

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

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| Remember to save your document regularly as you complete it! |

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

|  |
| --- |
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