

Faculty of Health Sciences Ethics Office for Research, Training and Support

[health-sciences.ac.za/healthethics](http://www.nwu.ac.za/healthethics)

|  |
| --- |
| **NWU-HREC** North-West University Health Research Ethics Committee *(REC-130913-037)* **Ethics Application Form – Health and Health Related Research** to apply for the approval of a **single** or **larger** **health-related**  study involving **human participants** for research or education/training  ***9.1.5.1.1\_NWU-HREC\_EAF\_Dec2019, Version: December 2019*** |
| **CONFIDENTIAL!** This document contains confidential information that is intended exclusively for the applicant(s), the North-West University Health Research Ethics Committee (NWU-HREC) of the Faculty of Health Sciences 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-HREC without delay or destroy it (Contact the administrative assistant at [Ethics-HRECApply@nwu.ac.za](mailto:Ethics-HRECApply@nwu.ac.za)). Unauthorised possession, reading, studying, copying or distribution of this material, or any other form of abuse, is illegal and punishable. |

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

1. The *research proposal and informed consent documentation form* the base document that are 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 and 4.
3. Select and complete the research-specific sub-sections from § 5 as applicable to the specific requirements of your study (utilise the table of contents).
4. **All required documentation (as indicated in the checklist under § 1.11) should be** **attached separately** to the e-mail in which the application is submitted as indicated under point g. (NB: Please do not upload the documentation into the application form, submit as separate attachments. Applicants must please ensure that all required finalised documents as indicated in the checklist are included with the application. **No additional late attachments or version corrections *can or will* be accepted.**  If this does occur and the application was originally incomplete, then it will have to be **resubmitted** with the application form and all the required attachments, which could mean that the application may miss the deadline for the closing of the agenda for the NWU-HREC meeting.).
5. Liaise with the appropriate officials and colleagues mentioned in § 6, complete and sign a printed copy.
6. Submit scanned copies of the signed pages.
7. Submit the completed Ethics Application Form (with all the required documents as attachments) via e-mail to [Ethics-HRECApply@nwu.ac.za](mailto:Ethics-HRECApply@nwu.ac.za).

|  |  |
| --- | --- |
| **Research Ethics Number** | NWU-?????-??-?? |
| **Campus** | Click here to enter text. |
| **Faculty** | Click here to enter text. |
| **Research Entity** | Click here to enter text. |
| **Discipline** | Click here to enter text. |
| **Principle Investigator/ Researcher/ Study Supervisor** | Click here to enter text. |
| **Student Name & Surname** | Click here to enter text. |
| **Student’s NWU Student Number** | Click here to enter text. |
| **Study Title** | Click here to enter text. |

Table of Contents

[1 SECTION 1: STUDY IDENTIFICATION 5](#_Toc26197716)

[1.1 Full, descriptive title of the study 5](#_Toc26197717)

[1.2 Name of the principal investigator (PI)/researcher/study supervisor and student 5](#_Toc26197718)

[1.3 Institutional structures and divisions under which the study resides 5](#_Toc26197719)

[1.4 Context of the study and researcher involvement 5](#_Toc26197720)

[1.5 Type of study 6](#_Toc26197721)

[1.6 Choice of methodology 6](#_Toc26197722)

[1.7 Track record of submission dates and version numbers 6](#_Toc26197723)

[1.8 Envisaged commencement and completion date of the study 7](#_Toc26197724)

[1.9 Estimated risk level 7](#_Toc26197725)

[1.10 This study encompasses aspects that require additional ethical explanation 8](#_Toc26197726)

[1.11 Checklist and attachments 9](#_Toc26197727)

[2 SECTION 2: DETAIL OF PRINCIPAL INVESTIGATOR/ RESEARCHER/STUDY SUPERVISOR, PROFESSIONAL SUPERVISORY PERSONS AND OTHER TEAM MEMBERS 10](#_Toc26197728)

[2.1 Summary of persons included in the study 10](#_Toc26197729)

[2.2 Summary of professional supervisory persons involved in this study 11](#_Toc26197730)

[2.3 Contact details of the PI / Researcher / Study Supervisor 11](#_Toc26197731)

[2.4 Details of Project Supervisor 12](#_Toc26197732)

[2.5 Student Information (If applicable) 13](#_Toc26197733)

[2.6 Professional supervisory persons 13](#_Toc26197734)

[2.7 Details of ALL Members of the study team 13](#_Toc26197735)

[2.8 Collaborators *(if applicable)* 14](#_Toc26197736)

[2.9 Conflict of Interests (if applicable) 14](#_Toc26197737)

[2.10 Sponsors (if applicable) 14](#_Toc26197738)

[2.11 Contractual Agreement(s) (if applicable) 15](#_Toc26197739)

[2.12 Confidentiality and non-disclosure agreements 15](#_Toc26197740)

[2.13 Indemnity 16](#_Toc26197741)

[2.14 Research Data Gatekeepers Committee (RDGC) 16](#_Toc26197742)

[3 SECTION 3: RESEARCH PROPOSAL AND PRIOR SCIENTIFIC COMMITTEE APPROVAL 17](#_Toc26197743)

[3.1 Executive summary of the study 17](#_Toc26197744)

[3.2 Proposal 17](#_Toc26197745)

[3.3 Scientific/Proposal committee approval 17](#_Toc26197746)

[4 SECTION 4: MORE COMPREHENSIVE AND DETAILED ETHICAL INFORMATION THAT COULD NOT BE PROVIDED IN THE PROPOSAL 18](#_Toc26197747)

[4.1 What will be *expected* of participants during data gathering? 18](#_Toc26197748)

[4.2 Risk of harms and precautionary measures 18](#_Toc26197749)

[4.3 Direct benefits for participants or indirect benefits for society at large or the scientific field 19](#_Toc26197750)

[4.4 Risk/benefit ratio analysis 19](#_Toc26197751)

[4.5 Privacy and Confidentiality 19](#_Toc26197752)

[4.6 Criteria for participant selection and recruitment 19](#_Toc26197753)

[4.7 Participant recruitment 20](#_Toc26197754)

[4.8 Informed consent (consent, permission, assent and dissent) 20](#_Toc26197755)

[4.9 Facilities 20](#_Toc26197756)

[4.10 Legal authorisation 21](#_Toc26197757)

[4.11 Goodwill permission 21](#_Toc26197758)

[4.12 Incentives and/or remuneration of participants 21](#_Toc26197759)

[4.13 Management, storage and destruction of data/biological samples 21](#_Toc26197760)

[4.14 Monitoring of research 22](#_Toc26197761)

[4.15 Dissemination of the findings of the study to participants 23](#_Toc26197762)

[4.16 Misleading of participants (if applicable) 23](#_Toc26197763)

[4.17 Use of previously collected data/biological samples (if applicable) 23](#_Toc26197764)

[4.18 Use of filed privileged documentation and/or information (if applicable) 25](#_Toc26197765)

[4.19 Justifiability of statistical procedures (for quantitative studies) 25](#_Toc26197766)

[5 SECTION 5: MATTERS THAT NECESSITATE ADDITIONAL INFORMATION 27](#_Toc26197767)

[5.1 Sec 5a: Vulnerable participants 27](#_Toc26197768)

[5.2 Sec 5b: Measuring instruments and questionnaires that need psychometric interpretation by a psychologist 28](#_Toc26197769)

[5.3 Sec 5c: Infection, genetic modification and commercialisation of cell and tissue cultures 29](#_Toc26197770)

[5.4 Sec 5d: Use of Drugs/Medicines 32](#_Toc26197771)

[5.5 Sec 5e: Use of drug delivery systems 34](#_Toc26197772)

[5.6 Sec 5f: Use of food, fluids or nutrients 35](#_Toc26197773)

[5.7 Sec 5g: Use of Radio-Active Substances 36](#_Toc26197774)

[5.8 Sec 5h: Use of Toxic Substances or Dangerous Substances 37](#_Toc26197775)

[5.9 Sec 5i: Possible impact on the environment 38](#_Toc26197776)

[6 SECTION 6: OTHER ETHICS EVALUATIONS AND RISK INSURANCE 41](#_Toc26197777)

[6.1 Sec 6a: Evaluation by other Research Ethics Committees 41](#_Toc26197778)

[6.2 Sec 6b: Risk Insurance 41](#_Toc26197779)

[7 SECTION 7: DECLARATIONS 43](#_Toc26197780)

[7.1 Sec 7a: Study supervisor/Researcher (if not a study conducted by a student) 43](#_Toc26197782)

[7.2 Sec 7b: Statistical Consultant (If applicable) 45](#_Toc26197783)

[7.3 Sec 7c: Bio-Safety Officer (If applicable) 46](#_Toc26197784)

[7.4 Sec 7d: Research Director (School director if Education request) 47](#_Toc26197785)

# SECTION 1: STUDY IDENTIFICATION

Provide the necessary descriptions below to identify this study application:

## Full, descriptive title of the study

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

## Name of the principal investigator (PI)/researcher/study supervisor and student

|  |
| --- |
| ***More information***  *In case of research studies this refers to the person who takes final* ***responsibility****, or in case of training courses, the lecturer. In the case of postgraduate studies, also provide the details of the postgraduate student and select the postgraduate level of the study from the dropdown list. The extended study team is described in Section 2.6.* |

|  |  |  |
| --- | --- | --- |
| **Role** | **Name** *(title, first name and surname)* | **NWU staff/student no.** |
| **PI / Researcher / Study Supervisor** | Click here to enter title, first name and surname. | Click here to enter number. |
| **Student  *(if applicable)*** | Click here to enter title, first name and surname. | Click here to enter number. |
| **Level of the study** | Choose an item. | |

## Institutional structures and divisions under which the study resides

|  |  |
| --- | --- |
| **Campus(es)** | Click here to enter details. |
| **Research entity(ies)** | Click here to enter details. |
| **Faculty(ies)** | Click here to enter details. |
| **Discipline(s)** | Click here to enter details. |

## Context of the study and researcher involvement

|  |  |  |  |
| --- | --- | --- | --- |
| **Aspect** | | **Yes** | **No** |
| **Scientific Research** | Study scope falls inside the focus of an NWU research entity |  |  |
| Study scope falls outside the focus of an NWU research entity |  |  |
| Self-initiated research with no student involvement |  |  |
| Self-initiated research with student involvement: | | |
| * Honours study (for publication purposes) |  |  |
| * Master’s degree |  |  |
| * Doctoral degree |  |  |
| Study involves contract work |  |  |
| **Education / Training** | For staff of the North-West University (NWU) |  |  |
| For NWU students (undergraduate or postgraduate) |  |  |
| For other learners (not associated with the NWU) |  |  |
| **Other (specify)** | Click or tap here to enter text. | | |

## Type of study

Is this an application for a *single*or a *larger study, affiliated study, or an educational (training) course*? Select the option from the dropdown list below *(see “[Choose an item]” below)* that best describes this application.

|  |
| --- |
| ***More information***  ***Please note:*** *“Single” study refers to a study consisting of one or more researchers not intending to involve master’s or doctoral students, or for the purpose of a single master’s or doctoral study, whereas a “larger” study refers to a study planning to involve several master’s and doctoral students and that includes the full methodology, as well as clearly identifies the objectives per student. For more elaborate definitions and explanations of “single” and “larger” studies you are referred to the latest version of the SOP for the research ethics approval application process, SOP-Ethics\_1.4), as available on the website of the Ethics Office (*[*http://health-sciences.nwu.ac.za/healthethics/sops*](http://health-sciences.nwu.ac.za/healthethics/sops)*).* |

|  |
| --- |
| Choose an item. |

For a **larger study** *(not necessary for a single study)*, also provide a clear outline of the possible number of Master’s and doctoral studies envisaged *(i.e. that can be accommodated in the larger study as sub-studies)*, as well as what each student will do *(i.e. which objectives of the larger study will apply to the sub-study for that student)*. You need not know the names of the students as yet.

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

## Choice of methodology

Mark ALL applicable options with “X” in the appropriate box – more than one option may be marked as “Yes”.

|  |  |  |
| --- | --- | --- |
| **Description** | | **Yes** |
| Human participants (subjects) | Qualitative |  |
| Quantitative |  |
| Mixed method |  |
| **Other e.g. program evaluation:**  *Click or tap here to enter text.* |  |
| Filed privileged information (e.g. medical files) or stored biological samples of human origin (e.g. samples collected for another study or medical diagnosis) | |  |

## Track record of submission dates and version numbers

Indicate the date of submission of the first application and of any subsequent revisions (based on feedback from NWU-HREC) until the current version.

|  |
| --- |
| ***More information***  *Provide a track record of the submissions and versions of this application, from the first submission, subsequent revisions until the current version. The 1st submission will be version no. 1, and thereafter, the 1st corrections based on comments from the Ethics Committee will be version no. 2, etc.). Complete the date until the current version and leave the dates for the remainder unselected.*  ***Please note:*** *The latest version will always be used as the current version for the purpose of any passive or active monitoring, or audit. The dates and version no. (based on previous submissions, corrections and/or amendments) may automatically be calculated by an electronic submission platform (once implemented).* |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | Select date. |  | Select date. |  | Select date. |
|  | Select date. |  | Select date. |  | Select date. |
|  | Select date. |  | Select date. |  | Select date. |

## 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 indicate a period of a few months 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 monitoring report. Ensure that the commencement date is at least a few weeks after the date of the NWU-HREC meeting, at which your application is to be reviewed. The NWU-HREC will only grant ethics approval for a* ***one-year period****. Continuation of the study is granted on an annual basis for another year, after submission and review of a monitoring report. This process continues until the study comes to an end.* ***NB:*** *A monitoring report should also be submitted when the study is completed.* |

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

## Estimated risk level

Please indicate *your own view* of the estimated risk level of the research by using one or both of the two risk level tables indicated for adult human participants or children/incapacitated adults.

|  |  |  |
| --- | --- | --- |
| **Estimated risk level for adult human participants** | | |
| Minimal risk |  |
| Medium risk |  |
| High risk |  |

|  |  |  |
| --- | --- | --- |
| **Estimated risk level for children/incapacitated adults** | | |
| No more than minimal risk of harm (negligible risk) |  |
| Greater than minimal risk but provides the prospect of direct benefit for the child/incapacitated adult |  |
| Greater than minimal risk with no prospect of direct benefit to the child/incapacitated adult, but a high probability of providing generalizable knowledge |  |

## This study encompasses aspects that require additional ethical explanation

Mark ALL options as with “X” in the appropriate box – more than one option may be marked. If a specific option is marked, **please complete the corresponding section in Section 5**.

|  |  |
| --- | --- |
| **Description** | **Yes** |
| Vulnerable participants |  |
| Measuring instruments and questionnaires that need psychometric interpretation by a psychologist |  |
| Infection, genetic modification and commercialisation of cell and tissue lines |  |
| Use of drugs / medicines |  |
| Use of drug delivery systems |  |
| Use of traditional medicines |  |
| Use of food, fluids or nutrients |  |
| Use of radio-active substances |  |
| Use of toxic substances or dangerous substances |  |
| Possible impact on the environment |  |
| Any other aspect of potentially ethically sensitive nature (specify below) |  |

***Other aspects (specify)***

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

## Checklist and attachments

Indicate the number of each type of attachment below, together with the document names of all the attachments. Document names, as explained below, should follow a systematic order.

|  |  |  |
| --- | --- | --- |
| **Document(s)** | **No.** | **Name(s) of documents** |
| 1. Cover letter for the application | **00** | Click or tap here to enter document name(s). |
| 1. Executive summary of the project | **00** | Click or tap here to enter document name(s). |
| 1. Research study proposal *(as approved)*  or study guide for training | **00** | Click or tap here to enter document name(s). |
| 1. This completed ethics application form | **00** | Click or tap here to enter document name(s). |
| 1. Informed consent documentation and checklist | **00** | Click or tap here to enter document name(s). |
| 1. Advertisements or recruitment materials | **00** | Click or tap here to enter document name(s). |
| 1. Questionnaires, interview schedule for interviews or focus groups | **00** | Click or tap here to enter document name(s). |
| 1. Approval letter from the Scientific Committee | **00** | Click or tap here to enter document name(s). |
| 1. 2-page narrative CVs of all researchers in the project | **00** | Click or tap here to enter document name(s). |
| 1. Proof of ethics training (<3 yrs.)  for all researchers in the project | **00** | Click or tap here to enter document name(s). |
| 1. Permission letters from governing bodies to conduct the research | **00** | Click or tap here to enter document name(s). |
| 1. Goodwill permission letters | **00** | Click or tap here to enter document name(s). |
| 1. Any other applicable documentation e.g. MOU, contracts with collaborators/laboratories, permits etc. | **00** | Click or tap here to enter document name(s). |
| 1. Signed NWU code of conduct  for all researchers in the project | **00** | Click or tap here to enter document name(s). |
| 1. Signed pages of the ethics application form for the declarations by the *project leader, statistical consultation services, biosafety officer and director of the research entity* | **00** | Click or tap here to enter document name(s). |
| 1. Checklist of attachments | **00** | Click or tap here to enter document name(s). |
| **The following documents only if applicable:** | | |
| 1. Signed statistical consultation form | **00** | Click or tap here to enter document name(s). |
| 1. Confidentiality agreement | **00** | Click or tap here to enter document name(s). |
| 1. Indemnity form | **00** | Click or tap here to enter document name(s). |
| 1. Permission from the project leader if a study is done as an affiliated study under another study or a sub-study under a larger study | **00** | Click or tap here to enter document name(s). |
| 1. Form A for delegated ministerial consent in the case of greater than minimal risk research in children with no prospect of direct benefit to them | **00** | Click or tap here to enter document name(s). |
| 1. If any non-registered medication is used, approval letter by SAHPRA | **00** | Click or tap here to enter document name(s). |
| 1. If radio-active substances are used, letter from the radiation control officer | **00** | Click or tap here to enter document name(s). |

# SECTION 2: DETAIL OF PRINCIPAL INVESTIGATOR/ RESEARCHER/STUDY SUPERVISOR, PROFESSIONAL SUPERVISORY PERSONS AND OTHER TEAM MEMBERS

## Summary of persons included in the study

Fill in the number concerned for *ALL* options. Ensure that the participant numbers in this table correspond with the individuals indicated in Section 2.3, 2.4, 2.5, 2.6 and 2.7

|  |
| --- |
| ***More information***  *The* ***study supervisor*** *is generally viewed as the individual who takes* ***the overall responsibility*** *for all aspects of the study e.g. study supervisor and principle investigator.*  *The* ***project supervisor*** *is generally the individual responsible for the* ***day-to-day management*** *of the study.* |

|  |  |  |  |
| --- | --- | --- | --- |
| **Description** | | **Number** | |
| **SA** | **Foreign** |
| **Only for research studies** | Study supervisor(s) (e.g. *PI/researcher/study supervisor*) | 0 | 0 |
| Project supervisor (day to day manager) | 0 | 0 |
| Internal co-workers (researchers and postgraduate students of the NWU) | 0 | 0 |
| External co-workers (researchers outside the NWU) | 0 | 0 |
| Assistants/field workers | 0 | 0 |
|  | Sponsors | 0 | 0 |
| **Only for education and training (e.g. undergraduate practicals)** | Educator | 0 | 0 |
| Internal co-workers (lecturers of the NWU) | 0 | 0 |
| External co-workers (lecturers outside the NWU) | 0 | 0 |
| Undergraduate students (of the NWU) | 0 | 0 |
| Postgraduate students (of the NWU) | 0 | 0 |
| Other learners (not associated with the NWU) | 0 | 0 |
| Assistants/field workers | 0 | 0 |

In the table above, NWU = North-West University

*Any other members of the study team not mentioned above (specify and explain)*

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

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

## Summary of professional supervisory persons involved in this study

Fill in the number concerned for ALL options. Ensure that the participant numbers in this table correspond with the individuals in § 2.5 below.

|  |
| --- |
| ***More information***  ***Professional supervisory person*** *indicates that the individual is an* ***independent person*** *in a supervisory capacity, that is involved during data gathering of the study, and provides specific required expertise to protect the participants. They may in no way be directly part of the research team. (Fill in the number involved in ALL options).* |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Researcher/ Supervisory person** | **Number** |  | **Researcher/ Supervisory Person** | **Number** |
| Supervisory Doctor | 0 |  | Supervisory Psychologist | 0 |
| Supervisory Nurse | 0 |  | Supervisory Pharmacist | 0 |
| Supervisory Psychiatrist | 0 |  | Supervisory Social worker | 0 |

*Specify any other supervisory person, if indicated above:*

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

## Contact details of the PI / Researcher / Study Supervisor

Name and details of the Principle Investigator (PI) / Researcher / Study Supervisor.

|  |
| --- |
| ***More information***  *The PI / Researcher / Study Supervisor is the member of the study team who assumes final, overall responsibility for all aspects of the study (i.e. management of the total study). Only NWU staff, or extraordinary professors in collaboration with staff of the North-West University, may register as PI / Researcher / Study Supervisor for ethics applications.* |

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Surname** | Click here to enter text. | | | | | | | |
| **Full names** | Click here to enter text. | | | | | | | |
| **Title** | Click here to enter text. | | **NWU staff no.** | | | Click here to enter text. | | |
| **Faculty** | Click here to enter text. | | | | **Entity** | Click here to enter text. | | |
| **E-mail** | Click here to enter text. | | | | | | | |
| **Cell** | Click here to enter no. | **Tel (w)** | | Click here to enter no. | | | **Tel (h)** | Click here to enter no. |
| **Office physical address** | Click here to enter text. | | | | | | | |
| **NWU box or postal address** | Click here to enter text. | | | | | | | |

***[PLEASE SUBMIT THE TWO-PAGE NARRATIVE CV OF THE PRINCIPAL INVESTIGATOR/ RESEARCHER/STUDY SUPERVISOR PROVIDING PROOF OF EXPERTISE FOR THE STUDY]***

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

## Details of Project Supervisor

Is the study supervisor also the project supervisor? (Please mark with an X in the appropriate box.)

|  |
| --- |
| ***More information***  *Where the PI / Researcher / Study Supervisor is not physically present or consistently available and where a more direct supervision of the research activities is necessary, or where the PI / Researcher / Study Supervisor is relatively inexperienced (e.g. junior researchers in the case of a research study, or lecturers in the case of education/training), a suitable researcher/lecturer may be designated as the Project Supervisor. The Project Supervisor is therefore the individual responsible for the day-to-day onsite/direct/one-on-one management of the study when the PI / Researcher / Study Supervisor cannot fulfil this responsibility, or for overseeing the study to support an inexperienced PI / Researcher / Study Supervisor, where this is deemed necessary. The Project Supervisor is part of the study team.* |

|  |  |
| --- | --- |
| **Yes** | **No** |
|  |  |

If “Yes”, this part can be left blank. If “No” (i.e. if the study supervisor is not the project supervisor) give details of the person below.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Surname** | Click here to enter text. | | | | | | | |
| **Full names** | Click here to enter text. | | | | | | | |
| **Title** | Click here to enter text. | | **NWU staff no.** | | | Click here to enter text. | | |
| **Faculty** | Click here to enter text. | | | | **Entity** | Click here to enter text. | | |
| **E-mail** | Click here to enter text. | | | | | | | |
| **Cell** | Click here to enter no. | **Tel (w)** | | Click here to enter no. | | | **Tel (h)** | Click here to enter no. |
| **Office physical address** | Click here to enter text. | | | | | | | |
| **NWU box or postal address** | Click here to enter text. | | | | | | | |

***[PLEASE SUBMIT THE TWO-PAGE NARRATIVE CV OF THE PROJECT SUPERVISOR PROVIDING PROOF OF EXPERTISE FOR THIS STUDY]***

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

## Student Information (If applicable)

Name and details of the student working the project

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Surname** | Click here to enter text. | | | |
| **Full names** | Click here to enter text. | | | |
| **Title** | Click here to enter text. | **NWU no.** | | Click here to enter text. |
| **Faculty** | Click here to enter text. | | **Entity** | Click here to enter text. |
| **E-mail** | Click here to enter text. | | | |
| **Cell** | Click here to enter no. | | | |

## Professional supervisory persons

Provide the names, functions & responsibilities, qualifications & professional registrations, and affiliation of ALL professional supervisory persons *(e.g. supervisory doctor, nurse, pharmacist, psychologists, etc.)*. This section is completed if applicable, as mentioned in point 2.2 (See definition of professional supervisory person under point 2.2) \*Add extra rows to the table if required.

|  |
| --- |
| ***More information***  *Professional supervisory person does not refer to the study supervisor or the project supervisor. In all cases where medical emergencies may possibly arise, the physical presence of a doctor and a registered nurse is required. For the drawing of blood samples (e.g. diet manipulation and similar studies) the presence of a registered nurse is sufficient (see definition of professional supervisory person under point 2.2).*  ***Please note:*** *The professional supervisory person(s) may NOT be part of the study team!*  ***Please note:******ATTACH*** *a two-page narrative curriculum vitae (CV) for all professional supervisory persons of the study.* |

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Functions and Responsibilities** | **Qualifications and Prof. Registr.** | **Affiliation** |
| Type name  or “not applicable”. | Type details  or “not applicable”. | Type details  or “not applicable”. | Type details  or “not applicable”. |

Enter any content that you want to repeat, including other content controls. You can also insert this control around table rows in order to repeat parts of a table.

***Please note:*** *Type the information for only one professional supervisory person per row. For more professional supervisory person, add more rows by clicking on the [Tab] key while the curser is in the last column.*

## Details of ALL Members of the study team

Provide the names, qualifications, professional registration and functions of all the other team members (researchers, postgraduate students in the case of a research study, or lecturers (in the case of training) and assistants or field workers who form part of the study team) should be indicated *but excluding professional supervisory persons who may not be directly involved in the study - see §2.5*. The information given in this table should correspond with the number of team members given in Section 2.1 \*Add extra rows to the table if required.

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Qualifications** | **Professional Registration** | **Function** |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |

**Note:** Type one name per row, or type “none” if there is no other team member. \*Add extra rows to the table if required.

***[PLEASE SUBMIT A TWO-PAGE NARRATIVE CV FOR ALL THE MENTIONED RESEARCH TEAM MEMBERS IN THIS SECTION PROVIDING PROOF OF EXPERTISE FOR THIS STUDY]***

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

## Collaborators *(if applicable)*

Declare with full details all collaboration agreement(s), e.g. with researchers or lecturers from another institution, national or international, who will be working on a defined section of the study. *Please note:* *A fully signed copy of any collaborative agreement(s)* must be submitted to the NWU-HREC together with the submission of the application. This agreement(s) should have gone through all the prescribed structures (e.g. legal office). \*Add extra rows to the table if required.

|  |
| --- |
| ***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** | **Full Description of the agreement(s) as well as functions and responsibilities** | **National or International** |
| Type name  or “not applicable”. | Type details  or “not applicable”. | Choose an item. |

Please note: Type the information for only one collaborator per row. For more collaborators, add more rows by clicking on the [Tab] key while the curser is in the last column.

***[PLEASE SUBMIT COLLABORATIVE AGREEMENTS IF APPLICABLE]***

## Conflict of Interests (if applicable)

Declare with full details any conflict of interests that any member of the study team or professional supervisory persons (see § 2.3, 2.4, 2.5, 2.6 and 2.7) might have and how it will be managed.

|  |
| --- |
| ***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. Clearly explain the type of conflict and how this will be managed or resolved.* |

|  |  |  |
| --- | --- | --- |
| **Name of researcher/ professional supervisory person** | **Detailed description of the conflict of interest** | **How it will be managed** |
| Click here to enter text. | Click here to enter text. |  |

Please note: Type one name per row, or type “Not applicable” if there is no member of the study team or professional supervisory persons with a conflict of interest. \*Add extra rows to the table if required.

## Sponsors (if applicable)

### Give full details of all the sponsors of the study

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Sponsor** | **Contact Details** | **Affiliation & Contribution** | **Nature & Extent** |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |

.

### Is any participant or member of the research team in the study directly or indirectly involved with one or more of the sponsors? Does any member of the study team receive any form of remuneration or other benefits from the sponsor(s), either directly or indirectly? *Give full details*

|  |  |  |
| --- | --- | --- |
| **Name of Researcher** | **Association with Sponsor** | **Details of Remuneration or Benefits** |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |

Please note: Type one name per row, or type “Not applicable” if there are no such participants. \*Add extra rows to the table, if required.

## Contractual Agreement(s) (if applicable)

Declare with full details all contractual agreement(s) (e.g. with team members, collaborators and sponsors) on the study. *Please note:* *A fully signed copy of any contractual agreement(s)* must be submitted to the NWU-HREC, together with the submission of this application.

NB**:**This agreement(s) should have gone through all the prescribed structures (e.g. legal office). \*Add extra rows to the table, if required.

|  |
| --- |
| ***More information***  *Sometimes there are contractual obligations with co-workers or organisations, that are outside the University. These contractual obligations may e.g. place restrictions on certain aspects regarding the availability of raw data i.t.o. intellectual right of ownership. Particularly, where foreign co-workers are involved, these contracts can get complex, therefore, you must please indicate here what these contractual obligations encompass, whether the University has approved and sanctioned it, and declare and describe any other potential legal and ethical implications thereof.* |

|  |  |  |
| --- | --- | --- |
| **Name of the involved contractor** | **Full description of the contractual agreement(s)** | **Contract included?** |
| Click here to enter text. | Click here to enter text. | Choose an item. |

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

***[******PLEASE SUBMIT ALL CONTRACTUAL AGREEMENTS]***

## Confidentiality and non-disclosure agreements

**Please note:** People other than the research team involved in the research that could pose a risk to confidentiality should sign confidentiality agreement(s) e.g. transcribers and co-coder/s. The people who need to sign these documents should be clearly indicated in your proposal.

***[******PLEASE SUBMIT AN EXAMPLE OF THE CONFIDENTIALITY AGREEMENT(S) (SEE CONFIDENTIALITY AGREEMENTS AS APPROVED BY THE LEGAL OFFICE OF THE NWU ON THE WEB PAGE)]***

## Indemnity

**Please note:** If people are involved in the research as part of the research team, *but are not 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 will thus have to sign an indemnity form.

***[PLEASE SUBMIT ALL INDEMNITY FORMS (SEE INDEMNITY FORMS AS APPROVED BY THE LEGAL OFFICE ON THE WEB PAGE)]***

## Research Data Gatekeepers Committee (RDGC)

Are you making use of students or staff of the NWU?

|  |
| --- |
| ***More information***  *When making use of any data/information of NWU students or staff or involving these two groups in collecting new data, permission must be obtained from the Research Data Gatekeeper Committee (RDGC),* ***after*** *your approval by the NWU-HREC. The NWU-HREC will provide you with* ***provisional approval****, in order to obtain permission. Providing the NWU-HREC with the approval letter from RDGC, will enable ethical approval by the NWU-HREC.* |

|  |  |  |
| --- | --- | --- |
| **NWU students** | Yes |  |
| No |  |
| **NWU staff** | Yes |  |
| No |  |
| **Not applicable** | |  |

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

# SECTION 3: RESEARCH PROPOSAL AND PRIOR SCIENTIFIC COMMITTEE APPROVAL

## Executive summary of the study

NB: The purpose of the executive summary is to present your study to the NWU-HREC for discussion during the NWU-HREC meeting. Provide an executive summary **(maximum 150 words)** of the study in the following format:

* brief problem statement (approx. 3 sentences)
* aims and objectives of the study
* study design and method (include description of sampling, data gathering and data analysis)

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

## Proposal

**Please note:** For each study a detailed proposal has to be submitted and is used as the main document for the review of your application. *The proposal should reflect the ethical aspects of the research throughout.* Attach the proposal approved by the Scientific/Proposal Committee of your research entity.

***[SUBMIT THE RESEARCH PROPOSAL]***

## Scientific/Proposal committee approval

This study should have been *first reviewed and approved by a Scientific/Proposal Committee prior* to your ethical approval applications. Please provide the relevant details below.

|  |
| --- |
| ***More information***  *The proposal first needs to be approved by a Scientific/Proposal Committee before it will be reviewed by the NWU-HREC. The NWU-HREC relies on the scientific expertise of this committee regarding the review of the scientific merit and design of the study.*  NB: Please do not include small group discussions. The details should only be that of the final Scientific/Proposal Committee approval. |

|  |  |  |
| --- | --- | --- |
| **Details** | | |
| **Name of the Scientific/Proposal Committee:** | | Click here to enter text. |
| **Titles, initials and surnames of all of the members of Scientific/Proposal Committee present during the review. NB: If the study supervisor/researcher is a member of this committee he/she should recuse him/herself.** | | Click here to enter text. |
| **Date of approval:** | | Click here to enter a date. |
| **Comments:** | Click here to enter text. | |
|

The NWU-HREC has to have proof of confirmation of the approval by the Scientific/Proposal Committee. A template is available on the web page for this purpose.

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

# SECTION 4: MORE COMPREHENSIVE AND DETAILED ETHICAL INFORMATION THAT COULD NOT BE PROVIDED IN THE PROPOSAL

*NB:* The information contained in this section is *more comprehensive and detailed,* as compared to what is contained in the proposal. *NB:* Sections 4.1 to 4.16 must be completed. Sections 4.17 to 4.19 are only completed if applicable to the research.

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

What will be expected of participants during data gathering e.g. a one-hour interview, venepuncture, needle prick, etc.?

|  |
| --- |
| ***More information***  *Highlight what participants will be* ***expected to do*** *during data gathering, what will be* ***done to them****, and* ***how long*** *it will take? This includes aspects such as procedures, sample collections and methods of information gathering as well as* ***what the probable associated experience*** *of the participants will be. Provide particular details that might violate privacy e.g. having to undress.* ***Please note:*** *This section supports you in the completion of the section in the informed consent form entitled, “What will your responsibilities be?”.* |

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

## Risk of harms and precautionary measures

In **column one**, name and describe *ALL the possible risks of harm* that the participants might experience, due to the research. Ensure that you identify and describe this in a systematic way for **each procedure**, as it enfolds in the research. Use the template at the back of the approved “risk level descriptor document” on the web page to guide you in identifying all the possible *types of risk* as well as the *probability* and *magnitude* of each possible harm. In **column two**, justify the fact that you have to expose your participants to the risk of harm. In **column three**, for each potential risk of harm, clearly describe the precautionary measures that you will apply to minimise or mitigate the possible identified risk of harm. Please note: By completing this section, it will help you in completing the following two sections i.e. “Are there risks involved in your taking part in research?” and “What will happen in the unlikely event of some form of harm occurring as a direct result of your taking part in this research study?”, in the informed consent form.

|  |  |  |
| --- | --- | --- |
| **Possible risk(s) of harm** (e.g. physical, psychological, social, legal, economic, dignitary and community). Identify and describe all the possible risks. | **Justification for the exposure to the identified risk(s) of harm** | **Precautionary measures to minimise or mitigate each possible identified risk of harm** |
| Click here to enter text. | Click or tap here to enter text. | Click here to enter text. |
| Click here to enter text. | Click or tap here to enter text. | Click here to enter text. |
| Click here to enter text. | Click or tap here to enter text. | Click here to enter text. |

\*Add extra rows to the table if required.

## Direct benefits for participants or indirect benefits for society at large or the scientific field

Describe 1) the potential *direct* benefits that the study might hold for the *individual participants*; or 2) the *indirect* benefits that the study might hold for the *society at large* or for *the research field*, through the knowledge gained. Please note:By completing this section, it will help you to complete the section entitled “Will you benefit from taking part in this research” in the informed consent form. \*Add extra rows to the table, if required.

|  |  |
| --- | --- |
| **Direct benefits** for participants (Only specify these benefits, if participants gain a tangible benefit(s) from participation in the study) | **Indirect benefits** for society at large or for the scientific field (Only specify the benefits for e.g. a community and/or for the scientific field) |
| Click here to enter text. | Click here to enter text. |

\*Add extra rows to the table if required.

## Risk/benefit ratio analysis

The overall benefits should, in general, *always outweigh the risks*, for a study to be considered safe. If this is not the case, there needs to be a *strong justification* for why participants should be exposed to the possible risk(s) of harm (see Section 5.2). Risks of harm and benefits to participants should be weighed to ensure they are equally distributed.

|  |  |
| --- | --- |
| **Benefit outweighs the risks** |  |
| **Risks outweigh the benefit** |  | Justify why participants should be exposed to the possible **risk**(s) of harm | Click here to enter text. |

## Privacy and Confidentiality

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

|  |
| --- |
| **Privacy**  Privacy is concerned when accessing *personal information and records* e.g. interviews, documents etc. of the participants, during data gathering, as well as *privacy during e.g. physical measurements* such as anthropometric measures, or *psychological procedures* e.g. interviews/focus groups etc. Explain how privacy will be ensured in your study. |
| Click here to enter text. |

|  |
| --- |
| **Confidentiality**  Confidentiality ensures that *appropriate measures* will be implemented, after data gathering, to *prevent disclosure of any information* that might identify the participant, either during the course of the research or afterwards e.g. anonymising data etc. Explain how confidentiality will be ensured in your study, as related to the data and/or samples collected. |
| Click here to enter text. |

## Criteria for participant selection and recruitment

In your proposal, you have described your inclusion and exclusion criteria for your study participants. NB: ensure that your exclusion criteria are not merely the opposite of the inclusion criteria. Mention your criteria in column one, in the table below, and justify *each criterion* in column two. If you include one of the following in your exclusion/inclusion criteria, the need for it in the research has to be justified i.e. *race or ethnic origin, person’s health or sex life, a person’s inherited characteristics or biometric information*.

|  |  |
| --- | --- |
| **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. |

## 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***  *The process of recruitment should take place in such a way that the principles of social justice, equity and fairness are applied, and that participants decide absolutely voluntarily to participate. Clearly describe aspects of community entry e.g. advertisements, community advisory boards and the use of gatekeepers and mediators etc.* |

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

## Informed consent (consent, permission, assent and dissent)

The focus in this section is on the detailed informed consent *process (*full description*)*. According to the guidelines, all participants must be fully informed about several aspects associated with participation in the study (see checklist for informed consent on the web page).

|  |
| --- |
| ***More information***  *The process should focus on how you will go about contacting participants and explaining the study and accompanying implications to them? 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 e.g. the informed consent documentation should be available in the participants’ mother tongue. Where participants are not literate, a witness should be involved in obtaining informed consent. Be clear on who will obtain the informed consent (independent person) and how the researcher will be included to explain the research, and answer questions. Discuss the role of the independent person. For your convenience you can use the template for informed consent on the webpage, as well as the accompanying checklist.* ***NB:*** *Be clear on your description of the use of informed consent, parental permission, child assent and dissent, or adolescent consent.*  ***Please note:*** *When including children in your study several informed consent forms might be required.* |

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

***[PLEASE SUBMIT YOUR INFORMED CONSENT FORM(S) FOR APPROVAL AND THE COMPLETED INFORMED CONSENT CHECKLIST (FOR EACH)]***

## Facilities

Describe the facilities and place(s) in detail where the study will be conducted. This description is applicable for both institutional and community facilities. Focus on a description of the facilities, the quality of the facilities’ privacy measures, as well as how emergencies will be handled.

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

## Legal authorisation

Describe in detail, *which bodies* must grant legal authorisation for this study (e.g. Department of Health, Department of Education, Department of Social Development, SAHPRA, etc.). Mention *whether authorisation has already been obtained*, with reference to attached proof, or *how you will go about* getting authorisation before the study commences. You will be provided with a *Gatekeeper Letter* indicating that all ethical aspects have been addressed in the study which can be used to obtain this authorisation, ***but the study cannot commence before the NWU-HREC has received the final documents and has provided you with a letter of approval***.

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

***[PLEASE SUBMIT ALL DOCUMENTS INDICATING LEGAL AUTHORISATION]***

## Goodwill permission

Describe in detail *what interest group representatives, managers etc.* must give goodwill permission for this study (e.g. community leaders, church leaders, tribal chiefs, managers etc.). Also mention *whether goodwill permission has already been obtained*, with reference to the attached proof (if applicable), or *how you will go about getting* permission before the study commences. This could be obtained while your study is “*in-process*” **but you first have to submit this to the NWU-HREC before you may commence with data gathering**.

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

***[PLEASE SUBMIT ALL LETTERS OF GOODWILL PERMISSION]***

## 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). If no remuneration is offered, *justify why this is not the case* (please mark with an X in the relevant block and provide details). Please note: Offering refreshments is not a form of remuneration and should be discussed during the data gathering process in the proposal.

|  |  |  |
| --- | --- | --- |
| **Yes** |  | **Description of incentive and/or remuneration** |
|  |  | Click here to enter text. |
| **No** |  | **Justification why no incentive and/or remuneration is needed** |
|  |  | Click or tap here to enter text. |

## Management, storage and destruction of data/biological samples

Describe how you will manage the collected data/biological samples, the storage thereof, as well as the destruction thereof.

|  |
| --- |
| **Data/biological samples management**  For management of data/biological samples, indicate:   * what data/biological samples will be stored * how it will be stored (e.g. data as hard copies as well as electronic versions) * how data/biological samples in its various forms will be managed e.g. questionnaires, recorded interviews or biological samples * who will have access to the stored data/biological samples * how will data/biological samples be distributed or regained from other research team members * if data sharing is to occur, how will this be managed (be clear whether the data will be shared on a national or international level) * how will data/biological samples be transferred e.g. transfer agreement and permit * How data/biological samples will be stored after concluding the study, etc.   Ensure that you refer to both the *electronic* and *hard copy versions* of data as well as *biological samples.* |
| Click here to enter text. |

|  |
| --- |
| **Storage of data/biological samples**  Describe:   * where and how data/biological samples will be stored * for how long it will be stored * and who will be responsible for the management of storage?   Ensure that you refer to both the *electronic* and *hard copy versions* of data as well as *biological samples* |
| Click here to enter text. |

|  |
| --- |
| **Destruction of data/biological samples**  Describe:   * how it will be destroyed?   Ensure that you refer to both *electronic* and *hard copy versions* of data as well as *biological samples* |
| Click here to enter text. |

## Monitoring of research

|  |
| --- |
| Describe how you as the researcher will monitor the implementation and the progress of the study:   * compliance with the approved proposal * the management of science and ethics throughout the research process * the management of amendments during the execution of the research study, should they be needed * how *incidents* and *adverse events/serious adverse events* (if applicable) will be reported * the appointment of a monitoring committee if required * and submission of monitoring reports as required by the NWU-HREC. |
| Click here to enter text. |

## Dissemination of the findings of the study to participants

Indicate in a very practical manner, *what, how, and when* you will communicate the results of the study to the participants. Indicate to *who else* and *how* you will disseminate the findings of your study.

|  |
| --- |
| **Dissemination of findings to participants:** |
| Click or tap here to enter text. |
| **Dissemination of findings to others than the participants:** |
| Click or tap here to enter text. |

## Misleading of participants (if applicable)

|  |
| --- |
| ***More information***  *In the case of misleading participants (e.g. during drug or psychotherapeutic intervention), justification has to be provided that there is no way. When such an alternative exists, the* ***standard of care*** *should be provided to both the experimental and control group. Standard of care refers to the minimum care that should be provided to participants during research that should be equal to care available in e.g. the health services.* |

Is use made of any form of misleading or deception during the research study, where the participants are not told the complete truth (e.g. placebo or psychotherapeutic interventions)?

If “*Yes*”, in either case i.e. for using a placebo or during a psychotherapeutic intervention:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **N/A** |  |  |  | |
| **No** |  |  |  | |
| **Yes** |  |  | **Justification and fill in why it is necessary** | **Precautionary measures against potential negative consequences** |
|  | Click here to enter text. | Click here to enter text. |
|  | **Disclosure** | |
|  | **When will you disclose and debrief participants?** | **How will you disclose and debrief participants?** |
|  | Click here to enter text. | Click here to enter text. |
|  | **Describe any correctional practices you might implement:** | |
|  | Click or tap here to enter text. | |

## Use of previously collected data/biological samples (if applicable)

When your research study is making use of previously collected data or biological samples, provide a comprehensive description of the following:

|  |  |  |
| --- | --- | --- |
| **N/A** | |  |
| **Did the study that originally collected the data/biological samples have ethical approval?** | | | | | | | | Choose an item. |
| **What was the purpose of the original collection?** | | | | | | | | |
| Click here to enter text. | | | | | | | | |
| **What was the nature of the predicted future research?** | | | | | | | | |
| Click or tap here to enter text. | | | | | | | | |
| **Did the original study have permission for further research?** | | | | | | | | Choose an item. |
| **What will the purpose of your study be?** | | | | | | | | |
| Click here to enter text. | | | | | | | | |
| **Give a description of how the integrity of your data/biological samples was ensured in the original study by referring to specific processes followed during data gathering:**   * ***how informed consent was obtained from participants*** * ***what they consented for*** * ***the circumstances under which the data/biological samples were gathered*** * ***and how the ethics of data/biological sample collection were ensured?*** | | | | | | | | |
| Click here to enter text. | | | | | | | | |
| **Give a detailed description of how data/biological sample integrity was ensured during storage:**   * ***how data/biological sample storage was managed*** * ***where and how data/biological samples were stored*** * ***for how long it was stored*** * ***for how long it may be stored*** * ***who was responsible for managing the storage?*** * ***and how it was ensured that no tampering occurred?*** | | | | | | | | |
| Click here to enter text. | | | | | | | | |
| **Please indicate any potential foreseeable risks of harm for the participants or researchers that were involved in the previous study, that may occur, now that you are using the previously collected data/biological samples, as well as the precautionary measures to be taken for the present study?** | | | | | | | | |
| **Potential risks of harm:** | | | | | | | **Precautionary measures:** | |
| **Participants:**  Click here to enter text.  **Researchers:**  Click or tap here to enter text. | | | | | | | **Participants:**  Click or tap here to enter text.  **Researchers:**  Click or tap here to enter text. | |
| **Will re-consent be necessary?**  **If “Yes” motivate:**   * ***why;*** * ***for what;*** * ***how this re-consent will be obtained*** | | | | | | | | |
| **No** |  | | |  |  |  | | |
| **Yes** |  | | |  | **Why?** | Click here to enter text. | | |
|  | **For what?** | Click here to enter text. | | |
|  | **How?** | Click here to enter text. | | |

**[SUBMIT A LETTER FROM THE PI OF THE ORIGINAL STUDY GIVING PERMISSION FOR THE USE OF THE DATA/BIOLOGICAL SAMPLES AND CLEARLY STIPULATING WHAT YOU ARE ALLOWED TO DO]**

**[SUBMIT THE ETHICAL APPROVAL OF THE ORIGINAL STUDY]**

**[SUBMIT THE INFORMED CONSENT DOCUMENTATION OF THE ORIGINAL STUDY]**

**[SUBMIT THE INFORMED CONSENT DOCUMENTATION FOR RE-CONSENT (IF APPLICABLE)]**

## Use of filed privileged documentation and/or information (if applicable)

Filed privileged information may be used for research purposes, with the research ethics committee becoming the “voice” of the participant and protecting their interests and then *waiving informed consent*. Give a detailed description of the process of access and use, under the following headings.

|  |  |
| --- | --- |
| **N/A** |  |
| **The nature of the documentation and/or information to be used:** | | | |
| Click here to enter text. | | | |
| **Process of obtaining permission to access documentation and/or information:** | | | |
| Click here to enter text. | | | |
| **Process of data collection:** | | | |
| Click here to enter text. | | | |
| **Process of anonymization of the data:** | | | |
| Click here to enter text. | | | |
| **Foreseeable potential risks of harm for participants whose filed privileged documentation and/or information is being accessed, as well as the precautionary measures to be taken:** | | | |
| **Potential risks of harm** | | | **Precautionary measures** |
| Click here to enter text. | | | Click here to enter text. |

## Justifiability of statistical procedures (for quantitative studies)

|  |  |
| --- | --- |
| N/A |  |

### Statistical consultation

Indicate how you ensured the suitability of the statistical procedures to be used in this study  
e.g. statistical consultation or proof of own expertise.

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

### Determining the sample size

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

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

### Actual number of participants

Indicate the actual number of participants that is going to be used

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

### Statistical methodology

Describe what type of 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 here to enter text. |

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

# SECTION 5: MATTERS THAT NECESSITATE ADDITIONAL INFORMATION

NB: This section is **only completed** if you marked an item in **1.14**

## Sec 5a: Vulnerable participants

Please complete this section if your study includes *minors, adults with incapacities, persons in dependent relationships e.g. prisoners, students, persons with physical disabilities, collectivities and/or research-naïve communities, or other possible vulnerability*(Mark ALL options as “Yes” in the appropriate box – more than one option may be “Yes”). Should you mark more than one option ensure that you mention and describe all the relevant groups under point 6.1.1 to 6.1.3.

|  |  |  |
| --- | --- | --- |
| **Description** | | **Yes** |
| Minors | |  |
| Adults with incapacities | |  |
| Persons in dependent relationships e.g. prisoners | |  |
| Students | |  |
| Persons with physical disabilities | |  |
| Collectivities | |  |
| Research-naïve communities | |  |
| Other | |  |
| ***If Other, please specify:*** | Click here to enter text. | |

### Description

Give a detailed description of the vulnerable group, by referring to:

* **Who they are?**

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

* **Where they come from?**

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

* **What makes them vulnerable (this should include aspects such as limited economic development, inadequate human rights protection, discrimination based on health status, Inadequate understanding of scientific research, limited health care and treatment, limited ability to provide individual informed consent)?**

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

### Justification for inclusion

Explain the necessity for including this specific group(s) of vulnerable people as human  
participants and why you are not including a less vulnerable participant group(s).

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

### Additional precautionary measures to reduce the risk of harm

You have discussed the potential risks of harm to participants under 4.2. Explain any additional precautionary measures that you will take to reduce the possibility of risk of harm due to their specific vulnerability.

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

## Sec 5b: Measuring instruments and questionnaires that need psychometric interpretation by a psychologist

Please complete this section **ONLY** if any measuring instruments or validated questionnaires are used in this study that *needs psychometric interpretation by a psychologist*. NB: Do not complete this section for any other types of questionnaires.

### Name

Which psychometric measuring instrument(s) and validated questionnaire(s) will be used in the study? *Please mention all*

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

\*Add extra rows to the table if required (Click on the “+” sign on the right bottom corner of the table)

### Information about the measuring instrument/questionnaire

Provide detailed information on the psychometric measuring instrument(s)/questionnaire(s), so that the reviewers can review the ethically justifiable use thereof. NB: If more than one psychometric measuring instrument(s)/questionnaire(s) is used, select and copy the whole table and paste as many tables underneath as is necessary for each instrument/questionnaire.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Psychometric measuring instrument/questionnaire** | | | | | |
| **Approved Name** | | | | **Normal Application** | |
| Click here to enter text. | | | | Click here to enter text. | |
| **Reliability** | | | | | **Validity** |
| Click here to enter text. | | | | | Click here to enter text. |
| **Other Relevant Information** | | | | | |
| Click here to enter text. | | | | | |
| **Permission required for use** | **No** |  |  | | |
| **Yes** |  | **Describe how this will be obtained and include proof:** | | |
|  | | | Click or tap here to enter text. | | |

***To add additional tables, copy the whole table above (select, then press Ctrl + C), click here, press enter and then paste (Ctrl + V).***

### Validation for target group

Is the measuring instrument(s)/questionnaire(s) validated for the target group (e.g. for South  
African circumstances)? Provide full details. Please mark with X in the appropriate box and provide details.

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | **No** |  | **Details** |
|  |  |  | Click here to enter text. |

## Sec 5c: Infection, genetic modification and commercialisation of cell and tissue cultures

### What will you be doing with the cell or tissue culture?

|  |  |
| --- | --- |
| Infection of the cell or tissue culture |  |
| Genetic modification of the cell or tissue culture |  |
| Commercialisation of the cell or tissue culture |  |

### Cell culture type and number

Which and how many cell and/or tissue lines will be used in the study?

|  |  |  |
| --- | --- | --- |
|  | **Description of cell culture and tissue culture types** | **Number** |
| **Cell culture** | Click or tap here to enter text. | 0 |
| **Tissue culture** | Click or tap here to enter text. | 0 |

**[OPEN UP THE APPROPRIATE AMOUNT OF SPACES IN SECTION 7.3.3 ACCORDING TO 7.3.2]**

### Product information

Provide detailed product information, so that the reviewers can evaluate the ethically  
justifiable use of the cell and tissue culture. Give the necessary details below.

|  |
| --- |
| ***More information***  ***Human origin and consent:*** *For standard cell and/or tissue cultures from banks such as the ATCC, informed consent already exists for general, ethically justifiable and medically related research.*  ***Potential dangers and risks:*** *Tissue banks such as the ATCC classify cell and/or tissue cultures as “bio safety level 1, 2 or 3”, depending on potential for infection with pathogens which may be harmful to man, or cancerous characteristics that would make growth in a person possible after undesirable, accidental inoculation. NB: These cell cultures may never be used in people.* |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Cell culture or Tissue culture** | | | | |
| **Approved Name & Code** | **Description** | | | |
| Click here to enter text. | Click here to enter text. | | | |
| **Source / Origin / Supplier** | **Catalogue No.** | | **Biosafety level?** | |
| Click here to enter text. | Click here to enter text. | | **Level 1** |  |
|  | | | **Level 2** |  |
| **Level 3** |  |
| **Method of Storage and Maintenance** | | | | |
| Click here to enter text. | | | | |
| **Intended research activity:** | | | | |
| Click here to enter text. | | | | |
| **Potential Dangers** | | **Precautionary measures** | | |
| Click here to enter text. | | Click here to enter text. | | |
| **Other Relevant Information** | | | | |
| Click here to enter text. | | | | |

***To add additional tables, copy the whole table above (select, then press Ctrl + C), click here, press enter and then paste (Ctrl + V).***

### Planned Research activity

#### Infection of the cell or tissue culture (if applicable)

* **Infectious agent to be used (if applicable)?**

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

* **Precautionary measures**

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

#### Genetic modification (if applicable)

* **Intended activities**

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

* **Precautionary measures**

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

#### Informed consent for commercialisation

* **Has the participant given informed consent for commercialisation of their cell culture?**

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | **No** |  | ***If “Yes”, ATTACH a copy of the completed informed consent form*** |
|  |  |  | **If “No”, justify why not:** |
|  |  |  | Click here to enter text. |

* **Benefit sharing agreement**

Has a benefit sharing agreement been undertaken with the participant if commercialisation of their cell culture is being undertaken?

*If “Yes” attach the agreement. If “No” justify why this is the case.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | **No** |  | ***If “Yes” ATTACH a copy of the completed benefit sharing document*** |
|  |  |  | **If “No”, justify why not:** |
|  |  |  | Click here to enter text. |

#### Expertise and facilities to work with cell lines

Do you have the necessary expertise to work with the cell culture and/or tissue cultures?  
Provide full details. Mark “Yes” or “No” with X in the appropriate box. Provide additional details as requested.

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** |  | **Details of expertise** | |
|  |  | **Principal investigator/researcher** | **Students/fieldworkers** |
|  | Click here to enter text. | Click here to enter text. |
| **No** |  | **How do you plan to get the expertise required if not available?** | |
|  |  | **Principal investigator/researcher** | **Students/fieldworkers** |
|  | Click here to enter text. | Click here to enter text. |

### Facilities

Describe the facilities that are in place to work with the cell and/or tissue culture.

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

### Biosafety

#### Protective measures

Explain the measures you have in place to protect the safety of researchers/workers/the  
environment against the potential detrimental effects of the infection, genetic modification or commercialisation of the cell and/or tissue culture and waste. \*Add rows as required.

|  |  |
| --- | --- |
| **Group** | **Protective measures to be undertaken** |
| Researchers | Click here to enter text. |
| Workers | Click here to enter text. |
| Environment | Click here to enter text. |

\*Add rows as required

#### Safety measures and methods

Specify safety measures and methods for the disposal of cell and/or tissue cultures.   
\*Add rows as required.

|  |
| --- |
| **Safety measures and methods** |
| Click here to enter text. |

\*Add rows as required

#### Standard operating procedures (SOPs)

If available, attach the standard operating procedures (SOPs) of these processes.

|  |  |
| --- | --- |
| **SOP #** | **SOP Description** |
| Click here to enter text. | Click here to enter text. |

## Sec 5d: Use of Drugs/Medicines

Please complete this section if any drugs or medicines are used or administered in this study.

### Number

How many types of drugs / medicines will be used in the study?If more than one dosage form or brand name of the same drug (active ingredient) is used, it must be counted and mentioned separately. Where applicable, placebos must also be mentioned and calculated.

|  |  |
| --- | --- |
| **Description of drugs/medication** | **Dosage** |
| Click here to enter text. | Click here to enter text. |

\*Add rows as required

**[OPEN UP THE APPROPRIATE AMOUNT OF SPACES IN SECTION 5.4.2 ACCORDING TO 5.4.1]**

### Product information

Provide detailed product information as requested

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Drug 1** | | | | |
| **Approved Pharmacological (Generic) Name** | | | | **Brand Name(s) (if applicable)** |
| Click here to enter text. | | | | Click here to enter text. |
| **Registered at  SAHPRA?[[1]](#footnote-1)** | | **If “Yes”, SAHPRA Registration Number[[2]](#footnote-2)** | **If registered with SAHPRA, is this for the indications, dosages and administrations as used in this study? Provide details where necessary.** | |
| **Yes** | **No** | Click here to enter text. | Click here to enter text. | |
|  |  |
| **Accepted Dosage(s)** | | | | **Accepted Administration Route(s)** |
| Click here to enter text. | | | | Click here to enter text. |
| **Pharmacological Action,  Therapeutic Effects & Indications** | | | | **Side-effects, Precautions  & Contra-indications** |
| Click here to enter text. | | | | Click here to enter text. |
| **Other Relevant Information** | | | | |
| Click here to enter text. | | | | |
| **Proof of preclinical approval of the product** | | | | |
| Click here to enter text. | | | | |

***To add additional tables, copy the whole table above (select, then press Ctrl + C), click here, press enter and then paste (Ctrl + V).***

### Special authorisation for use in humans

If any of the medication is not registered with SAHPRA or, if it is registered but the study deals with indications for which it is not specifically registered, or if other doses, dosages, dosage forms or administration routes are used than what is registered, *special approval* must be obtained for the clinical test from SAHPRA. Has such special authorisation been obtained?

Please mark with X in the appropriate box and complete further as applicable.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Yes** | **No** |  | **Authorisation Number** |  | **Date of Authorisation** |
|  |  |  | Click here to enter text. |  | Click here to enter a date. |

If “Yes” please upload a copy of the approval letter. If “No” please explain the manner in which you plan to go about obtaining approval before the study begins. NB: Final approval of the application by the NWU-HREC is dependent on the approval of the study by SAHPRA. No study may continue before written approval is obtained.

|  |
| --- |
| If “No” type explanation here, or type “Not Applicable”. |

**[PLEASE SUBMIT THE APPROVAL LETTER FROM SAHPRA]**

### Explain the measures that will be in place to protect the workers, participants and the environment against the potential side-effects of the medicinal substances and waste (disposal)

|  |  |
| --- | --- |
| **Groups** | **Description of protective measures** |
| Workers | Click here to enter text. |
| Participants | Click here to enter text. |
| Environment | Click here to enter text. |

## Sec 5e: Use of drug delivery systems

Please complete this section if any drug delivery systems are used or administered in this study.

### Number

How many types of drug delivery systems will be used in the study?If more than one dosage form of a drug delivery system is used, it must be counted and mentioned separately.

|  |  |
| --- | --- |
| **Description of drug delivery system** | **Dosage** |
| Click here to enter text. | Click here to enter text. |

**[OPEN UP THE APPROPRIATE AMOUNT OF SPACES IN SECTION 7.5.2 ACCORDING TO 7.5.1]**

### Drug delivery system information

Provide detailed drug delivery system information as requested?If more than one drug delivery system is used, it must be counted and mentioned separately.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Drug delivery system 1** | | | | | | |
| **Approved Name** | | | | |
| Click here to enter text. | | | | |
| **Registered at SAHPRA?** | | **If “Yes”, SAHPRA Registration Number** | | **If registered at SAHPRA, is this for the indications, dosages and administrations as used in this study? Provide details where necessary.** | | |
| Yes |  | Click here to enter text. | | Click here to enter text. | | |
| No |  |
| **Accepted Dosage(s)** | | | | | **Proof of Accepted Administration Route(s)** | |
| Click here to enter text. | | | | | Click here to enter text. | |
| **Side-effects** | | | **Contra-indications** | | | **Precautions** |
| Click here to enter text. | | | Click here to enter text. | | | Click here to enter text. |
| **Other Relevant Information** | | | | | | |
| Click here to enter text. | | | | | | |

***To add additional tables, copy the whole table above (select, then press Ctrl + C), click here, press enter and then paste (Ctrl + V).***

### Special authorisation for use in humans

If any of the drug delivery systems are not registered with SAHPRA or, if it is registered but the study deals with indications for which it is not specifically registered, or if other doses, dosages, dosage forms or administration routes are used than what is registered, special approval must be obtained for the clinical test from SAHPRA. Has such special authorisation been obtained?

Please mark with X in the appropriate box and complete further as applicable.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Yes** | **No** |  | **Authorisation Number** |  | **Date of Authorisation** |
|  |  |  | Type no. here, or type “Not Applicable”. |  | Click here to enter a date. |

If “Yes” please upload a copy of the approval letter**.**

If “No” please explain the manner in which you plan to go about obtaining approval before the study begins. NB: Final approval of the application by the NWU-HREC is dependent on the approval of the study by SAHPRA. No study may continue before written approval is obtained.

|  |
| --- |
| If “No” type explanation here, or type “Not Applicable”. |

**[PLEASE SUBMIT THE APPROVAL LETTER FROM SAHPRA]**

### Explain the measures that will be in place to protect the workers, participants and the environment against the potential side-effects of the drug delivery system and waste (disposal).

|  |  |
| --- | --- |
| **Groups** | **Description of protective measures** |
| Workers | Click here to enter text. |
| Participants | Click here to enter text. |
| Environment | Click here to enter text. |

## Sec 5f: Use of food, fluids or nutrients

Please complete this section if any food, fluids or nutrients (alone or in combination) are used or administered in this study. This also applies to dangers with abuse, whether or not it holds any potential danger for people, animals or the environment. Please note: This does not include the provision of a regular plate of food for maintenance during residence.

### Number

How many kinds of food, fluids or nutrients will be used in the study?

|  |
| --- |
| ***More information***  *If more than one dosage form or brand name of the food, fluids or nutrient is used, it must be counted and mentioned separately. Placebos are also included, except if the placebo treatment includes no administration.* |

|  |  |
| --- | --- |
| **Description** | **Number** |
| Food | 0 |
| Fluids | 0 |
| Nutrients / nutrient combinations | 0 |

**[OPEN UP THE APPROPRIATE AMOUNT OF SPACES IN SECTION 7.6.25.6.2 ACCORDING TO 7.6.1]**

### Product information

Provide detailed product information, so that the reviewers can evaluate the ethically justifiable use of the food, fluids and nutrients.

|  |  |  |  |
| --- | --- | --- | --- |
| **Food, Fluid or Nutrient** | | | |
| **Approved Name** | | **Normal Quantities and Uses** | |
| Click here to enter text. | | Click here to enter text. | |
| **Potential Dangers with Abuse** | **Contra-indications** | | **Precautions** |
| Click here to enter text. | Click here to enter text. | | Click here to enter text. |
| **Other Relevant Information & Literature References** | | | |
| Click here to enter text. | | | |

***To add additional tables, copy the whole table above (select, then press Ctrl + C), click here, press enter and then paste (Ctrl + V).***

### Explain the measures that will be in place to protect the workers, participants and the environment against the potential detrimental effects of the food, fluids or nutrients and waste

|  |  |
| --- | --- |
| **Groups** | **Description of protective measures** |
| Workers | Click here to enter text. |
| Participants | Click here to enter text. |
| Environment | Click here to enter text. |

## Sec 5g: Use of Radio-Active Substances

### Description

Where any radio-active substances are used in experiments or administered to participants, give full details thereof, including the isotopes and possible risks it may hold for the participants/researchers/workers/environment.

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

### Competence and licensing

Do you have the necessary competence and licensing from the Department of Health at your disposal to work with radio-active substances? Mark “Yes” or “No” with X in the appropriate box. Provide the authorisation number if “Yes”.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Yes** |  | **Details** | | |
|  |  | **Principle investigator/researcher/study supervisor** | | **Students/fieldworkers** |
|  | Click here to enter text. | | Click here to enter text. |
|  | **Authorisation number** | Click here to enter text. | |
| **No** |  | **How do you plan to get the expertise required?** | | |
|  |  | **Principle investigator/researcher/study supervisor** | | **Students/fieldworkers** |
|  | Click here to enter text. | | Click here to enter text. |

**[PLEASE SUBMIT THE APPROVAL LETTER FROM THE RADIATION CONTROL OFFICER]**

### Facilities

Describe the facilities and procedures to ensure safe use and disposal of the radio-active substances?

|  |
| --- |
| Type here |

### Protective measures

Explain the measures you have in place to protect the safety of researchers/workers/participants/ environment against the potential detrimental effects of the radio-active substances and waste.

|  |  |
| --- | --- |
| **Groups** | **Description of protective measures** |
| **Researchers** | Click here to enter text. |
| **Workers** | Click here to enter text. |
| **Participants** | Click here to enter text. |
| **Environment** | Click here to enter text. |

### Disposal

If applicable, also specify safety measures and methods for the disposal of radio-active contaminated body fluids and tissue.

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

## Sec 5h: Use of Toxic Substances or Dangerous Substances

Please complete this section if any toxic or dangerous substances are used or administered in this study. This also applies to dangers with abuse, whether or not it holds any potential danger for people, animals or the environment.

### Type and number

How many toxic substances/dangerous substances will be used in the study?

|  |  |
| --- | --- |
| **Description** | **Number** |
| Toxic substances | 0 |
| Other dangerous substances | 0 |

### Product information

Provide detailed product information, so that the reviewers can evaluate the ethically justifiable use of the toxic and dangerous substances. NB: If more than one such substance is used, select and copy the whole table and paste as many tables underneath as is necessary.

|  |  |  |  |
| --- | --- | --- | --- |
| **Substance 1** | | | |
| **Approved Name** | | **Normal Uses & Dosages** | |
| Type here | | Type here | |
| **Action & Toxic Effects/Dangers** | **Contra-indications** | | **Precautions** |
| Type here | Type here | | Type here |
| **Other Relevant Information** | | | |
| Type here | | | |

***To add additional tables, copy the whole table above (select, then press Ctrl + C), click here, press enter and then paste (Ctrl + V).***

### Explain the measures that will be in place to protect the workers, participants and the environment against the potential detrimental effects of the toxic or dangerous substances and waste

|  |  |  |
| --- | --- | --- |
| **Groups** | **Possible detrimental effects** | **Precautionary measures** |
| **Workers** | Click or tap here to enter text. | Click or tap here to enter text. |
| **Participants** | Click or tap here to enter text. | Click or tap here to enter text. |
| **Environment** | Click or tap here to enter text. | Click or tap here to enter text. |

## Sec 5i: Possible impact on the environment

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.

|  |
| --- |
| Type here |

### Name and explain *all the possible risks* of harm for the environment that may occur during the research. Use the template included in the approved *risk level descriptor document for studies with environmental impact* to guide you into identifying all the possible types of risks of harm as well as the *probability* and *magnitude* of harm. Please also include *all the precautionary measures* that will be taken in order to mitigate the risks to the environment.

|  |  |
| --- | --- |
| **Risks of harm** (e.g. effect on environment, legal implications, potential impact on the reputation of the NWU, etc.). | **Precautionary measures** (When describing these precautionary measures be clear on how they will mitigate all the identified risks) |
| Type here | Type here |

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

# SECTION 6: OTHER ETHICS EVALUATIONS AND RISK INSURANCE

## Sec 6a: Evaluation by other Research Ethics Committees

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

|  |  |  |
| --- | --- | --- |
| **Not Applicable** |  | |
| **Name of the Research Ethics Committee** | **Approval Status:** | | | | **Approval Number:** | **Contact Number or E-mail address of the research ethics committee** |
|  | **In Process** | | |  |  |  |
|  | **Approved** | | |  |  |  |
| Type details here |  | **If Approved:**  Date:  Type details here | | | Type details here | Type details here |
| Type details here |  |  | | | Type details here | Type details here |

## Sec 6b: Risk Insurance

The North-West University has insurance at its disposal to cover the risk of claims against the University in case of damage to participants due to professional negligence – the maximum cover is currently R100 million per annum (all studies included). However, this is only available if studies were approved by a research ethics committee and researchers have kept to the approved proposal by the research ethics committee.

### Briefly describe the potential risks to which the participants/researchers/assistants/ field workers or other individuals are going to be subject to in so far as complications may lead to summonses. NB: Use section 4.2 to guide you.

|  |  |
| --- | --- |
| **Group** | **Potential risks of harm** |
| Participants | Click here to enter text. |
| Researchers | Click here to enter text. |
| Assistants and/or field workers | Click here to enter text. |
| Others | Click here to enter text. |

### These potential risks of harm are covered by:

|  |  |
| --- | --- |
| North-West University |  |
| Sponsor/s |  |
| **Other: Specify**: Click here to enter text. |  |

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

Please mark with X in the appropriate box.

|  |  |  |
| --- | --- | --- |
| **Yes** | **No** | **If “No”, indicate what will be done to ensure that there is sufficient coverage?** |
|  |  | Click here to enter text. |

### Additional Insurance

In the case of trial research additional insurance should be available to participants to cover any possible bodily harm they might suffer.

Please mark with a “X” in the appropriate box

|  |  |  |
| --- | --- | --- |
| **No** |  | **Motivate why not:**  Click or tap here to enter text. |
| **Yes** |  | **Description:**  Click or tap here to enter text. |
| **Any additional comments:**  Click or tap here to enter text. |

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

# SECTION 7: DECLARATIONS

Applications and declaration are filled in and signed by:

Sec 7a: Study supervisor/Researcher ***if*** ***not a study conducted by a student***

Sec 7b: Statistical Consultant

Sec 7c: Bio-safety Officer

Sec 7d: Research Director

The pages with declarations and signatures must be **scanned** with this form.

**[SCAN AND SUBMIT ALL SIGNED DECLARATIONS IF NOT SIGNED ELECTRONICALLY]**

**NWU Health Research Ethics Application**

|  |  |
| --- | --- |
| **Study supervisor/Researcher** (if not a study conducted by a student) (Title, Initials and Surname) | **Study Title** (see § 1.1) |
| Click here to enter text. | Click here to enter text. |

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



## Sec 7a: Study supervisor/Researcher (if not a study conducted by a student)

Application and Declarations by Study Supervisor/Researcher

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

### The information in this application is, to the best of my knowledge, correct and that no ethical codes will be violated with the study;

### I will make sure that the study is managed ethically justifiably from start to finish;

### In the case of human participants;

#### I will put it clearly to all participants that participation (including assent) in any research study is absolutely voluntary and that no pressure, of whatever nature, will be placed on any potential participant to take part;

#### I will put it clearly to all participants that any participant may withdraw from the study at any time and may ask that his/her data no longer be used in the study, without stating reasons and without fear of any form of prejudice;

#### every participant who takes part in the study will receive the accompanying form for informed consent and it will be ensured that every participant understands the information (including the process and risks) fully;

#### every participant will sign the informed consent in writing before the study commences, or a witness will stand in on behalf of the participant when the participant is illiterate;

#### the written permission of the parent or legal guardians and childe ascent of all minor subjects will be obtained before the research commences;

#### any foreseeable risk is restricted to the minimum, any permanent damage is avoided as far as possible and that appropriate precautions and safety measures are in place;

#### confidentiality of all the information of all participants will be respected and ensured;

### I and all co-workers/assistants/field workers are appropriately qualified, capable and legally competent to implement the proposed studies/procedures/interventions;

### 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;

### the study is scientifically justifiable;

### where necessary, all contracts, permits and the applicable documents of relevance will be obtained before the research commences;

### I will ensure that all data/biological samples are stored safely and remain in the possession of the North-West University;

### I will report in writing any incidents or adverse events/serious adverse events that occur during the study without delay to the Health Research Ethics Committee;

### I undertake to respect intellectual property rights throughout and to avoid any form of plagiarism;

### I will obtain permission for amendments to the protocol and report annually (or more often for medium and high risk studies) to the Health Research Ethics Committee on the prescribed monitoring report concerning progress of the study;

### I will notify the Health Research Ethics Committee should the study be terminated.

|  |  |
| --- | --- |
| **Study supervisor’s/Researcher’s Name (Title, Full Names & Surname)** | **Qualifications** |
| Click here to enter text. | Click here to enter text. |
|  | |
|  |  |
| Click here to enter a date. |
| **Signature** | **Date** |

## Sec 7b: Statistical Consultant (If applicable)

The statistician of the Statistical Consultation Service of the North-West University or an appropriately qualified statistician should complete this section (where applicable).

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

Please mark with X in the appropriate box and provide details

|  |  |  |  |
| --- | --- | --- | --- |
| **Yes** | **No** |  | **Remarks** |
|  |  |  | Click here to enter text. |

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

## Sec 7c: Bio-Safety Officer (If applicable)

The bio-safety officer of the North-West University should complete this section where bio-safety issues are part of the research.

### Have you ascertained that all bio-safety measures are in place to ensure the safety of participants/researchers/technicians?

Please mark with X in the appropriate box and provide details.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Yes** | **No** |  | **Remarks** | |
|  |  |  | Click here to enter text. | |
|  | | | | | |
|  | | | |  |
| Click here to enter a date. |
| Signature | | | | Date |

## Sec 7d: Research Director (School director if Education request)

I, the undersigned, hereby declare that the above study has been reviewed by a Scientific/Proposal Committee and may proceed to the Health Research Ethics Committee and that the Study Supervisor/Researcher has the appropriate Ethics and enough physical facilities, equipment and money at his/her disposal to implement and complete the study.

### Research Director

The director of the research entity signs here.

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

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

Credits:

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

Current details: (23239522) G:\My Drive\9. Research and Postgraduate Education\9.1.5.1.1\_NWU-HREC\_EAF\_Dec2019docx.docx  
2 December 2019

1. SAHPRA = South African Health Products Regulatory Authority [↑](#footnote-ref-1)
2. The SAHPRA registration number can be found on medicine product leaflets. [↑](#footnote-ref-2)