NWU Engineering Research Ethics

Application Form[[1]](#footnote-1)

**Confidentiality**

This document contains confidential information that is intended exclusively for the applicant(s), the North-West University Engineering Research Ethics Committee (NWU-ENG-REC) and the designated reviewers. Should this document or parts thereof come into your possession in error, you are requested to return it to the NWU-ENG-REC 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 for completing this form**

* All applicants complete Section 1, 2 & 7 - 10.
* If the answer to any of below screening questions are ‘yes’, please complete the indicated sections of this application form and attach the indicated documents
* Once completed, please save the application form as a PDF
* Submit the completed Ethics Application Form (with all the required attachments) via email to ENG-REC@nwu.ac.za. Kindly ensure that all required *finalised* documents are included in the email. Should the application be incomplete (additional attachments or version corrections need to be send afterwards), the application will have to be resubmitted with the application form and all the required attachments (in one email) which could mean that the application may miss the deadline for the closing of the agenda for the next NWU-ENG-REC meeting

|  | **Additional section(s) to complete** | **Attachment** | **NA** | **Attached** |
| --- | --- | --- | --- | --- |
| * Has the **research proposa**l been approved by a Scientific Committee?
 |  | Research proposal |  |[ ]
|  |  | Research proposal evaluation form |  |[ ]
|  |  | Scientific Committee ethics screening form |  |[ ]
|  |  | Code of conduct |  |[ ]
| * Copies of **proof of ethics training** for all researchers involved in the study (not older than three years).
 |  | Proof of ethics training |  |[ ]
| * Can the research activities potentially bring **physical harm** to yourself and/or other people (such as civilians, laboratory personnel, assistants and/or students) Refer to the Faculty’s HIRA process
 |  | HIRA |[ ] [x]
| * Will the research be done by means of **interviews**
 | 3 | Interview schedule | [ ]  |[ ]
|  |  | Informed consent form | [ ]  |[ ]
| * Will the research be done by means of **focus groups**
 | 3 | Discussion points | [ ]  |[ ]
|  |  | Informed consent form | [ ]  |[ ]
| * Will the research be done by means of a **questionnaire**
 | 3 | Questionnaire | [ ]  |[ ]
|  |  | Informed consent form (could form part of questionnaire document) |[ ] [ ]
| * Will there be an **advertisement** for recruiting participants?
 | 3 | Advertisement | [ ]  |[ ]
| * Will the study be conducted on **private property** outside of the NWU?
 | 4 | Permission letter |[x] [ ]
| * Will **company** (included NWU) **data** be used for the study that is not publically available?
 |  |  |  |  |
| * Will the research possibly have an effect on the **environment** (Excluding laboratory work which should refers to HIRA process)
 | 5 | Copy of the risk level descriptor for environmental impact |[ ] [ ]
| * Will the study make use of **statistical** **analysis** of **qualitative** data (e.g. interviews and/or questionnaires)?
 | 6 | NA |[ ] [ ]

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# Section 1: Study identification

## Title of study

|  |  |
| --- | --- |
| Approved title of study: | Click or tap here to enter text. |

## Type of application

|  |  |  |
| --- | --- | --- |
|  | Ethics nr (if available) |  |
| Single study (application for ethics approval for an entire study) |  |[x]
| Phase of single study (application for ethics approval for part of a study) |  |[x]
| Larger study |  |[x]
| Single study affiliated to another study |  |[x]
| Other: Specify  | Click or tap here to enter text. |

## Abstract (applicable to this application)

|  |  |
| --- | --- |
| Abstract Including at least: Background, problem statement, project aim, high-level method (e.g. simulations, laboratory work, interviews, focus groups) |  Click or tap here to enter text. |

## Type of data

This study makes use of the following data.

Select the correct option. More than one option may be marked as “Yes”.

|  |  |  |
| --- | --- | --- |
| **Description** | **Yes** | **No** |
| Human participants | Qualitative |[ ] [ ]
|  | Quantitative |[ ] [ ]
|  | Mixed method |[ ] [ ]
| Filed privileged information (e.g. personal files)  |[ ] [ ]
| Stored data(e.g. data collected for another study) |[ ] [ ]

## Scientific Committee approval

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. The proposal needs to be approved by a Scientific Committee before it will be reviewed by the NWU-REC-REC. The NWU-REC-REC relies on the scientific expertise of this committee regarding the evaluation of the scientific merit and design of the study, as well as the recommendation of the ethics risk level that should be allocated

|  |  |
| --- | --- |
| Documents attached | Attached |
| Scientific Committee ethics screening checklist |[ ]
| Research proposal evaluation form  |[ ]

## Envisaged commencement and completion date of the study

Please indicate the expected commencement and ending dates of the study.

Ensure that the commencement date is at least a few weeks after the date of the NWU-ENG-REC meeting at which your application is to be reviewed.

The NWU-ENG-REC 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 NWU-ENG-REC two months before the expiry of the study.

|  |  |
| --- | --- |
| Commencement Date | Estimated Completion Date |
| Click or tap to enter a date. | Click or tap to enter a date. |

# Section 2: Details of Study Team

## Principle Investigator

|  |  |
| --- | --- |
| Principal Investigator (main supervisor): | Click or tap here to enter text. |
| Research entity: | Click or tap here to enter text. |
| Email address (If not internal to NWU): | Click or tap here to enter text. |

## Student (if applicable)

|  |  |
| --- | --- |
| Student name and surname: | Click or tap here to enter text. |
| University number: | Click or tap here to enter text. | Degree enrolled for: | Click or tap here to enter text. |
| First year of registration | Click or tap here to enter text. |
| Student email address: | Click or tap here to enter text. |

## Other members of the study team

Names, qualifications, professional registration and functions of all the other co-workers (co-supervisors, researchers, postgraduate students in the case of a research study and assistants/field workers who form part of the study team) should be indicated.

|  |  |
| --- | --- |
| Other members of the study team: | Name, Qualification, Function |
| Click or tap here to enter text. | Click or tap here to enter text. |

## Conflict of Interests and Sponsors (if applicable)

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

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

Note: Indicate “Not applicable” if there is no member of the study team or professional supervisor with a conflict of interest.

|  |  |
| --- | --- |
| Name of Researcher | Complete description of the conflict and how it will be managed |
| Click or tap here to enter text. | Click or tap here to enter text. |

## Confidentiality

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

|  |  |  |
| --- | --- | --- |
| Documents attached | Not applicable to this study | Attached |
| Confidentiality agreements (see confidentiality agreements as approved by the legal office of the NWU) |[ ] [ ]

## Indemnity

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

|  |  |  |
| --- | --- | --- |
| Documents attached | Not applicable to this study | Attached |
| Indemnity forms (see indemnity forms as approved by the legal office) | [ ]  |[ ]

# Section 3: Research including human participants

|  |  |  |
| --- | --- | --- |
| **Applicable to this study** | **Yes** |[x]  **No** |[ ]

Please complete the section if the study will make use of human participant at any point during the study. This section is based on the research proposal. Where applicable, copy and paste information from the research proposal.

## What will be expected of participants during data gathering?

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

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

|  |  |
| --- | --- |
| Data gathering process | Click or tap here to enter text. |

## Criteria for participant selection and recruitment

Describe in full which inclusion and exclusion criteria will be used to select participants and justify each of your choices.

More information - The need for the inclusion/exclusion criteria it in the research has to be justified i.e. race or ethnic origin, person’s health, a person’s inherited characteristics or biometric information. Ensure that your exclusion criteria are not merely the opposite of the inclusion criteria.

|  |  |
| --- | --- |
| **Inclusion criteria** | **Justification** |
| Click or tap here to enter text. | Click or tap here to enter text. |
| **Exclusion criteria** | **Justification** |
| Click or tap here to enter text. | Click or tap here to enter text. |

## Participant recruitment

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

More information - This process should take place in such a way that the participants do not feel intimidated by the process or implicitly “bribed”, but decide absolutely voluntarily to participate. It should be fair and equitable.

|  |  |
| --- | --- |
| Recruitment process | Click or tap here to enter text. |

|  |  |  |
| --- | --- | --- |
| Documents attached | Not applicable to this study | Attached |
| **Advertisement** for recruiting participants | [ ]  |[ ]

## Privacy and Confidentiality

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

|  |
| --- |
| **Privacy**Privacy is concerned with who has access to *personal information and records* about the participant as well as *privacy* duringinterviews/focus groups. Explain how privacy will be ensured in your study. |
| Click or tap here to enter text. |
| **Confidentiality**Confidentiality ensures that *appropriate measures* will be implemented to *prevent disclosure of information* that might identify the participant either during the course of the research or afterwards e.g. anonymising data or pooling results. Explain how confidentiality will be ensured in your study. |
| Click or tap here to enter text. |

## Facilities

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

|  |  |
| --- | --- |
| Facilities to be used | Click or tap here to enter text. |

## Participant Informed Consent

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

More information - How will you go about contacting them and explaining the study and accompanying implications to all participants?

Ensure that participants are aware that participation in the research is voluntary and that they may withdraw from the study at any time.

Where research is not carried out in participants’ mother tongue, explain how you will go about conveying the information in an understandable manner. Where participants are not literate, a witness should be involved in obtaining informed consent.

For your convenience you can use the template for informed consent. Be clear on your description of the use of consent and permission.

|  |  |
| --- | --- |
| Informed consent procedure | Click or tap here to enter text. |

|  |  |  |
| --- | --- | --- |
| Documents attached | Not applicable to this study | Attached |
| Copy of the I**nformed Consent Form**, which has been compiled according to the template supplied by the NWU-ENG-REC office. |[ ] [ ]

## Incentives and/or remuneration of participants

Is any form of incentive and/or reimbursement offered to the participants?

If “Yes”, describe it in full in terms of *what, how, where, when, how much, terms and conditions*, etc. Remember to work according to the TIE principle (**t**ime, **i**nconvenience, **e**xpenses e.g. transport and meals).

If no remuneration is offered, *justify why this is not the case* (Please mark with X in the relevant block and provide details).

|  |  |  |
| --- | --- | --- |
| Yes | No | Description |
|[ ] [ ]  Click or tap here to enter text. |

# Section 4: Research using company data (without human participants)

|  |  |  |
| --- | --- | --- |
| **Applicable to this study** | **Yes** |[ ]  **No** |[ ]

Please complete this section if the study will make use of company (including NWU) data and/or if a member of the research team will conduct research on private property outside of the NWU.

## Company information

|  |  |
| --- | --- |
| Organisation name | Click or tap here to enter text. |
| Will the research be conducted on the organisation’s premises? | Yes |[ ]  No |[ ]

## Company data

|  |  |
| --- | --- |
| Elaborate on the type of company data that will be used | Click or tap here to enter text. |

|  |  |  |
| --- | --- | --- |
| Documents attached | Not applicable to this study | Attached |
| Copy of the **Permission Letter**, that has been compiled according to the template supplied by the NWU-ENG-REC office. |[ ] [ ]

# Section 5: Research that will have a possible impact on the environment

|  |  |  |
| --- | --- | --- |
| **Applicable to this study** | **Yes** |[ ]  **No** |[ ]

Please complete this section if the study to be undertaken will have any impact on the environment as determined by evaluation of the study using the risk level descriptor for environmental impact. If this section is to be completed, please ensure that a completed copy of the risk level descriptor for environmental impact is attached to the application that is submitted.

## Please indicate the risk level of the current study in terms of environmental impact.

|  |  |  |
| --- | --- | --- |
| **Category** | **Description** | **Select** |
| **0** | **None****Effect on the environment:** Potential for incidental and/or transient changes to valued flora and fauna, ecosystem processes and structure, including ecosystem services; **or****Legal implications:** No legal implications. No need to apply for any environmental authorisations; **or****Potential impact on reputation of the NWU:** No discernible impact on reputation. |[ ]
| **1** | **Mild****Effect on the environment:** Potential for acceptable, short term changes to valued flora and fauna, ecosystem processes and structure, including ecosystem services; **or****Legal implications:** Complaints for the public and/or regulator. No need to apply for any environmental authorisations; **or****Potential impact on reputation of the NWU:** Potential impact on reputation. |[ ]
| **2** | **Medium****Effect on the environment:** Potential for acceptable, longer term changes to valued flora and fauna, ecosystem processes and structure, including ecosystem services; **or****Legal implications:** Departmental enquiry and correspondence. Environmental authorisation may be required; **or****Potential impact on reputation of the NWU:** Limited, reputation impacted with small number of people. |[ ]
| **3** | **Severe****Effect on the environment:** Potential for unacceptable, short term changes to valued flora and fauna, ecosystem processes and structure, including ecosystem services; **or****Legal implications:** Notification of intent to issue a directive. Environmental authorisation required; **or****Potential impact on reputation of the NWU:** Reputation impacted with some stakeholders. |[ ]
| **4** | **Very severe****Effect on the environment:** Potential for unacceptable, longer term changes to valued flora and fauna, ecosystem processes and structure, including ecosystem services; **or****Legal implications:** Withdrawal of permit. Environmental authorisation required; **or****Potential impact on reputation of the NWU:** Reputation impacted with significant number of key stakeholders. |[ ]
| **5** | **Intolerable****Effect on the environment:** Potential for irreversible changes to valued flora and fauna, ecosystem processes and structure, including ecosystem services; **or****Legal implications:** Referral to the National Prosecuting Authority. Potential investigation by authority with prosecution and fines. Environmental authorisation required; **or****Potential impact on reputation of the NWU:** Reputation impacted with majority of key stakeholders. |[ ]

## Explain the type of environmental impact that the study will have.

|  |
| --- |
| Explain the possible Environmental impact of the study |
| Click or tap here to enter text. |

# Section 6: Justifiability of statistical procedures

|  |  |  |
| --- | --- | --- |
| **Applicable to this study** | **Yes** |[ ]  **No** |[ ]

Please complete this section if the study made use of a statistical analysis of qualitative data (e.g. interviews and/or questionnaires)?

## Statistical methodology

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

## Justification of sample size/strategy

|  |
| --- |
| Indicate how the sample size was determined e.g. power calculation or previously reported study designs. |
| Click or tap here to enter text. |

## Statistical consultation (if applicable)

|  |
| --- |
| Indicate how you ensured the suitability of the statistical procedures to be used in this study e.g. consultation or proof of expertise. |
| Click or tap here to enter text. |

## Method of randomisation (if applicable)

|  |
| --- |
| If randomisation is to be used in this study, please indicate the manner by which randomisation will be assured. |
| Click or tap here to enter text. |

# Section 7: Risk/benefit ratio analysis

## Risks and precautions

Name and explain *all the possible risks* for *all procedures* that the participants/organisation might experience during the research. Use the template at the back of the approved risk level descriptor document (Within the ENG-REC ToR) to guide you into identifying all the possible types of risk as well as the probability and magnitude of harm.

(By completing this section it will help you to answer the two sections on “Are there risks involved in you/your organisation taking part in research?” and “What will happen in the unlikely event of some form of harm occurring as a direct result of your taking part in this research study?” in the Informed Consent Form / Permission letter. )

|  |  |
| --- | --- |
| **Risks** (e.g. physical, psychological, social, legal, economic, dignitary and community)Identify all the possible risks. | **Precautions** (When describing these precautions be clear on how they will mitigate all the identified risks) |
| Click or tap here to enter text. | Click or tap here to enter text. |

## Benefits for participants/organisation

Describe 1) the potential *direct* benefits that the study might hold for the *individual participants or organisation*; or 2) the *indirect* benefits that the study holds for the *society at large* or for *the researchers and the organisations/institutions* they are working for, through the knowledge gained.

(By completing this section it will help you to answer the section on “Will you, the organisation, the community at large or the environment benefit from taking part in this research” in the Informed Consent Form.)

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

## Risk/benefit ratio

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

|  |  |
| --- | --- |
| Benefit outweighs the risks | Click or tap here to enter text. |
| Risks outweigh the benefit | Choose an item. | Justify: | Click or tap here to enter text. |

# Section 8: Data handling

## Management, storage and destruction of data

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

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

Ensure that you refer to both *electronic* and *hard copy versions* of data*.* |
| Click or tap here to enter text. |
| **Storage and destruction of data**Describe: * where and how data will be stored
* for how long it will be stored
* who will be responsible for storage
* how it will be destroyed?

Ensure that you refer to both *electronic* and *hard copy versions* of data  |
| Click or tap here to enter text. |

## Use of previously collected data (if applicable)

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

|  |
| --- |
| What was the purpose of the original collection? |
| Click or tap here to enter text. |
| What will your purpose be? |
| Click or tap here to enter text. |
| Give a description of how research integrity was ensured in the original study by referring to:* how informed consent was obtained from participants
* what they consented for
* the circumstances under which the data were gathered
* how the ethics of data collection was ensured?
 |
| Click or tap here to enter text. |
| Give a detailed description of:* how data storage was managed
* where and how data were stored
* for how long it was stored
* who was responsible for storage
* how it was ensured that no tampering occurred?
 |
| Click or tap here to enter text. |
| Foreseeable risks for participants or researchers involved in using the previously collected data? |
| Risks | Precautions |
| Click or tap here to enter text. | Click or tap here to enter text. |
| Will re-consent be necessary? | Yes | No |
| If “Yes” motivate: why, and how this re-consent will be obtained.  |
| Why? | Click or tap here to enter text. |
| How? | Click or tap here to enter text. |

|  |  |  |
| --- | --- | --- |
| Documents attached | Not applicable to this study | Attached |
| Letter from study leader for the use of the data | [ ]  |[ ]
| Ethical approval of the original study | [ ]  |[ ]
| Informed consent document for the re-consent | [ ]  |[ ]

## Use of filed privileged information (if applicable)

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

|  |
| --- |
| The nature of the information to be used: |
| Click or tap here to enter text. |
| Process of obtaining permission/ethical approval for access: |
| Click or tap here to enter text. |
| Process of data collection: |
| Click or tap here to enter text. |
| Process of anonymisation of the data: |
| Click or tap here to enter text. |
| Foreseeable risks for participants whose filed privileged information is being accessed: |
| Risks | Precautions |
| Click or tap here to enter text. | Click or tap here to enter text. |

# Section 9: Dissemination of study results to participants/organisation

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

|  |  |
| --- | --- |
| What? | Click or tap here to enter text. |
| How? | Click or tap here to enter text. |
| When? | Click or tap here to enter text. |
| To whom? | Click or tap here to enter text. |

# Section 10: Principle Investigator (Supervisor) Declaration

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

1. The information in this application is, to the best of my knowledge, correct and that no ethical codes will be violated with the study;
2. I will make sure that the study is managed ethically justifiably from start to finish;
3. In the case of human participants;
	1. I will put it clearly to all participants that participation (including assent) in any research study is absolutely voluntary and that no pressure, of whatever nature, will be placed on any potential participant to take part;
	2. I will put it clearly to all participants that any participant may withdraw from the study at any time and may ask that his/her data no longer be used in the study, without stating reasons and without fear of any form of prejudice;
	3. every participant who takes part in the study will receive the accompanying form for informed consent and it will be ensured that every participant understands the information (including the process and risks) fully;
	4. every participant will sign the informed consent in writing before the study commences, or a witness will stand in on behalf of the participant when the participant is illiterate;
	5. the written permission of the parent or legal guardians of all minor subjects will be obtained before the research commences;
	6. any foreseeable risk is restricted to the minimum, any permanent damage is avoided as far as possible and that appropriate precautions and safety measures are in place;
	7. confidentiality of all the information of all participants will be respected and ensured;
4. I and all co-workers/assistants/field workers are appropriately qualified, capable and legally competent to implement the proposed studies/procedures/interventions;
5. I will not deviate from the approved proposal and that I understand approval for the study will be cancelled if I deviate from the proposal without the approval of the North-West University Engineering Research Ethics Committee (NWU-ENG-REC);
6. the study is scientifically justifiable;
7. where necessary, all contracts, permits and the applicable documents of relevance will be obtained before the research commences;
8. I will ensure that all data are stored safely and remain in the possession of the North-West University;
9. I will report in writing any incidents or adverse events/serious adverse events that occur during the study without delay to the North-West University Engineering Research Ethics Committee (NWU-ENG-REC);
10. I undertake to respect intellectual property rights throughout and to avoid any form of plagiarism;
11. I will obtain permission for amendments to the protocol and report annually to the North-West University Engineering Research Ethics Committee (NWU-ENG-REC) on the prescribed monitoring report concerning progress of the study;
12. I will notify the North-West University Engineering Research Ethics Committee (NWU-ENG-REC) should the study be terminated.

|  |  |
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|  **Principal investigator (supervisor) signature** |  **Date** |

1. The Faculty of Health Sciences Ethics Office and NWU-EMELTEN-REC of the North-West University is acknowledged for the se of their documents with adjustments made by the North-West University Engineering Research Ethics Committee (NWU-ENG-REC) [↑](#footnote-ref-1)