Basic and Social Science Research

Ethics Committee
(BaSSREC)

Standard Operating Procedures
(SOPs)

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Revised by: Prof Erhabor Idemudia

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1 COMPILATION AND AUTHORISATION

Action	Designated person	Signature	Date
Compiled by:	Prof. C. van Eeden		2017
Revised by:	Prof. E. Idemudia		2023
Checked by:	Dr.J. Morelli		2023
Authorised by:	Prof. M. Nel		2023

2 DISTRIBUTION FOR FURTHER APPROVAL

Department/Unit	Name	Signature	Date
BaSSREC	Prof. E. Idemudia		2023
Faculty of Humanities: Faculty Board	Prof Mirna Nel		02 May 2023
Committee for Research, Innovation and Higher Degrees	Prof. M. Nel		2023

3 DOCUMENT HISTORY

Date	Version No	Reason for revision
2017	1	Original BaSSREC SOP compiled by Prof. Chrizanne van Eeden.
28 October 2021	2	Revision of 2017 by Prof Jacques Rothmann.
2 November 2021	3	Critical reader: Prof Albi Odendaal.
24 November 2021	4	Ratification by BaSSREC Committee.
02 May 2023	5	Final approval by Faculty of Humanities.

Faculty of Humanities

STANDARD OPERATING PROCEDURE: BaSSREC

Basic and Social Sciences Research Ethics Committee (BaSSREC), Faculty of Humanities, North-West University

Accountable manager	Chairperson: BaSSREC
SOP owner	Administrator: BaSSREC
Responsible faculty	Faculty of Humanities
Status	Draft 5
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ABBREVIATIONS

- BaSSREC – Basic and Social Sciences Research Ethics Committee
- NWU SCRE – North-West University Senate Committee for Research Ethics
- REC – Research Ethics Committee
- SOP – Standard Operating Procedure
- HSSREC – Human and Social Sciences Research Ethics Committee
- HREC – Health Research Ethics Committee
- FoH – Faculty of Humanities.

1. STANDARD OPERATING PROCEDURES (SOP) of BaSSREC

PURPOSE OF THIS SOP

1.1. This SOP supports processes for speedy approval of all ethics applications by BaSSREC.

1.2. This SOP promotes understanding of the responsibilities of the BaSSREC chair, co-chair, 15 committee members (17 academics, potential community members), potential ad-hoc member(s), administrator(s), and applicants.

1.3. This SOP will explain the requirements for all ethics applications.

1.4. The purpose is to establish a clear line of responsibility for submitting, evaluating and approving ethics applications.

1.5. This SOP will be approved by BaSSREC and reviewed every 1-2 years, where necessary amendments will be made.

1.6. In the case of administrative support not being available, the BaSSREC chairperson or another appointed BaSSREC member will fulfil all activities ascribed to the administrator in the following documents.

2. TERMS OF REFERENCE (ToR):

Purpose

2.1. These terms of reference provide guidelines and a minimum standard of procedure for the BaSSREC operational management of the ethics process within the Faculty of Humanities. It ensures that the BaSSREC observes its core objectives, i.e. to protect the dignity, rights, safety and wellbeing of all researchers and human participants in social, political, cultural and environmental research done by staff and registered students of the NWU in the FoH.

2.2. The BaSSREC is an independent committee of the Faculty of Humanities, North-West University, functioning in collaboration with the HSSREC and SCRE.

Scope

2.3. BaSSREC will review, for ethics approval purposes, studies within the broader field of humanistic and social scientific disciplines that research human functioning in social, political, institutional, cultural and historical environments and developmental contexts.

2.4. These studies should be classified as no-risk, minimal risk and/or low-risk studies in order for BaSSREC to initiate the review process (see attached document with risk level descriptors).

2.5. BaSSREC cannot review studies that involve vulnerable groups, children and health or health-related research. *Vulnerable groups may refer to children, NWU staff members and/or students, elders, prisoners, mentally disabled people, participants from low socio-economic groups, people in dependent/power relations, ethnic, religious and gender minorities.* This is, however, not an exhaustive list. In this regard, is it important that the BaSSREC directly aligns with the North-West University's Research Ethics Policy (2021). This document describes vulnerability as not being "an absolute condition but rather occurs on a sliding scale depending on personal and environmental circumstances" (North-West University Research Ethics Policy, 2021).

2.6. The following actions can be taken with studies that fall outside of the scope of the BaSSREC review mandate:

a. Should the study involve vulnerable participants and/or be a greater than low risk study (i.e., medium or high risk), the ethics application will be referred to an appropriate National Health Research Ethics Council (NHREC)- registered REC, based on the focus of the study. The relevant REC within the Faculty of Humanities is the registered NWU Human and Social Sciences Research Ethics Committee (HSSREC).

b. Should the study be "health or health-related", statutory regulations require that an NHREC-registered Health Research Ethics Committee or the NWU-HREC review the study.

c. Should the study topic otherwise fall outside the expertise of a particular Faculty REC, the ethics application should be referred to a REC with appropriate expertise.

2.7. All research proposals/protocols must first be evaluated and approved by a Scientific Research Committee within the different schools (for honours' projects applications) or

research entities (for staff projects; Master's and Doctoral research) of the Faculty of Humanities prior to applying for ethics approval of projects/studies (A-rule 4.9.4 of 2019).

2.8. Research proposals should be provisionally classified according to risk levels (no/low/), medium; high) by these Scientific Research Committees. The BaSSREC will verify this classification. No application will be accepted without a formally signed and dated Scientific Research Committee letter stating the risk category. NWU Title Registration documentation for the proposed application will not be accepted as proof of scientific approval.

2.9. Proposal/protocols of projects/studies with apparently no risk (systematic literature reviews, postal surveys with validated questionnaires, unidentifiable electronic surveys and public observation without identification or intervention, etc.) will be evaluated by the BaSSREC for confirmation of risk status and will be tabled for noting if the risk status is no risk.

2.10. All ethics applications for new projects/studies, sub-study inclusion under approved umbrella projects and amendments to or extensions of approved projects/studies must be evaluated and approved by the BaSSREC and signed by the BaSSREC chairperson.

2.11. Irrespective of the risk level of the application, the primary investigator should strictly observe the applicable Covid-19 regulations as part of their research proposal, ethics application and empirical work. Refer to the Addendum (7.10) in this regard.

2.12. The BaSSREC will, in line with NWU research ethics policy, not consider research studies for approval if it is apparent that the data collection for the research has been completed or has been started. Such retrospective projects/studies will immediately be terminated.

2.13. BaSSREC-members are required to have the necessary/relevant expertise about the subject matter and about research ethics principles.

2.14. BaSSREC will follow a collective decision-making process, including:

a. Aggregating at least two individual reviews by BaSSREC academic members.
b. Deliberating the ethical implications implicit in the contents of these reviews during the scheduled in-person, virtual or round-robin meetings.
c. Engaging in analogue reasoning (i.e., reaching consensus).
d. In instances where consensus is not reached, a decision is reached via secret ballot. If the votes are equal, the chairperson will have the deciding vote.

2.15 An Ethics Approval Certificate from the North-West University SRCE must be obtained before commencing any project/study. Without an ethics approval certificate, studies involving human participants may not commence.

3. MEMBERSHIP

The BaSSREC membership comprises of a chairperson, a deputy chairperson, 15 committee members (academics) and an administrator. Research interns may be invited to sit on the committee (for the duration of their internship) with observer status as part of their training.

3.1. The term of BaSSREC membership is for three years, depending on the agreement with and availability of the committee member.

3.2. New BaSSREC members are approved by BaSSREC, Deputy Dean Research and Innovation, and the Faculty Board and on appointment, will sign an appointment letter, confidentiality clause and a code of conduct. The appointment of academic members must reflect in their task agreements as staff members.

3.3. Responsibilities of BaSSREC committee members:

Table 1 below sets out the responsibilities of applicants and of the various members of BaSSREC.

Table 1: Responsibilities of Applicants and Members of BaSSREC

Person	Responsibilities
Researcher / Primary investigator Supervisor / Promotor	● The applicant and their supervisor should attend at least one session of NWU or Faculty-facilitated ethics training, or other Faculty-approved ethics training, to verify their ethics training. Proof of ethics training is valid for a period of three-years. After this time the applicant and supervisor should again submit proof of ethics training. ● For own research projects, timeously submit a completed, participant-respecting application that includes all necessary documents. ● Timeously and diligently responding to recommendations for revision through the completion of the BaSSREC rebuttal report. ● Inform BaSSREC in writing as soon as any part of protocol/research design changes through the detailed completion of the BaSSREC Monitoring and Amendment Report. ● Report all adverse events relating to your study's participants to BaSSREC (even if these do not apparently relate to your research) through the detailed completion of the BaSSREC Monitoring and Amendment Report. ● Provide annual written and/or verbal feedback to BaSSREC on ethical aspects of your research, particularly ethical issues/risks that were not predicted

	beforehand through the detailed completion of the BaSSREC Monitoring and Amendment Report.
BaSSREC Chairperson	• Convene meetings as needed. • Facilitate BaSSREC meetings and optimal turnaround time for applications. • Declare all conflicts of interest. • Assign reviewers to ethics applications. • Review ethics applications and peruse all reviewers' reports (i.e., note all ethical red flags not identified by reviewers and/or make recommendations where there exists an incongruence between the final assessment of the reviewers). • Facilitate deliberation about and final approval of applications. • Sign-off on all approved applications within one week of its final approval. • Monitor that the BaSSREC only reviews ethics applications as specified by its scope of practice. • Train or arrange for training of faculty-affiliated researchers/students to submit efficient applications. • Be a whistle-blower about unethical research practices within the faculty.
BaSSREC Academic members	• Attend all scheduled meetings. • Be available for extraordinary meetings as needed. • Declare all conflicts of interest. • Review applications, as requested, within 10 working days and submit reviews to the Chairperson and Administrator. • Engage in deliberation about and final approval of applications. • Finalise further review requested within 3 calendar days. • In the case of major revisions, re-review application and present findings to BaSSREC Chairperson in writing and/or during a scheduled BaSSREC meeting. • Continuously sensitise colleagues and students to the importance of ethical research. • Be a whistle-blower about unethical research practices within the faculty.
BaSSREC community members	• Attend scheduled meetings. • Be available for extraordinary meetings as needed. • Declare all conflicts of interest. • Engage in deliberation about and final approval of applications. • Be a whistle-blower about unethical research practices within the faculty.

BaSSREC Administrator	● Facilitate all correspondence between applicants and BaSSREC, including: o Checking completeness of applications and requesting outstanding documents from applicants. o Forwarding all complete applications to the chairperson. o On the chairperson's advice, send applications to reviewers, including reviewer report templates. o Sending letters of feedback to applicants as advised by the chairperson. This is done using the official BaSSREC feedback letter template. o In cases of minor revision, forwarding applicant revisions to reviewers for approval and facilitating further exchanges as needed. o In cases of major revision, forwarding applicant revisions to reviewers for re-review. o Once approved, formulate an ethics approval letter, which will be signed off by the chairperson, deputy chairperson or assigned BaSSREC committee member, and send this to the applicant and SCRE. ● Record the dates of all of the above and include this record in agendas/minutes. ● Finalise the agenda prior to the scheduled meeting date. ● Facilitate signing when necessary, of confidentiality, conflict of interest, and permission to audio-record meeting by all BaSSREC meeting attendees at the beginning of the meeting (and as applicants enter the meeting). ● Take the minutes. Send minutes to the chairperson for approval one week prior to the scheduled BaSSREC meeting. ● Keep a clear document trail (electronic and paper copies) for 10 years. ● Store audio-records of BaSSREC meetings in a password-protected computer for 10 years. ● Remind applicants to submit their annual BaSSREC Monitoring and Amendment Report if these applicants fail to submit it on time.
Ad-hoc member(s)	● Review applications where additional subject/professional expertise is required to fully comprehend the ethical implications of an application. ● Submit written review to BaSSREC Chairperson within 10 working days.

Project leader / Study leader/ Promotor/Supervisor	• Support student to submit a complete application. To this end, the supervisor, study leader, project leader or promotor must attend at least one NWU or Faculty-facilitated ethics training every three years and submit proof of such training along with that of their students. • Support student to timeously and diligently respond to recommendations for revision. • Ensure that student informs BaSSREC in writing as soon as any part of protocol/research design changes. • Ensure that student reports all adverse events relating to study's participants to BaSSREC (even if these do not apparently relate to study). • Support student to provide annual written and/or verbal feedback to BaSSREC on ethical aspects of their research, particularly ethical issues/risks that were not predicted beforehand. • Take ultimate responsibility for students conducting ethical research.

4. MEETINGS

4.1. BaSSREC meetings will be held once a month in-person, virtually or via round robin to prevent undue delay of finalisation of applications.

4.2. A complete agenda will guide all BaSSREC meetings.

4.3. The BaSSREC chairperson, committee members (academic and community), and the administrator will attend all the meetings to ensure a 60% quorum. The administrator and intern/interns will not be part of the 60% quorum. Members must inform the Chairperson/Administrator before the meeting if they cannot attend.

4.4. Ad-hoc BaSSREC members will be requested to attend meetings as the need for their expertise may arise.

4.5. *If applicable:* Applicants (or their delegate if not available– i.e. someone involved in the study) could (as applicable) be invited by BaSSREC to a specific meeting. Applicants (or their delegates) may be asked to address ethics issues that might arise from an application during the meeting. Following the meeting, applicants could be asked to repeat the answers given, in writing, and/or to correct/amend an application and send these, together with a cover letter explaining the corrections/amendments, to the BaSSREC administrator as soon as possible.

4.6. BaSSREC members will disclose conflicts of interest and agree to uphold the confidentiality of all discussions and decisions about ethics applications during meetings.

4.7. Minutes will be taken at every meeting and approved at the following meeting.

5. CORRESPONDENCE

5.1. All correspondence with regards to new applications, amendments to or extensions of approved projects/studies, sub-study inclusion under umbrella projects as well as responses to recommended amendments and inquiries must be sent to the BaSSREC Chairperson and Administrator.

5.2. The BaSSREC Chairperson/Administrator will ensure that all correspondence reaches the relevant parties.

5.3. BaSSREC will enter into no correspondence with sponsors/funders of research projects. All correspondence is with applicant and study leader/promoter.

5.4. The BaSSREC chairperson will correspond with research participants who have comments/ queries/concerns/ complaints about BaSSREC-approved studies or studies by researchers affiliated with the FoH that relate to human participants.

6. BaSSREC APPLICATIONS: PROCEDURES

6.1 It is the responsibility of the researcher/project leader/study leader/promoter to submit ethics applications, using the official NWU ethics application form as available on the official BaSSREC web page Link: http://humanities.nwu.ac.za/basic-and-social- sciences-research-ethics-committee-bassrec Students should complete ethical applications under the supervision of study leaders/promoter. The final responsibility remains that of the study leaders/promoter to ensure that said application is detailed and in order before its submission to the BaSSREC.

6.2 All ethics applications must be submitted via the submission process detailed on the BaSSREC website.

6.3 The BaSSREC administrator advises the applicant (or delegate if not available) at which meeting the application will be evaluated. Where applicable, the applicant (or delegate) could be invited to attend the BaSSREC meeting and represent the application should reviewers have questions. Attendance also has educational potential.

6.4 It remains the responsibility of the BaSSREC applicant and their supervisor/promotor to familiarise themselves with the due dates of that particular year on the official BaSSREC web page.

6.5 Applications for a **first-time single study (i.e. Master's and doctoral studies)** should include the following **documentation**. *Please note: No application will be sent for review if any of the applicable documentation is outstanding.*

1. The Scientific Committee letter (in the case of post-graduate students) of approval for the research proposal.
2. The complete official BaSSREC Ethics Application Form

   Note: This form is available on the BaSSREC Ethics website and from the BaSSREC administrator.
3. The proposal for the study approved by the Scientific Committee (in the case of post-graduate students).
4. Letters to gatekeepers requesting permission to do the research (where necessary).
5. Letters from gatekeepers giving permission to do the research if available. Gatekeepers may require ethics clearance before they give their approval and in such instances the gatekeeper's approval must be submitted to the BaSSREC as soon as possible. In these cases, the BaSSREC may grant conditional approval until receipt of all relevant documents.
6. The official BaSSREC Informed Consent Statement.

   Note: This form is available on the BaSSREC Ethics website and from the BaSSREC administrator.
7. Where support, debriefing or counselling will be made available for participants who may experience emotional discomfort related to the research, a letter to the counsellor who will perform such service as well as the agreement by the counsellor to provide the service, must be included.
8. All data collection instruments (e.g. interview guides; interview schedules; questionnaires) to be used in the study.

   Note: If questionnaires are to be developed after ethics approval have been requested, it must be stated clearly in the application form and requested that conditional approval be granted by the BaSSREC until receipt of the measuring instruments. No data gathering may proceed before final approval has been granted. The data collection instruments have to be submitted to the BaSSREC within **three months** (for a Master's study) and **six months** (for a Doctoral study), otherwise conditional approval will be withdrawn.

9. The interview schedule of questions to be used in qualitative research.

   Note: Please note item 8 above. The same conditions apply for interview protocols that still have to be developed.

10. An indication or proof of ethics training received from both the applicant and their supervisor/promotor (where applicable). This may not be older than three years.
11. Where a researcher intends to do research in any other country than the RSA, documents pertaining to the approval of such research by the authorities of the relevant country, must be submitted.

12. The application documents for ethics approval from the BaSSREC, must be proofread for language and typing errors before submission. If necessary, it should be language edited.

6.6 The following procedures inform the ethics application process for **first-time single study (i.e. Master's and doctoral studies) applications**:

Procedures in the application by researchers (staff and students) for ethics clearance:

1. Supervisors or project leaders (applicants) submit the complete ethics application via email (in 2023) and later applications should be submitted using ADEP portal (to be later added). *BaSSREC webpage:https://humanities.nwu.ac.za/basic-and-social-sciences-research-ethics-committee-bassec.*
2. *for the links to the BaSSREC Administrator's email address: bassrec-admin@nwu.ac.za and procedures and meeting dates.*
3. The BaSSREC Chairperson will send received application for review to one or two selected members of the BaSSREC on the scheduled dates indicated on the calendar of that year.
4. Reviewers will submit a feedback report with their recommendations regarding the application to the BaSSREC Chairperson on the dates indicated on the BaSSREC calendar of that year.
5. The BaSSREC chairperson consolidates the reviewer reports using the BaSSREC summary report and indicates a final assessment recommendation for discussion during the scheduled BaSSREC meeting.
6. The BaSSREC chairperson and administrator compiles the agenda and supporting documentation for the scheduled BaSSREC meeting.
7. The BaSSREC chairperson and committee members discuss, make recommendations and decide on a final assessment regarding the approval or further referrals of the application. After consensus has been reached, the meeting will be adjourned.
8. If the final assessment of an application requires a deferral with major revisions, applicants will be required to resubmit the application to the BaSSREC to be tabled at the next BaSSREC meeting. After amendments have been submitted to the administrator, along with response to the feedback (rebuttal) letter, the application is placed on the relevant next BaSSREC agenda. The administrator sends the revised documents and applicant response to the chairperson and the same reviewers for re-evaluation. This is followed by presentation at the relevant BaSSREC meeting, and debate to reach consensus on decision (i.e., approve, approve with minimal/minor corrections, defer again because of major corrections, or disapprove).
9. Reviewers' feedback and BaSSREC recommendations will be sent to the applicant by the BaSSREC within three (3) days following the meeting. The researcher/project leader/study leader/promoter is responsible for supporting the necessary corrections/amendments to ethics applications. Students should be guided in this process.

10. The applicant or student advised by the supervisor, will make the recommended changes to both the application and proposal, indicate such changes in a contrasting colour and submit the official BaSSREC rebuttal report and full ethics application (with indications of where changes were made or how recommendations were implemented, by highlighting these in YELLOW).
11. After receipt of the changes and report pertaining thereto, reviewers will peruse the changed documents and make final recommendations regarding approval. Reviewers have five (5) working days to review, confer and approve, or confer and request further minor revisions (the latter speaks to the teaching mandate of the university: reviewers support applicants to perfect their application). Should reviewers not have consensus, the chairperson and/or deputy chairperson will arbitrate. Should approval be recommended, the final information/consent documents must be forwarded (via the administrator) to the chairperson to be signed off. Once approved by the appointed committee members, the BaSSREC administrator will formulate an ethics approval letter, which the chairperson or deputy chairperson will sign off. The BaSSREC administrator will send the ethics approval letter to the applicant and to the North-West University SCRE.
12. After final recommendations, the signed BaSSREC approval letter and, where applicable, BaSSREC informed consent statement, will be sent to the applicant.
13. Once approved by BaSSREC, the applicant must submit a set of completed, updated, corrected study documents (proposal, informed consents, and participants' information leaflets) to the BaSSREC administrator. These documents must indicate the final ethics approval number and respective date in a header or footer format. If the informed consent letters will be used in a language other than English, the translated versions (designed for Gr 8. Readership level) and a letter of a formally registered language practitioner (responsible for the translation and/or editing of the informed consent statement) must be submitted to BaSSREC at this final stage too. No fieldwork may commence without these documents.
14. When making use of NWU students in research, the NWU Gatekeeper's permission must be obtained after the BaSSREC approval letter has been awarded. The contact person is MS. F Mseleni at the Research Support Office:Feziwe.Mseleni@nwu.ac.za.

6.7 The following procedures inform the ethics application process for **first-time single and low risk studies of honours' research project** applications:

Submit all **low risk** (refer to the risk descriptions on the BaSSREC web page) ethics applications to the BaSSREC for review. This will not be an expedited process.

The project leader of the particular module should complete the following documentation:

1. BaSSREC checklist: Ensure that this is completed and signed by the applicant and research director or programme leader.
2. BaSSREC ethics application form (full document).
    i. Indicate the module code and name for the title of the study.
    ii. Complete the relevant subsections of the application form.
3. Short research proposal:
    i. Write a 2-page background in which you outline the following:
        i. The title: The module code and name.
        ii. The background/orientation for the proposed student projects: include references to the particular module name and its outcomes.
        iii. The research design, sampling procedures and methods of data collection and analysis.
        iv. A brief ethics component that corresponds with the content in the ethics application form.
4. Scientific approval letter/letter from the programme leader approving the project.
5. Gatekeeper approval letters (if applicable): This may include the NWU Gatekeeper letter or letters from particular organisations or institutions that provide approval/consent for the students to undertake their fieldwork in that organisation/institution's contexts.
6. Informed Consent leaflet:
    i. Indicate the module code and name in the informed consent leaflet.
    ii. When students commence with their fieldwork for their respect projects that form part of this larger research project/research module, simply indicate a *sub-title* for their study on the informed consent leaflet under the overarching title.
    iii. Adapt this ICS to the particular study of the student.
    iv. The student may then commence with their fieldwork and use this informed consent leaflet to gain consent from their participants.
    v. Please note – these are only applicable to low-risk studies; medium and high risk studies require the full HSSREC-application.
7. Examples of data collection instrument(s): Since students might only develop these instruments later in the year, the project leader and supervisors will be required to take responsibility for the content of these instruments (as it forms parts of the research module).

i. This does not have to be submitted to BaSSREC.

ii. Please note – these guidelines are only applicable to low-risk studies; medium and high-risk studies require the full HSSREC-application.

iii. It is, however, important to note that BaSSREC is required to monitor every approved ethics application throughout the year and such proof must be attached then.

8. Project leader and supervisors' proof of ethics training: Proof of the successful completion of ethics training courses should accompany the application.

9. Very important: After approval, the project leader will be responsible to submit an annual monitoring report to the BaSSREC Chairperson (available on the BaSSREC web page) in which they indicate the continuation of the approved project and/or any potential amendments to the study that requires approval.

10. Successful applications will be approved for a period of five (5) years – depending on the submission of annual monitoring reports. Any and all changes should be reported to the BaSSREC during this time as part of the noted monitoring report.

Please note: Incomplete documentation will not be sent out for review and will be returned to the applicant.

6.8 The following procedures inform the ethics application process for **first-time single and no risk studies of honours' research project applications.**

Submit all **no risk** (refer to the risk descriptions on the BaSSREC web page) ethics applications to the BaSSREC for review. This will qualify for an expedited process.

The project leader should complete the following documentation:

BaSSREC short form

- Ensure that this is signed by the applicant and research director or programme leader.
- This will serve as the ethics application form.

Short research proposal:

- Write a 2-page background in which you outline the following:

  The title: The module code and name.

- The background/orientation for the proposed student projects:

  Include references to the particular module name and its outcomes.

  The research design, sampling procedures and methods of data collection and analysis.

  A brief ethics component that corresponds with the content in the ethics application form.

- Scientific approval letter/letter from the programme leader approving the project.

- Gatekeeper approval letters (if applicable): This may include the NWU Gatekeeper letter or letters from particular organisations or institutions that provide approval/consent for the students to use the literature or documents for the purpose of their study.
- Project leader and supervisors' proof of ethics training: Proof of the successful completion of ethics training courses should accompany the application.
- Very important: After approval, the project leader will be responsible to submit an annual monitoring report to the BaSSREC Chairperson (available on the BaSSREC web page) in which they indicate the continuation of the approved project and/or any potential amendments to the study that requires approval.
- Successful applications will be approved for a period of five (5) years – depending on the submission of annual monitoring reports. Any and all changes should be reported to the BaSSREC during this time as part of he noted monitoring report.

Please note: Incomplete documentation will not be sent out for review and will be returned to the applicant .

6.8 The following procedures inform the ethics application process for **sub-studies included under umbrella projects (larger studies)**:

A written permission letter must be obtained from the umbrella project researcher/project leader/study leader/promoter to include additional studies and be submitted with the application.

The remaining steps/processes are exactly the same as for new project/single study applications.

6.9 The following procedures inform the ethics application process for **the monitoring of existing studies, amendments made to or extensions of approved projects/studies**:

Monitoring reports:

All approved ethics applications are monitored by the BaSSREC annually. This is clearly stated on the official BaSSREC ethics approval letter.

Applicants and their supervisors/promotors are expected to complete the official BaSSREC monitoring report (available on the BaSSREC web page) and submit to the BaSSREC administrator one month before the lapse of the yearlong approval granted to the study. If the applicant fails to do so, the BaSSREC approval will be revoked.

3. In addition to this passive monitoring process, the BaSSREC chairperson may select at least one approved BaSSREC study for active monitoring per semester, i.e. they will randomly monitor the ethics process of applications approved by BaSSREC. This could include asking to see the stored consent forms, and/or asking to speak with study participants about their experience of being part of the study, etc. This will be done in accordance with the Protection of Personal Information Act (POPIA).

Amendments to or extension of existing studies:

1. All applications/requests for amendments to or extensions of already approved projects must be submitted in writing (via email) to the BaSSREC administrator. The written application must include the existing ethical clearance certificate, the original ethics application and informed consent documents, and a letter tabulating all the proposed changes with explicit comment on the ethical implications of each change. If the changes imply the need for re-consent, the adapted informed consent documents must be included.
2. For preparation of the next meeting, the BaSSREC administrator will email the application/request for evaluation to the BaSSREC chairperson as soon as all the relevant information has been received.
3. The BaSSREC administrator will include the application/request on the agenda for the next relevant meeting. The remaining steps/processes are exactly the same as for new project/single study applications.

6.10 The following procedures inform the ethics application process for **secondary data analysis/desktop studies**:

1. All secondary data analyses studies after Scientific Committee approval require BaSSREC clearance (unless these were conceptualised and BaSSREC -approved as part of an umbrella/single study). Meta-analyses of published studies and reputable public archives will be excluded from this process, but still requires approval by the SC.
2. The ethics surrounding the use of secondary data include that the current analysis is absolutely compatible with the aim of the original study, or, in the original informed consents, participants were made explicitly aware how data would be shared with others for secondary data analyses purposes, what these purposes would be, and if this would entail data being sent out of the country where it was generated. If this is not so, re-consent procedures must be followed before submitting an application to BaSSREC.

3. If re-consent is not needed, the application must include the fully completed BaSSREC application form the completed checklist and all of the following:

    a. Proof that the study in which the data were generated was ethically cleared (e.g., copy of ethics clearance certificate).

    b. The research protocol of the previous study (and, where relevant, the instruments used to collect the data).

    c. The informed consent documentation of the previous study

    d. A letter of permission from the principal investigator of the original study granting permission for secondary data analysis unless open access.

4. If the data constitute published findings (which will be meta-analysed) or data obtained from reputable research archives/public data-bases then i-iv are not required However, applicants are to provide proof of permission to use data from reputable archive/data-base, or proof of purchase of such data (i.e., applicants need to prove legitimacy of their access to these data).

6.11 The following procedures inform the ethics application process for **expedited ethical approvals**:

1. The BaSSREC will only consider no risk ethics applications for possible expedited review. This will be dependent on:

(a) the timely submission of said application;(b) whether said application is complete and (c) if there is the available committee member capacity to review the application. An expedited review will be sent to the allocated reviewers who will be granted a period of five (5) working days to review and return the application and BaSSREC reviewer report to the administrator and chairperson for consolidation.

2. After consolidation of the reviewer reports is completed, the BaSSREC chairperson will request the committee members to ratify his/her recommendations via a three-day round robin consultation process.

3. In addition, the BaSSREC may schedule extraordinary committee meetings to facilitate **urgent** ethics applications/amendments to existing applications. Such a meeting will not consist of standing members, but will be convened from available members.

4. Urgent' does not include applications that were not submitted timeously (based on inadequate planning on the part of the applicant and/or their supervisor/promotor), or that were held up by

ADEP (to be later added) processes (given that applicants have the responsibility of informing the administrator when an application has been uploaded onto ADEP(to be later added)

6.12 For **appeals and complaints**, please follow the following procedures:

1. If an applicant believes that BaSSREC did not evaluate his/her/their application fairly, or within reasonable turnaround time, then applicants are advised to:
2. Send a letter of appeal to the BaSSREC chairperson, via the BaSSREC administrator. The BaSSREC chair will then set up an appointment with the applicant/s to consider how the appeal could be addressed.
3. Should the above not facilitate resolution, send a letter of appeal to the Deputy Dean Research and Innovation, who will attempt to facilitate resolution.
4. Should the above not facilitate resolution, direct an appeal to SCRE.

6. ADDENDA

7.1. Ethical risk descriptors.

7.2. BaSSREC application form.

7.3. BaSSREC checklist list.

7.4. BaSSREC monitoring report and amendments application.

7.5. BaSSREC list of procedures and responsibilities.

7.6. BaSSREC informed consent form.

7.7. BaSSREC reviewer's report form.

7.8. BaSSREC rebuttal report form.

7.9. BaSSREC appointment letter.

7.10. BaSSREC code of conduct.

7.11. BaSSREC confidentiality agreement.

7.12. NWU Covid-19 regulations.

7.1 ETHICAL RISK LEVEL DESCRIPTORS ADAPTED FROM THE NWU ETHICAL RISK LEVEL DESCRIPTORS – RESEARCH

RISK LEVELS	DESCRIPTIONS
High risk Please complete the NWU Ethics application form and send all relevant documentation with the application	o Research with human participants. o Any research with children. o Research with people suffering from psychological conditions that affect their cognitive, behavioural, or social functioning so that they cannot take informed decisions. o Any research done that is outside of the researcher's field of expertise can be seen as high risk. The competence of the researcher within this specific field will be a determining factor for the risk assessment of the research. o Research involving human participants with research-related medical or psychopathology o Research involving vulnerable human participants. o Research involving sensitive ethical dilemmas in society o Research that may affect public or environmental safety or sensitive ecosystems o Research budget higher than R1 million per annum o Any research deemed to present potential high risk for whatever reason by any applicant or committee.
Medium risk Please complete the NWU Ethics application form and send all relevant documentation with the application.	o Collaborative human social sciences research involving people. o Multi-centre human social sciences studies involving people. o Long-term human social sciences studies exceeding one year in duration. o Umbrella human social sciences projects involving human participants o Research involving face-to-face psycho-social contact with participants e.g. interviews, focus groups. o Any human social sciences intervention studies individually or in communities. o Non-clinical Research/Research with vulnerable communities/people (older persons and their care givers, patients and health-care professionals, students and teachers, persons with life-threatening diseases and their care givers, people living with HIV, wards of the state and guardians or care-givers, employees and employers, prisoners and the relevant prison authorities, members of the SA Defence Force and their supervisors, children, mentally ill persons own direct students) o Research budget not higher than R999 999 per annum and not lower that R250 000.00 per annum **All research not described under high risk, but where the following criteria apply:** Human social sciences projects involving: o Collaborative research o Multi-centre studies o Long-term studies exceeding one year in duration o Umbrella projects.
Low risk **(Low risk to human participants)** Please complete the NWU Ethics Checklist together with the project/research proposal/protocol	**All research not described under high risk or medium risk, but where the following criteria applies:** o Surveys by means of validated interview schedules o Documented data or analyses with identifiable human participants o Simple questionnaire or instrument development o Questionnaire or instrument development o Research involving retrospective data. o System research using structured survey forms. o Interventions based on professional, scientific base protocols. o Research budget under R250 000 but higher than R100 000.

	The following are guidelines to low risk research: Low risk: • These studies include the use of questions about people's everyday lives, activities and opinions. It may include their biographical information and some potentially sensitive questions and/or topics. These are, however, not intrusive. • The research may include some vulnerable participants and/or contexts. The focus of the study and the questions, however, are non-intrusive and do not foreground the particular identity category of said participants as primary research focus/variable. • Questions about people's everyday lives, activities and opinions are surveyed rather than their detailed biographical information. • No sensitive questions or topics are included in the data collection instruments.
No risk **Only ethical clearance required from BaSSREC** (If you need ethical approval for funding opportunities/journal publications, you will have to follow the low risk process)	**All research not described under high risk, medium risk or low risk, including the following:** o Systematic reviews/Literature reviews o Postal / surveys with validated questionnaires o Document/artefact analyses without identifiable human participants o Unidentifiable electronic surveys o Public observation without interaction or intervention. **Please note:** No risk studies may be **escalated to a Low risk level** if the literature, scoping and/or scoping review includes the use of privileged information (e.g. documentation not publicly available, e.g. policy documentation; private diaries and journals, among others.).

7.2 BaSSREC application form

NWU Human Subjects Ethics Application Form

Application for ethical approval: Basic and Social Sciences Research Ethics Committee (BaSSREC)

Please read the Ethical Clearance Guidelines for Researchers before completing this form. Complete all sections of this form and attach all necessary documents as indicated – incomplete applications will not be reviewed and may delay the approval process. Please feel free to contact the BaSSREC for more information or further assistance and advice in this regard.

Section A: Project / Study Details **Title:**			
Date of submission:	**Duration of Project/Study**	**Start Date:**	**End Date:**

Details of Primary Investigator, Co-researchers, Research Assistants, Field Workers, etc.

Name	Start Date	End Date
Primary Investigator:		

<u>Section B: Project funding, purpose and research design:</u>

Project Funding:

Is project funding sought / achieved? Yes _____ No _____

Will members of the research team have a financial interest in, receive personal compensation from, or hold a position in an industry sponsoring this study? Yes _____ No _____

Will the research subjects receive any financial or other personal compensation for participating in this research study? Yes _____ No _____

Additional details regarding any possible conflict of interest on the part of the researchers or funders, as well as appropriate steps taken in consideration of such possible conflict of interest:

Provide a brief summary (300 words or less) of the purpose of the research project. Include necessary background information, research questions and motivating factors for conducting this research:

Provide a description of the research design, including procedures and methodology. Specify the type of data that will be collected, primary outcome measurements and anticipated follow-up processes and actions (Copies of all data collection instruments, such as questionnaires or survey forms, should be attached to this application. Please see the note in section G). Include details on procedures in place to monitor the research, including those by funding agencies, supervisors, etc.:

Section C – Proposed research subjects:

Provide details of the proposed human subjects to be included in the research, including number of participants, gender, ethnicity, socio-economic level, educational level and any other categorising details that could impact on this study. Specify the required characteristics of potential human subjects, both for inclusion criteria as well as exclusion criteria.

How will prospective subjects be contacted/recruited? Attach copies of planned written text, advertisements, telephone scripts, etc.

Detail the requirements of subjects to participate in this research. Specify what they are expected to do, how long their involvement will take and whether the study will require multiple or follow-up activities.

Detail the location of subjects when participating in this research. Specify any potential hazards or risks that could arise from participating in this location.

Section D – Obtaining free and informed consent:

Have you arranged to obtain clear and informed consent from all human subjects that may be involved in this research? Yes _____ No _____

Attach copies of all consent and information forms to this application. Consent information forms should indicate briefly the purpose of the study and specify what would be expected of participants. If measurements will be used, they must be informed of the nature of these; if interviews are held, the questions must be stated; similarly any other form of data collection must be specified. If recordings of any nature will be made, the participants have to give consent. Note that prospective participants should have consent forms provided in the language they are most familiar with and illiterate subjects will require detailed verbal description of the consent form.

Will deception in any form be practiced against the research subjects during the course of this research?

Yes _____ No _____

If so, specify the justifications for such deception and detail how full disclosure and free and informed consent will be achieved before dissemination of the findings of this research:

Will you be deliberately involving any of the following vulnerable population groups in the research project?

Description of vulnerable group	Yes	No
Very young children (0 – 5 years old)		
Children (6 – 18 years old)		
People unfamiliar with the language the research is being conducted in		
People with physical disabilities		
People with a cognitive disability		
People with any other type of disability		
People suffering from health related problems		
People who have experienced acute psychological trauma (e.g. rape or abuse)		
People in dependent/unequal relationships (in prison or in the military)		
North-West University students (your own students)		
University students (not your own)		
Illiterate people or those with a poor level of formal education		
People living in vulnerable life circumstances (e.g. poverty or refugee status)		
People over 65 years of age		
Any other perceived vulnerability		

Please provide information justifying and detailing your use of any of the above mentioned groups in your research, as well as detailing extra precautions taken to protect vulnerable subjects:

Risk mitigation:

Please provide details regarding any risk factors for general subject involvement, including emotional distress, personal or cultural embarrassment, breach of confidentiality, economic harm, legal jeopardy, physical pain or injury, AND the intended method(s) of mitigating such possible risks. In the consent information letter, any possible risk or lack thereof, must be stated, *as well as what the benefits of participation would be*. Also specify any risks to the researchers themselves and what steps will be taken to protect them:

Compensation:

Will participants be compensated in any way (even by means of tokens of appreciation)? Who will pay for such expenses?

Third party data:

Will data on research subjects be accessed via a third party (e.g. school or other gatekeeper)?

No _____

Yes _____

What legal and informed consent arrangements have been made in this regard? Letters of request for such permission and of the gatekeeper's permission, must be submitted.

Section E – Confidentiality and data storage:

How will the confidentiality of the data collected be protected? What steps will be taken to protect participants against breaches of confidentiality or invasion of privacy? Specify intended plans for storage of data, access by researchers and others to this data and what plans are in place to de-identify and anonymise the data (particularly audio/video recording or photos taken). Specify how long data will be stored and if and how it will be disposed of.

Data security for storage and transmission. Select all that will apply to this research:

Electronic data:

Description	Yes	No
Secure network		
Data password protected		
Data encrypted		
Data stored on portable storage device (CD/laptop/flash disk/external drive)		

Hardcopy data:

Description	Yes	No
Data de-identified by research team		
Locked office		
Locked filing cabinet		
Data coded and master list secured elsewhere		

Section F – Data analyses and outcomes:

How will the data be evaluated?

Where and by whom will data analyses be performed?

What training or supervision will be provided to research assistants (or student researchers) to collate, analyse and prepare data?

Projected outcomes for the research project:

What population, organisation or entity will likely derive the greatest benefit from the results of this research?

What are the intended avenues for publication and dissemination of the results of this research study? Note that it is not necessary to name a specific journal or publication. Stipulate rather how this data and related findings will be disseminated and to what audience. Also, will the data be reused for multiple publications and will it be shared with other researchers for secondary outcomes?

What steps have been/will be taken to ensure the research results are unbiased and fairly disseminated? (Note that steps must be taken to ensure no unfavourable data is ignored or discarded and that the research may be scrutinised publicly).

Section G – Attachments:

Please ensure that the following, relevant documentation is to be included together with this application:

1. Copy of approved research proposal.
2. Copy of letter of approval of research proposal by the Scientific Committee.
3. Copies of all data collection instruments including survey forms, interview questions, etc. (See the note below)
4. Copies of any psychometric or other tests to be used by research subjects. (See note below)
5. Copies of all consent or information forms, including translated forms if needed.
6. Copies of all written text, advertising or script used to recruit subjects.
7. Copies of any third party or sponsorship agreements related to the research.
8. Signed approval from any relevant authorities required for this project, including from other institutions linked to this research.
9. Short CV of research assistants (one page each).
10. Copies of prior ethical clearance or denial (A letter noting revisions made since, may be attached).
11. Any relevant budgetary outlines, resource or equipment lists that may impact on the research.
12. Any other relevant documentation which may impact on the research itself.
13. Short CV of the principal researcher (one page).

Note: If questionnaires and/or interview questions are to be developed after ethics approval have been requested, it must be stated clearly in the application form and requested that conditional approval be granted by the BaSSREC until receipt of the measuring instruments and/or interview protocol. No data gathering may proceed before final approval has been granted. The questionnaires and/or interview protocol have to be submitted to the BaSSREC within three months (for a Master's study) and six months (for a Doctoral study), otherwise conditional approval will be withdrawn.

Section H – Declaration by applicant:

- I certify that all researchers involved in this research project have thoroughly examined the Ethical Clearance Guidelines for Researchers document and have agreed to abide by this code of conduct in their research.
- I am aware of the relevant ethics authority and legal requirements associated with the research to be conducted and will undertake to ensure no illegal activities are engaged in, with regards to this research.
- I declare that all information provided by me in this application is true and honest and that I will abide by the undertakings I have provided in this application.
- I declare that this application has been proof read and/or language edited.
- I agree to keep the relevant ethics committee updated on any changes or adjustments to the research procedures and to obtain written approval before engaging in said changes.
- I will submit progress reports at least annually (for long term research projects) as well as a final report within 30 days of the project completion.

I HAVE READ AND AGREED TO THE ABOVE STIPULATIONS.

Signed by the Applicant: **Date:**

Basic Social Sciences Research Ethics Committee (BaSSREC)

DATE: ……

BaSSREC Authorisation

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

Title of the research project	
Ethics number	
Principal investigator	
Student number	
Address	
Email address	
Contact number	

You are being invited to take part in a research project that forms part of my..... Please take some time to read the information presented here, which will explain the details of this project. Please ask the researcher any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research is about and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part. Prior to publication of the study's results (or the point that publication is in process), you may also withdraw the data you generate.

This study has been approved by the **Basic and Social Sciences Research Ethics Committee (BaSSREC) of the Faculty of Humanities of the North-West University (NWU.....)** and will be conducted according to the ethical guidelines and principles of the international Singapore Statement on Research Integrity (2010) and the ethical guidelines of the National Health Research Ethics Council. It might be necessary for the research ethics committee

members or relevant authorities to inspect the research records to make sure that we (the researchers) are conducting research in an ethical manner.

What is this research study all about?

- This study is an investigation of ... and will involve the use of … (*methods*)
- The researcher has been trained to use the methods mentioned in the previous sentence.
- Approximately … (*number*) participants will be included in this study.
- The objectives of this research are:
    - …
    - …

Why have you been invited to participate?

- You have been invited to participate because you are …
- You have also complied with the following inclusion criteria: … *(be specific about gender, race, socio-economic class, level of education, occupation, etc.).*
- You will be excluded if … *(be specific about gender, race, socio-economic class, level of education, occupation, etc.).*

What will your responsibilities be?

- You will be invited to participate in the noted study by ... (*interviews; focus group discussions; online questionnaires, etc.*).
- You will have … days/weeks to indicate whether you would be willing to participate.
- You will be requested to sign this Informed Consent Statement before the commencement of the study.

Will you benefit from taking part in this research?

- The direct benefits for you as a participant will probably be … (*e.g. skill development*).
- The indirect benefit will probably be … *(e.g. contributing to knowledge generation).*

Are there risks involved in your taking part in this research and how will these be managed?

The possible risks in this study, and how these will be managed, are summarised in the table below:

Possible risk	**Mitigation strategy**
COVID 19 risk during face-to-face interviews.	Due to the potential of Covid-19 infection, the researcher will observe the following rules during in-person/face-to-face data collection: • If the current Covid-19 restriction levels do not allow for such in-person meetings, the interviews will not take place. • That all persons wear a three-ply mask throughout the interview. • That the researcher takes the temperature of the participants before the start of the interview and FGD. If this is too high, then you will not be allowed to participate.

	• That hand-sanitizer (with 70% alcohol-content) be used *before, during* and *after* the interview. • That social-distancing of 1.5-2 meters be observed between all persons *before, during* and *after* the interview. • If the participants do not have a three-ply mask or hand-sanitizer, this will be provided cost-free by the researcher. (*Apply to your study)*
Emotional distress of the participants.	E.g. counsellor; psychologist, psychiatrist. *Provide their details; the process of contacting these persons; payment (the first session should be paid for by the researcher, thereafter the participant takes responsibility for that).*
Tiredness and discomfort.	Comfort breaks of … minutes.
Lack of privacy and comfort during interviews due to …	This will be addressed by …
Please add/edit based on your study. Be very specific. All of this information must be copied into the research proposal and ethics application form.	*Please add/edit based on your study. Be very specific. All of this information must be copied into the research proposal and ethics application form.*

- *However, we do believe that the benefits to you and to science (as noted in the previous section) outweigh the risks we have listed. If you disagree, then please feel free not to participate in this study. We will respect your decision.*
- *Should we learn, in the course of the research, that someone is harming you, or that you are intending to harm someone, then we must tell someone who can help you/warn the person you are intending to harm.*

Who will have access to the data?

The following procedures will be observed in line with the Protection of Personal Information Act (POPIA):

Principle	How will this be done?	When will this be done?
Anonymity	Anonymity will be ensured by choosing your own fictitious names/I (the principal investigator) will assign a fictitious name/code to you before the interview starts. Only this name will be used in the research process. (*Apply to your study)*	Before the interview commence. After the interview has been conducted. Other (please explain). (*Apply to your study)*
Confidentiality	Confidentiality will include the use of pseudonyms/codes (*apply to your study*) for participants, organisations and locations. It involves not disclosing any information gained from an interviewee deliberately or accidentally in ways that might identify an individual, organisation and location.	During the recruitment process. Before the fieldwork commences. During the fieldwork. After the fieldwork has been completed During analysis and the write-up of findings.

		During the reporting of findings. During the publication of findings in the form of articles, books, conference proceedings, etc. (*Apply to your study*)
De-identification of data	All identifiable personal information will be de-identifies to ensure that no information identifies any participants, organisations and locations.	After the fieldwork has been completed. After you, as participant, has signed-off on the interview transcripts/responses/any other relevant information sent to you to check. Before data analysis and the write-up of findings start. (*Apply to your study*)
Data storage	All data collected for the purpose of the research will be stored safely in electronic format/hardcopy format for a period of five years after which it will be destroyed. The primary investigator will ensure data that both hard-(printed) and soft copy (electronic) are safely locked away and password-protected, respectively. Only approved people in my research team (*if applicable*) will/may have access to my raw data where the need arises. At the analysis stage, as will be the case throughout, the use of coding will reinforce participants' non-identification, hence upholding the assurance of confidentiality and anonymity. (*Apply to your study*)	During the recruitment process. Before the fieldwork commences. During the fieldwork. After the fieldwork has been completed During analysis and the write-up of findings. During the reporting of findings. During the publication of findings in the form of articles, books, conference proceedings, etc. (*Apply to your study*)
Privacy	*Privacy* will be ensured by not probing unnecessarily if you do not wish to discuss particular matters. (*Apply to your study*)	During the fieldwork. During follow-up fieldwork. (*Apply to your study*)
Transcription/coding of data	I will/will not use a *transcriber* for the purpose of the transcripts after the interview. I will/will not use a *statistician/coder* for the purpose of the transcripts after the interview. (*Apply to your study*)	*If the primary investigator is responsible for transcribing/coding the data*: The primary investigator will be responsible for transcribing the data. Therefore, no other person will have access to the data. The primary investigator will be required to sign a NWU Confidentiality Agreement before the study commences.

		If a subject expert (e.g. transcriber/language editor/coder/statistician) assists with/takes responsibility for transcribing/coding the data: This/These persons /s will be responsible for transcribing the data. Therefore, no other person will have access to the data. This/These persons /s will be required to sign a NWU Confidentiality Agreement before the study commences. (*Apply to your study*)
Translation/interpreter services	I will/will not use a *translator/interpreter* for the purpose of the interviews/explaining the informed consent, etc. (*Apply to your study*)	This person will be required to sign a NWU Confidentiality Agreement and will not be permitted to share any information relating to the study with anyone else. (*Apply to your study*)

Collection of only relevant personal information:

Collection of only relevant personal information	I, the principal investigator and members of the research team (if applicable), will only collect personal biographical and opinion-related data about the topic I/we are studying.	Shortly list the *biographical* and *opinion-related* (*main themes*) information that will be collected for the purpose of the study. (*Apply to your study*)

What will happen to the data?

The data from this study will be reported in the following ways: ..... In all of this reporting, you will not be personally identified. This means that the reporting will not include your name or details that will help others to know that you participated.

This is a once-off study, so the data will not be re-used / Data may be re-used in the form of ...

Will you be paid/compensated to take part in this study and are there any costs involved?

No/yes, you will/will not be paid/compensated to take part in the study, but pre-packaged refreshments will be provided before/during/after the study. If participating in the research means that you have to travel especially for the purpose of participating, then your travel costs will be paid. There will thus be no costs involved. (*Apply to your study*)

How will you know about the findings?

- The general findings of the research will be shared with you by …
- If you would like feedback on your personal results, then ... (*Apply to your study*)

Is there anything else that you should know or do?

- You can contact ... (researcher) at … (cell phone number) and … (email address) if you have any further queries or encounter any problems.
- You can contact the chair of the Human Social Sciences Research Ethics Committee (Prof Erharbor Idemudia) at 018 389 2899 or Erhabor.Idemudia@nwu.ac.za if you have any concerns or complaints that have not been adequately addressed by the researcher.
- You will receive a copy of this information and consent form for your own records.

Declaration by participant

By signing below, I _____ agree to take part in a research study entitled: "…". (*Apply to your study)*

I declare that:

- I provide *informed consent.*
  - Thus, I have read and understood this information and consent form and it is written in a language with which I am fluent and comfortable.
  - Thus, I have had a chance to ask questions to both the person obtaining consent, as well as the researcher (if this is a different person), and all my questions have been adequately answered.

- I provide *voluntary consent.*
  - Thus, I understand that taking part in this study is voluntary and I have not been pressurised to take part.
  - Thus, I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
  - Thus, I am aware of the fact that I may request that the researcher does not continue with said recording if I request it.

- I provide *specific consent.*
  - Thus, I understand that what I contribute (what I report/say/write/draw/produce visually) could be reproduced publically and/or quoted, but without reference to my personal identity.
  - I provide *specific consent.* Thus, I consent to an audio and/or audio-visual recording of the … (*Apply to your study*).

Signed at (*place*) _____ on (*date*) _____ 20 _____

_____ _____

Signature of participant **Signature of witness**

- You may contact me again ☐ **Yes** ☐ **No**
- I would like a summary of the findings of this research ☐ **Yes** ☐ **No**
- I would like feedback on my functioning/wellbeing as reflected in the questionnaires I completed ☐ **Yes** ☐ **No**

The best way to reach me is:

Name & Surname: _____
Postal Address: _____
Email: _____
Phone Number: _____
Cell Phone Number: _____

In case the above details change, please contact the following person who knows me well and who does not live with me and who will help you to contact me:

Name & Surname: _____

Phone/ Cell Phone Number /Email: _____

_____

Declaration by person obtaining consent (if not the researcher/primary investigator)

I *(name)* _____ declare that:

- I explained the information in this document to _____
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use an interpreter.

Signed at (*place*) _____ on (*date*) _____20 ____

_____ _____

Signature of person obtaining consent **Signature of witness**

Declaration by researcher/primary investigator

I *(name)* _____ declare that:

- I explained the information in this document to _____
- I encouraged them to ask questions and took adequate time to answer them.
- I am satisfied that they adequately understand all aspects of the research, as discussed above
- I did/did not use an interpreter.

Signed at (*place*) _____ on (*date*) _____20 _____

_____ _____

Signature of researcher **Signature of witness**

_____

Declaration by researcher and participant

Personal face-to-face interviews during Covid-19 restrictions (*if applicable*)

Additional declaration by participant in those instances where the participant requests to participate in a personal face-to-face semi-structured interview:

By signing below, I _____, acknowledge the following information related to the required measures regarding Covid-19:

I declare that:

- It is my personal choice and preference to participate in a personal face-to-face semi-structured interview with the researcher.
- This requires that I consent to the following strict measures to safeguard the personal health and safety of myself and that of the researcher/interviewer/primary investigator:

  - I consent to the researcher taking my temperature before the interview using a thermometer. ☐ **Yes** ☐ **No**
  - I confirm that my temperature measured at _____ degrees. ☐ **Yes** ☐ **No**
  - I consent to use the three-ply mask provided by the researcher. ☐ **Yes** ☐ **No**
  - I consent to wear the three-ply mask for the full duration of the interview. ☐ **Yes** ☐ **No**
  - I consent to the researcher sanitising the interview context using a sanitiser with an 80% alcohol content before the commencement of the interview. ☐ **Yes** ☐ **No**
  - I consent to the researcher using a sanitiser with an 80% alcohol content before and during the interview if required. ☐ **Yes** ☐ **No**

Signed at (*place*) _____ on (*date*) _____ 20 ____

_____ _____

Signature of participant **Signature of researcher**

Basic and Social Sciences Research Ethics Committee (BaSSREC)
Application for ethical approval: No-risk studies

Please read the Ethical Clearance Guidelines for Researchers before completing this form. Complete all sections of this form and attach all necessary documents as indicated – incomplete applications will not be reviewed and may delay the approval process. Please feel free to contact the BaSSREC secretariat (BaSSREC-admin@nwu.ac.za) for more information or further assistance or advice in this regard.

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

- The completed short ethics application should be submitted along with supporting documents stated below to BaSSREC.
- All applications must be signed by the student/applicant, the supervisor (where applicable) and the scientific committee director or school director (honours applications).
- All applications must be signed and submitted in Electronic Format.
- Incomplete applications will not be reviewed.
- The following documents should be submitted along with a no-risk application:
  a. Signed BaSSREC short application form
  b. Scientific committee letter stating that the proposal was reviewed and accepted and that the committee deem this study no-risk and therefore request for Ethics approval
  c. Proof that the applicant/student and their supervisor have completed one of the suggested research ethics training sessions.

Section A: Project /Study Details

Title, initials, surname:

Student or staff number:

School or research unit:

Telephone:

Cell phone:

Email:

First Application ◯ Resubmission ◯

Project/ study title:

Supervisor/ Primary investigator:

Honours ◯ Masters ◯ PhD ◯ Staff project ◯

Funding (if applicable):

Purpose statement/aims and objectives/hypotheses:

Overview of research design:

Start date: End date:

Section B: Risk Level Assessment

	Yes	No
1. Does the study involve any contact with human participants?	☐	☐
2. Does the study include the observation of people in a public space without any interaction with the researcher and where the persons being observed do not have a reasonable expectation of privacy?	☐	☐
3. Does the study rely exclusively on the secondary use of anonymous information?	☐	☐
4. Does the study rely exclusively on publicly available information or information accessible through legislation or regulation (including literature)?	☐	☐
5. Does this study involve the study of a work of art or music?	☐	☐
6. Does the study involve participants who are vulnerable?	☐	☐
7. Will students or staff members of the NWU be participants?	☐	☐
8. Will the study require the co-operation of a gatekeeper?	☐	☐
9. Will it be necessary for participants to take part in the study without their knowledge and consent at the time?	☐	☐
10. Will the study involve discussion of or questions about a sensitive topic?	☐	☐
11. Could the study induce physical, psychological or social stress or anxiety or cause harm or negative consequences beyond the risks encountered in normal life?	☐	☐
12. Will financial inducements (other than reasonable expenses and compensation for time) or inducements of any other kind be offered to participants?	☐	☐
13. Could the image of the NWU, the relevant academic department, your employer, or any other institution however affected by/involved in the project be negatively affected by this research or put in a bad light?	☐	☐

Candidate
Name and Surname:
Signature

Supervisor
Name and Surname:
Signature:

Research director/School director
Name and Surname:
Signature:

BaSSREC Office
Name and Surname:
Signature:

7.4 BaSSREC monitoring report and amendment application

BASIC AND SOCIAL SCIENCES ETHICS COMMITTEE
ANNUAL MONITORING REPORT

Please complete the form according to the following guidelines:

- *All researchers* need to complete Sections A and E.
- Section B is only completed if the research project is *quantitative* in nature.
- Section C is only completed if the research project is *qualitative* in nature.
- Section D is only completed if the researchers are making use of *previously collected biological samples or data.*

SECTION A: GENERAL INFORMATION AND PROGRESS

1. Project Head/Principle Investigator/Study leader Details						
Surname		**Initials**		**Title**		
Department						
E-mail						
Telephone	**Work**		**Cell**		**Fax**	
2. Student Details						
Surname		**Initials**		**Title**		
Department						
E-mail						
Telephone	**Work**		**Cell**		**Fax**	
3. Details of approved proposal/protocol						
Title						
Ethics Approval Number				**Risk level**		
Approval date		**Expiry date**				

Are there any sub-studies/affiliated studies linked to this project?	**Yes**		**If yes, please indicate titles of the sub-study/affiliated study below and mark whether a report has been submitted.**
	No		

Titles of sub-studies/affiliated studies	**Students/researchers included**	**Report in? (Please attach)**	
		Yes	**No**

4. Funding details (Where do you receive your funding from? Please mark with an X)

Internal		**National (NRF/MRC)**		**NIH/US Gov**	
Industry		**International grant**		**Self**	

	Yes	No	NA
Were you able to fund your project as initially intended? **If not, please indicate here in what way it has changed:**			

5. Summary of progress to date

Shortly describe the overall progress to date of the project (500 words):

Please describe any ethical issues (both minor and/or major) that may have arisen during the past year (500 words):

Describe the research monitoring approach you followed:

	Yes	No	NA
Has the level of risk to the participants changed during the past year? **If yes, please explain here (new level, reason, how HSSREC was notified):**			
Has any new conflict of interest occurred during the past year? **If yes, please explain here:**			
Have the research records produced (both hard and soft copies) been correctly maintained and secured as stated in the application? **Please explain your system here:**			
If the Human Social Sciences Research Ethics Committee (HSSREC), has provided *provisional approval* for your project, have you fulfilled the conditions of the provisional approval e.g. approval from the Department of Health, goodwill permission from the school principal etc. and provided the HSSREC with these? **Please give greater detail regarding the manner in which you *have/have not* adhered to the conditions of provisional approval provided by the ethics committee:**			

6. Adverse events/Serious adverse events/Incidents (if applicable)	Yes	No	NA

Has there been any adverse events/serious adverse events/incidents in the project during the past year? **Please give the following for each of the adverse events/serious adverse events/incidents: the date, a narrative overview, how it was managed and how the HSSREC was notified.** 1) 2) 3)			
If a data safety monitoring board was part of your planned research have they evaluated the adverse events/serious adverse events/incidents? **If yes, please attach a copy of the report.**			
7. External monitoring (if applicable)	**Yes**	**No**	**NA**
Has the study been externally monitored or audited? **If yes, please indicate the name of the agency:** **Please attach a copy of the report.**			

SECTION B: QUANTITATIVE STUDIES

8. Enrolment of participants	
Total number of participants planned to be included in the project.	
Actual number of participants enrolled in the project.	
Number of participants that withdrew from the project out of own choice. **Please provide reasons here for participants' withdrawal:**	
Number of participants withdrawn by primary investigator due to adverse events/serious adverse events/incidents/other reasons. **Please provide reasons here for these withdrawals:**	
Number of participants lost to follow-up (if appropriate). **Please explain here why they were lost:**	

SECTION C: QUALITATIVE ANALYSES

9. Methods used	
How many participants have been enrolled to date?	

	Yes	No	NA
Has data saturation been reached in this project?			

Please give an overview of the methodology used to determine the indicated data saturation:	
Number of participants that withdrew from the project out of own choice. **Please provide reasons for participants' withdrawal:**	
Number of participants withdrawn by the primary investigator due to adverse events/serious adverse events/incidents/other reasons. **Please provide reasons for these withdrawals:**	
Number of participants lost to follow-up (if appropriate). **Please explain why they were lost:**	

SECTION D: USE OF PREVIOUSLY COLLECTED DATA

10. Databases	Yes	No	NA
Was the database you received anonymised? **Describe the process:**			
Was the database you received password protected?			

SECTION E: PROJECT AMENDMENTS AND STUDY STATUS

12. Amendments	Yes	No	NA
Has the study been amended or changed during the past year?			
Amendments	**Date**		
13. Status of study	**Yes**	**No**	**NA**
Has the study been completed and does this serve as your final report?			
Has this project been terminated? **If so, please indicate the date, reason for termination and when the HSSREC was notified:**			

Does the project have to continue in the following year?			

14. Signature

By signing this document, I certify that the information provided is accurate and complete.			
Signature by the primary investigator		**Date**	

Some sections of this document have been adapted from similar HREC documentation of the University of Stellenbosch and the University of the Cape Town.

Content adapted from HSSREC Standard Operating Procedure compiled by Professor Chrizanne van Eeden.

7.5 BaSSREC list of procedures and responsibilities

Table 2: Ethics Applications for New Projects/Studies (Summary of process)		
1	Submit ethics application *via email to the BaSSREC administrator.* together with all the relevant forms. *Depending on feedback from BaSSREC chairperson, applicants may be requested to submit the full applications via email to the BaSSREC chairperson and administrator.*	Applicant
2	Applicant to notify BaSSREC administrator once ADEPT (to be later added) application is completed.	Applicant
3	Administrator to ensure inclusion of all relevant documents before sending approval request to BaSSREC chairperson.	Administrator
4	BaSSREC chairperson to assign reviewers to every application. Administrator notifies reviewers and sends them the full documentation.	BaSSREC chairperson. BaSSREC administrator.
5	Reviewers submit finalised reports on the BaSSREC report forms no later than ten (10) calendar days.	BaSSREC reviewers. BaSSREC administrator.
6	Reviews are consolidated using the BaSSREC summary documentation.	BaSSREC chairperson. BaSSREC administrator.
7	Administrator collates reviews and sends letter of feedback to applicant within three working days following the relevant BaSSREC meeting.	BaSSREC administrator.
8	Applications with revisions and a rebuttal letter to be returned to administrator as soon as possible.	Applicant. Supervisor/Promotor.
9	Applications with major revisions to be reviewed again by a formal BaSSREC meeting after amendments were completed by the applicant.	BaSSREC chairperson. BaSSREC reviewers. Applicants and supervisor/promotor.
10	Approved applications must be submitted to administrator together will complete a set of corrected study documents.	Applicant. Supervisor/Promotor.
11	BaSSREC to submit ethics approval letter to NWU SCRE.	BaSSREC administrator.
12	BaSSREC issues official NWU Ethics Approval Certificate to applicant.	BaSSREC administrator.
13	BaSSREC administrator to send copy of the BaSSREC approval letter/certificate to SCRE.	BaSSREC administrator.
14	BaSSREC to monitor the research process.	BaSSREC chairperson.

Basic and Social Sciences Research Ethics Committee (BaSSREC)
Reviewer Report: No-risk studies

Researcher:

Project Title:

Reviewer:

The following subsections provide reviewers with guidance to remind them about important ethical issues that applicants are expected to address in their ethics applications. Reviewers may simply select the appropriate option (Yes; No; N/A) next to each of the comments below. Reviewers are, however, encouraged to provide additional comments if required to assist the BaSSREC chairperson and the applicants to address particular concerns or to complement the applicant on a good

1. Aims, background and significance	Yes	No
The study aims are clearly specified.	☐	☐
The candidate provides an adequate background to the proposed study.	☐	☐
2. Scientific design and procedures		
The applicant provides an adequate discussion of and justification for their chosen scientific design.	☐	☐
The rationale and details of research procedures are adequately described and acceptable. These include, among others, further details about the sampling procedures, methods of data collection and data analysis.	☐	☐
The principal and co-investigators (including students and/or fieldworkers collecting the data) have appropriate academic credentials and/or experience to conduct this study.	☐	☐

3. Inclusion and exclusion criteria	Yes	No
The applicant has inclusion and exclusion criteria for data (literature or secondary data)	☐	☐
The inclusion and exclusion criteria are reasonable.	☐	☐
I confirm that this study does not include any human participants.	☐	☐

4. Recruitment and enrollment		
In my review, I confirm that this study does not include any human participants.	☐	☐

5. Risks and benefits		
I confirm that this study does not pose any risk to human participants.	☐	☐
I confirm that this study does not pose reputational risk to the NWU	☐	☐

6. Gaining informed consent		
I confirm that conducting this study does not require gaining informed consent from human participants.	☐	☐

7. Anonymity, confidentiality and privacy		
I confirm that this study only includes publicly available data (such as literature or publicly available secondary data).	☐	☐

8. Reimbursement		
I confirm that no persons will be reimbursed for participating in this study	☐	☐

9. What happens at the end of the study?		
The applicant adequately discusses how findings from the study will be disseminated to the wider research community (e.g. peer-reviewed scientific journals, conference presentation, and internal report).	☐	☐

10. Conflicts of interest		
Do any of the persons involved in the design, research process or analysis of the research have any proprietary interests (e.g. royalties, patents, trademarks, copyrights or licensing agreements) involving any agent, device or software being evaluated in the study?	☐	☐
If yes, is this adequately justified by the applicant?	☐	☐

11. Additional comments or questions

12. Final assessment

No risk ◯ Low risk ◯

13. I recommend for the application to be (check):

Approved: ◯

Accept unconditionally.

Conditional approval with minor changes: ◯

Accepted with minor changes as indicated on report (for final assessment of the chairperson/BaSSREC nominee). The full application should be resubmitted via email to the BaSSREC administrator.

Deferred with major changes: ◯

Revised protocol must be sent to the chairperson and reviewers. The full application should be resubmitted via email to the BaSSREC administrator.

Deferred with major changes:

Revised application to be tabled at a full committee meeting. The full application should be resubmitted via email to the BaSSREC administrator. ◯

Disapproved:

Risks significantly outweigh the benefit or value of the knowledge to be gained; there are significant ethical concerns or questions that make the study unacceptable. ◯

Referred to another Research Ethics Committee (e.g. HSSREC or HREC) for review (please motivate below).

7.7 BaSSREC reviewer report

BASIC SOCIAL SCIENCES RESEARCH ETHICS COMMITTEE (BaSSREC)

REVIEWER REPORT

Researcher: _____

Project Title: _____

Ethics Number: _____

Reviewer: _____

The following subsections provide reviewers with guidance to remind them about important ethical issues that applicants are expected to address in their ethics applications. Reviewers may simply select the appropriate option (Yes; No; N/A) next to each of the comments below. Reviewers are, however, encouraged to provide additional comments if required to assist the BaSSREC chairperson and the applicants to address particular concerns or to complement the applicant on a good application.

1. Aims, background and significance

Criteria	Yes	No
The study aims are clearly specified.		
The candidate provides an adequate background to the proposed study.		
Comments or questions		

2. Scientific design and procedures

Criteria	Yes	No
The applicant provides an adequate discussion of and justification for their chosen scientific design.		
The rationale and details of research procedures are adequately described and acceptable. These include, among others, further details about the sampling procedures, methods of data collection and data analysis.		
The principal and co-investigators (including students and/or fieldworkers collecting the data) have appropriate academic credentials and/or experience to conduct this study.		
Adequate measures are in place for data-monitoring (e.g. the reliability, validity and/or trustworthiness of the data).		
Comments or questions		

3. Inclusion and exclusion criteria

Criteria	Yes	No	N/A

The selection of participants is appropriate for the question being asked.			

The inclusion and exclusion criteria (if applicable), are clearly stated and reasonable (in-keeping with the principal of distributive justice).			
If there are vulnerable groups included, is the inclusion of vulnerable populations justified?			
If yes, are adequate safeguards included to protect their rights and welfare?			
The researcher has taken steps to ensure that the participants' decision to enrol will not be influenced by their potential relationship to the researcher, i.e. if any potential participants are in a dependent relationship with the researchers or persons recruiting for the study (e.g. student/lecturer, doctor/patient, and employer/employee).			
Comments or questions			

4. Recruitment and enrolment

Criteria	Yes	No	N/A
The applicant clearly identifies how and by whom prospective participants will be identified for recruitment into the study, i.e. the step-by-step recruiting process is discussed and justified.			
The location, setting, and timing of recruitment are acceptable.			
The recruitment methods are discussed (e.g. the materials to be used such as flyers, posters, or advertisements).			
The recruitment material is attached to this application (if applicable).			
The attached recruitment material is in order.			
The study requires NWU Gatekeeper Approval, i.e. reference should be made to gaining NWU Gatekeeper Approval from the NWU Registrar directly following the ethics approval.			
Comments or questions			

5. Risks and benefits

Criteria	Yes	No	N/A
The applicant has adequately identified, evaluated and described the potential risks and benefits associated with the study (e.g. physical, psychological, social, and economic, etc.). This speaks to the importance of observing the ethical principles of non-maleficence and beneficence.			
The applicant adequately identifies the risks to the community or a particular group of individuals (e.g. stigmatisation).			
The location of the study is adequate to assure participants' safety and comfort.			
The applicant provides clear explanations of how potential risk will be minimised/managed.			
The applicant attached written proof of agreement from potential counsellors, psychologists and/or social workers who are willing to assist participants when requested (if applicable).			
The risks are reasonable in relation to anticipated benefits.			
Reference is made to Covid-19 risks and its mitigation (if applicable).			

Comments or questions

6. Gaining informed consent

Criteria	Yes	No	N/A
The applicant clearly identifies who will obtain informed consent from the prospective participants, i.e. the step-by-step informed consent process is discussed and justified.			
The applicant clearly identifies how the above person(s) will obtain informed consent from the prospective participants, i.e. the step-by-step informed consent process is discussed and justified.			
The process minimises the possibility of undue influence/coercion.			
The process provides sufficient time, privacy and an adequate setting for participants to decide whether to consent.			
The applicant will appoint a translator to ensure that participants clearly understand their role in the study and the consent process (if applicable).			
The applicant used and attached the prescribed BaSSREC informed consent leaflet to the application.			
The language used in the consent forms is appropriate for participants' level of understanding.			
The risks and mitigation strategies align directly with those identified in the ethics application form and research proposal.			
Reference is made to the fact that informed consent and participation are voluntary.			
Comments or questions			

7. Anonymity, confidentiality and privacy

Criteria	Yes	No	N/A
The applicant adequately describes the measures to protect participants' privacy.			
The applicant adequately describes the measures to protect participants' anonymity.			
The applicant adequately describes the measures to protect participants' confidentiality.			
The protocol describes how written records, video or audio-recordings will be secured (i.e. storage and its or final disposal). Please note: Data should be safely stored for a period of five (5) years.			
Comments or questions			

8. Reimbursement

Criteria	Yes	No	N/A
The applicant adequately discusses how they will avoid out-of-pocket expenses and costs incurred by participants (e.g. travel expenses, parking costs, data-costs for virtual interviews and lost wages).			
Will participants be compensated for their participation?			
If participants are compensated for the study, is this reasonable?			
Comments or questions			

9. What happens at the end of the study?

Criteria	Yes	No	N/A
The applicant adequately discusses how findings from the study will be disseminated to the wider research community (e.g. peer-reviewed scientific journals, conference presentation, and internal report).			
The applicant adequately explains how they will inform participants about the findings of the study.			
Comments or questions			

10. Conflicts of interest

Criteria	Yes	No	N/A
Do any of the persons involved in the design, research process or analysis of the research have any proprietary interests (e.g. royalties, patents, trademarks, copyrights or licensing agreements) involving any agent, device or software being evaluated in the study?			
If yes, is this adequately justified by the applicant?			
Comments or questions			

11. Additional comments or questions

Comments or questions
Please complete the BaSSREC Rebuttal Report and submit along with the full BaSSREC application upon resubmission. Highlight all changes made in the relevant documents in YELLOW. Ensure that the content of the BaSSREC application form, research proposal and consent/assent documentation **align directly**. Please consultthe BaSSREC website for further information: http://humanities.nwu.ac.za/basic-and-social-sciences-research-ethics-committee-bassrec

12. Final assessment

Risk level (check)

No risk	
Low risk	
Medium risk	
High risk	

I recommend for the application to be (check):

Approved: Accept unconditionally.	
Conditional approval with minor changes: Accepted with minor changes as indicated on report (for final assessment of the chairperson/BaSSREC nominee). *The full application should be resubmitted via email to the BaSSREC administrator.*	
Deferred with major changes: Revised protocol must be sent to the chairperson and reviewers. *The full application should be resubmitted via email to the BaSSREC administrator.*	
Deferred with major changes: Revised application to be tabled at a full committee meeting. *The full application should be resubmitted via email to the BaSSREC administrator.*	
Disapproved: Risks significantly outweigh the benefit or value of the knowledge to be gained; there are significant ethical concerns or questions that make the study unacceptable.	
Referred to another Research Ethics Committee (e.g. HSSREC or HREC) for review (please motivate below).	

7.8 BaSSREC rebuttal report

Faculty of Humanities: Research & Innovation - M&D Administration

BaSSREC REBUTTAL REPORT– AMENDMENTS TO ETHICS APPLICATION

NAME	
STUDENT NUMBER	
RESEARCH TITLE	

		Recommendations of reviewers *Please type the remarks of the reviewer in this column as it relates to the particular component of your application.* ● *If there were no comments, simply indicate "No reviewer comments".*	**Response of student and supervisor/promoter** ● *Please type your detailed rebuttal to the reviewers' comments.* ● *Remember to highlight ALL changes in your research proposal, informed consent statement and ethics application.*	*Page*
1	Aims, background and significance			
2	Scientific design and procedures			
3	Inclusion and exclusion criteria			
4	Recruitment and enrolment			
5	Risks and benefits			
6	Gaining informed consent			
7	Anonymity, confidentiality and privacy			
8	Reimbursement			
9	What happens at the end of the study?			
10	Conflicts of interest			
11	Additional comments or questions			

7.9 BaSSREC appointment letter

NWU Senate Committee for Research Ethics

Dear

NWU RESEARCH ETHICS COMMITTEE for Basic and Social Sciences (BaSSREC)

APPOINTMENT

We hereby confirm your appointment as member of the NWU **Research Ethics Committee for Basic and Social Sciences (BaSSREC)** as approved by the Faculty of Humanities on - - - - - - - - - and the NWU Research Ethics Regulatory Committee on - -.

Appointment date: **Appointment expiry date**:

NWU has Public Liability Insurance cover in terms of which the aforementioned committee member is indemnified in respect of any claim related to his/her activities as a member of the committee.

The attached Code of Conduct for BaSSREC members and the Confidentiality Undertaking of the NWU, are to be signed by you and returned to the chairperson of the BaSSREC.

The terms of reference for the BaSSREC as well as the standard operating procedures will be sent to you after receipt of the signed documents referred to above.

Yours sincerely

Prof. Mirna Nel
Deputy-Dean Faculty of Humanities

7.10 BaSSREC code of conduct

Code of conduct for members of the Research Ethics Committee for Basic and Social Sciences (BaSSREC)

All BaSSREC members will be expected to sign the NWU code of conduct for researchers.

Over and above this code of conduct it will be expected of BaSSREC members to:

- Agree to a term of office of five years;
- Familiarise themselves with the institutional documentation as well as national and international research ethics guidelines;
- Attend research ethics training sessions to keep abreast with the latest changes in this field (proof of evidence at least once every three years);
- Always act with integrity;
- Regularly attend BaSSREC meetings;
- Be punctual in the attendance of these meetings;
- Diligently perform all responsibilities delegated to them;
- Maintain all of these responsibilities in compliance with national and international ethical and regulatory requirements;
- Consider and declare any prior interest and/or involvement in any matter being discussed at a BaSSREC meeting to avoid potential conflict of interest (personal or financial);
- To adhere to the Confidentiality Agreement of the NWU and to keep confidential information pertaining to research ethics applications.

I _____will adhere to the terms set out above.

Signature: _____

Date: _____

7.11 BaSSREC and NWU Confidentiality Agreement

NORTH-WEST UNIVERSITY
YUNIBESITI YA BOKONE-BOPHIRIMA
NOORDWES-UNIVERSITEIT

RESEARCH ETHICS COMMITTEE FOR BASIC AND SOCIAL SCIENCES (BaSSREC)
CONFIDENTIALITY UNDERTAKING

entered into between:

I, the undersigned

Prof / Dr / Mr / Ms _____

Identity Number:_____

Address:_____

hereby undertake in favor of the **NORTH-WEST UNIVERSITY**, a public higher education institution established in terms of the Higher Education Act No. 101 of 1997

Address: Office of the Institutional Registrar, Building C1, 53 Borcherd Street, Potchefstroom, 2520

(hereinafter the "NWU")

1 Interpretation and definitions

1.1 In this undertaking, unless inconsistent with, or otherwise indicated by the context:

1.1.1 "Confidential Information" shall include all information that is confidential in its nature or marked as confidential and shall include any existing and new information obtained by me after the Commencement Date, including but not be limited in its interpretation to, research data, information concerning research participants, all secret knowledge, technical information and specifications, manufacturing techniques, designs, diagrams, instruction manuals, blueprints, electronic artwork, samples, devices, demonstrations, formulae, know-how, intellectual property, information concerning materials, marketing and business information generally, financial information that may include remuneration detail, pay slips, information relating to human capital and employment contract, employment conditions, ledgers, income and expenditures and other materials of whatever description in which the NWU has an interest in being kept confidential; and

1.1.2 "Commencement Date" means the date of signature of this undertaking by myself.

1.2 The headings of clauses are intended for convenience only and shall not affect the interpretation of this undertaking.

2 Preamble

2.1 In performing certain duties requested by the NWU, I will have access to certain Confidential Information provided by the NWU in order to perform the said duties and I agree that it must be kept confidential.

2.2 The NWU has agreed to disclose certain of this Confidential Information and other information to me subject to me agreeing to the terms of confidentiality set out herein.

3 Title to the Confidential Information

I hereby acknowledge that all right, title and interest in and to the Confidential Information vests in the NWU and that I will have no claim of any nature in and to the Confidential Information.

4 Period of confidentiality

The provisions of this undertaking shall begin on the Commencement Date and remain in force indefinitely.

5 Non-disclosure and undertakings

I undertake:

5.1 to maintain the confidentiality of any Confidential Information to which I shall be allowed access by the NWU, whether before or after the Commencement Date of this undertaking. I will not divulge or permit to be divulged to any person any aspect of such Confidential Information otherwise than may be allowed in terms of this undertaking;

5.2 to take all such steps as may be necessary to prevent the Confidential Information falling into the hands of an unauthorised third party;

5.3 not to make use of any of the Confidential Information in the development, manufacture, marketing and/or sale of any goods;

5.4 not to use any research data to which I shall be allowed access by the NWU as Confidential Information, for my own publication purposes;

5.5 not to use or disclose or attempt to use or disclose the Confidential Information for any purpose other than performing research purposes only and includes questionnaires, interviews with participants, data gathering, data analysis and personal information of participants/research subjects;

5.6 not to use or attempt to use the Confidential Information in any manner which will cause or be likely to cause injury or loss to a research participant or the NWU; and

5.7 that all documentation furnished to me by the NWU pursuant to this undertaking will remain the property of the NWU and upon the request of the NWU will be returned to the NWU. I shall not distribute copies of any such documentation without the prior written consent of the NWU.

6 Exception

The above undertakings by myself shall not apply to Confidential Information which I am compelled to disclose in terms of a court order.

7 Jurisdiction

This undertaking shall be governed by South African law be subject to the jurisdiction of South African courts in respect of any dispute flowing from this undertaking.

8 Whole agreement

8.1 This document constitutes the whole of this undertaking to the exclusion of all else.

8.2 No amendment, alteration, addition, variation or consensual cancellation of this undertaking will be valid unless in writing and signed by me and the NWU.

Dated at Vanderbijlpark, this _____20____

Witnesses:

1 .....

2 ....

(*Signatures of witnesses*) (*Signature*)

7.12 Covid-19 research-related regulations

IMPLICATIONS OF ALERT LEVELS FOR RESEARCHERS AND POSTGRADUATE STUDENTS DURING THE COVID-19 PANDEMIC (VERSION 3)

Prof Minrie Greeff

Emeritus Professor: Africa Unit for Transdisciplinary Health Research (AUTHeR)

North-West University

23 September 2020

1. Background of this document

South Africa went in a lockdown at midnight on the 26 March 2020 at a lockdown alert level 5 in response to the COVID-19 pandemic and since then moved to different levels as the pandemic progressed. However, to manage the risk associated with the pandemic and its impact on the livelihoods of South Africans, the SA government decided to follow a *risk-adjusted approach* based on specific criteria and will adjust the levels across the country based on these criteria (different provinces may be placed under different lockdown levels based on the level of COVID-19 infections in the particular province).

Criteria for the risk-adjusted approach:

- The level of the infection rate
- The rate of transmission
- Capacity of health facilities
- Extent of the public health intervention
- The economic and social impact of continued restrictions

2. Risks involved in conducting research during the COVID-19 pandemic

To be able to manage the risks inherent in undertaking research during a global pandemic, it is necessary to be aware of these risks. As such, the following section indicates the main risks that have to be addressed before research can proceed.

2.1 Risk to the researcher:

- Researcher/postgraduate student becoming infected due to contact with an asymptomatic/symptomatic person (fellow researcher or participant).
- Researcher/postgraduate student becoming infected by handling objects contaminated by the virus.
- Researcher/postgraduate student becoming infected by entering a high-risk COVID 19 area.
- Infecting co-researchers due to the aforementioned actions.
- Infecting own family members due to the aforementioned actions.
- More severely affected by COVID-19 if over the age of 60 and having a comorbidity or an illness causing an immunocompromised health status.
- Being fined or arrested for not adhering to appropriate lockdown alert level restrictions e.g. not wearing masks, travelling without appropriate permits etc.

2.2 Risk to the participant:

- Infected by a researcher or fellow research participant that might be asymptomatic/symptomatic during a visit to the HEI.
- Infected by a researcher that might be asymptomatic/symptomatic during a visit by the researcher to his/her home or community centre.
- Infected by handling objects contaminated by the virus.
- More severely affected by COVID-19 if over the age of 60 and having a comorbidity or an illness causing an immunocompromised health status.
- Carrying the virus from the research site into the home or community.
- Being fined or arrested for not adhering to appropriate lockdown alert level restrictions e.g. not wearing masks, travelling without appropriate permits etc.

2.3 Reputational damage to researchers and/or the university:

- Participants infected by the researcher during the conduct of research blaming the university.
- The researcher carrying the virus into a private home or the community and the university being blamed for it.
- Researchers and postgraduate students becoming infected during research and blaming the university.
- Researchers not adhering to disaster and lockdown regulations e.g. visiting participants at their houses when social interaction is prohibited.

3. Health guidelines to follow during the COVID-19 pandemic

Specific guidelines have been formulated by the SA government to follow during the pandemic.

- Social distancing of at least 1.5 metres.
- Regular handwashing with soap or 80% alcohol-based sanitising hand rub.
- Wearing an appropriate mask when leaving home.
- Not to touch your face with unwashed hands.
- Covering your mouth and nose when you cough or sneeze, preferably into a tissue or your elbow.
- Sanitising all areas and surfaces.
- Avoid unnecessary public travelling and stay away from large groups of people.
- Refrain from smoking and other activities that weaken the lungs.
- Stay home if you feel unwell.
- Contact the appropriate health authorities, if you suspect you have COVID-19, to arrange for screening testing and possible treatment.
- Making use of the COVID app.

4. Implications of the lockdown levels for researchers

The government is following a risk-adjusted approach based on the following criteria:

- The level of the infection rate
- The rate of transmission
- Capacity of health facilities
- Extent of the public health intervention
- The economic and social impact of continued restrictions

Important note: It is the responsibility of each researcher to be aware of the alert level and to adhere to all regulations and guidelines of the specified level. Should a level revert back to a higher level, the researcher should adjust to the indicated implications discussed in the table below.

Level	Regulation Implications for Social Interaction and Movement	Higher Education Guidelines	Implications for Researchers
Alert Level 5 **Drastic measures to contain the spread of the virus and save lives**	• Stay home. • Leave house only to do allowable shopping/work/medical care/funeral of close family members. • Only essential services. • Transport restrictions. • Movement restrictions. • No gatherings of more than 10 people outside of a workplace will be permitted.	• Higher Education under total lockdown with only essential services allowed on campus. • Only permits to do essential upkeep of the university.	• No research activities e.g. laboratory work or contact with human participants. • **Only** clinical research as part of patient care or treatment and vaccine trial research or laboratory work linked to COVID-19 research. • Telephone and/or online platform interaction with human participants. • Online quantitative research e.g. surveys.
Alert Level 4 **Extreme precautions to limit**	• Leave house only to do allowable shopping/work/medical care/funeral of close family members. • To perform an essential and/or permitted service.	• Higher Education under lockdown with extremely limited and restricted access to the university by permit only.	• Essential laboratory work with a permit. • No research that requires physical human participant interaction in close proximity e.g. face-to-face
community transmission and outbreaks while allowing some limited activity	• Have to go home after work. • Home between 20:00 and 05:00. • Preferably work from home. • People above 60 and with co-morbidities to work from home. • Not allowed to visit with friends and family. • No social activities or gatherings. • No movement over provincial boundaries except for work and school. • Wear a mask when you leave home. • Courier and postal services available . • Limited public transport. • No gatherings of more than 10 people outside of a workplace will be permitted	• Only permits to do essential upkeep of the university.	interviews, focus groups, human sample collection, etc. except clinical research as part of patient care or treatment and vaccine trial research or laboratory work linked to COVID-19 research. • Telephone and/or online platform interaction with human participants. • Online quantitative research e.g. surveys.
Alert Level 3 **Restrictions on many activities, including at work-places and socially, to address a high risk of transmission**	• Leave house only to do allowable shopping/work/medical care/funeral of close family members. • To perform an essential and/or permitted service. • Have to go home after work. • Preferably work from home. • People above 60 and with co-morbidities to work from home. • Not allowed to visit with friends and family. • No social activities or gatherings. • No movement over provincial boundaries except for work and school. • Wear a mask when you leave home. • Courier and postal services available. • Transport restrictions. • Movement restrictions.	• Maximum of 33% of students return to campus. • Age and co-morbidity of staff managed. • Campus readiness and preparedness must be well managed. • Daily screening. • Hand sanitisers available. • High-risk areas identified and monitored e.g. libraries and laboratories. • Issuing of permits as the phase-in process occurs. • Ensure physical distancing. • Controlled return of students: - Final year students - Practical/clinical training - Laboratory work.	• Essential laboratory work with a permit and appropriate safety measures as indicated under section 3 or laboratory work linked to COVID-19 research. • Access to the university and research activities only if you are: - A final year student - Need to do practical/clinical training - Laboratory work. • No research that requires physical human participant interaction in close proximity e.g. face-to-face interviews, focus groups, human sample collection, etc. except clinical research as part of patient care or

	• No gatherings of more than 10 people outside of a workplace will be permitted.		treatment and vaccine trial research. • Telephone and/or online platform interaction with human participants. • Online quantitative research e.g. surveys. • No research that is to be conducted in homes, communities, restricted government facilities, schools and facilities for the aged .
Alert Level 2 **Social distancing and restrictions on leisure and social activities to prevent a resurgence of the virus**	• Wear a mask when you leave home, wash or sanitize hands, adhere to social distancing of at least 2 metres, and sanitize surfaces (see health guidelines for more detail). • Leave house to do allowable shopping/work/medical care/funeral of close family members. • Preferably work from home. • People above 60 and with co-morbidities to work from home and take additional preventive measures e.g. voluntary self-isolation. • Home between 22:00 and 04:00. • Allowed to visit with friends and family but not more than 10 people. • Interprovincial movement allowed. • Domestic air travel/car rental. • No international travel. • Visits of members of the public to governmental facilities e.g. correctional centres, health establishments, as well as	• Maximum of 66% of the student population to return to campus • Staff allowed in a phased in manner. • Age and co-morbidity of staff managed. • Campus readiness and preparedness must be well managed. • Daily screening. • Hand sanitisers available. • High-risk areas identified and monitored e.g. libraries and laboratories. • Issuing of permits as the phase-in occurs. • Ensure physical distancing. • Controlled return of students: - Final year students - Practical/clinical training - Laboratory work	• Essential laboratory work with permission and appropriate safety measures as indicated under alert level 3. • Access to the university and research activities only if you are: - A final year undergraduate student - Need to do practical/clinical training - Laboratory work - Postgraduate students - Special requests • No research participant allowed at the university • Restricted research that requires physical human participant interaction in close proximity, which must be conducted under strict precautionary measures, where there is not more than 2 researchers present in a participant's *home*.
	to older persons' residential facilities are prohibited except to the extent and in the manner directed by the relevant Cabinet member.	- First-year undergraduate students.	• Restricted research that requires physical human participant interaction in close proximity, which must be conducted under strict precautionary measures, where there is not more than 2 researchers and 8 participants present for any type of *group work* in *community facilities* e.g. church hall, community centre etc. • Prohibition placed by the government on any visits by researchers to any governmental facilities e.g. correctional centres, health establishments, educational facilities e.g. school or universities, as well as to older persons' residential facilities. • Researcher has to ensure that the research team and participants have been screened for COVID-19, have masks, have used sanitiser and adhere to social distancing of at least 2 metres. • All possible risk mitigating measures should have been taken to ensure safety of the participants and the researchers. • Telephone and/or online platform interaction with human participants can continue as before. • Online quantitative research e.g. surveys, continue as before.

			Note: Please use the document "COVID-19 research risk assessment and management approach" (Greeff, Version 2 of 17 July 2020) for details on precautionary measures.
Alert Level 1 **Most normal activity resume, with precautions and health guidelines, followed at all times.** **All prepared for an increase in alert levels if necessary**	• Wear a mask when in a public place, except when undertaking vigourous exercise. • Adhere to all the health protocols i.e. wash or sanitize hands, adhere to social distancing of at least 1.5 metres, and sanitize surfaces (see health guidelines for more detail). • An owner of any indoor or outdoor facility where gatherings are held must display the certificate of occupancy which sets out the maximum number of persons the facility may hold. • Most gatherings are limited to 250 persons or less in the case of indoor gatherings. Provided that no more than 50 percent of the capacity of the venue is used, with persons observing a distance of at least one and a half metres from each other. • Gatherings at a workplace for work purposes are allowed. • All sectors permitted to work except night clubs, passenger ships for international leisure purposes, and attendance of sports event.	• 100% of student population returns to campus with: - Social distancing - Health protocols - International students return. • Age and co-morbidity of staff managed. • Campus readiness and preparedness must be well managed. • Daily screening. • Hand sanitisers available. • High-risk areas identified and monitored e.g. libraries and laboratories. • Issuing of permits as the phase-in occurs. • Ensure physical distancing.	• Wear a mask and adhere to all health protocols. • Laboratory work and appropriate safety measures. • Access to universities and research activities open to all students and staff but managed according to each institutions own specific guidelines. • It would be the choice of the universities whether they allow on site research participants. Provided that no more than 50 percent of the capacity of the venue is used, with persons observing a distance of at least one and a half metres from each other. • Restricted research that requires physical human participant interaction in close proximity, which must be conducted under strict precautionary measures, where there is not more than 2 researchers present in a participant's *home*. • Restricted research that requires physical human participant
	• Visits of members of the public to governmental facilities e.g. correctional centres, health establishments, as well as to older persons' residential facilities are prohibited except to the extent and in the manner directed by the relevant Cabinet member. • Home between 00:01 and 04:00. • All modes of transportation allowed with restrictions of stringent hygiene conditions. • The 18 land borders which were partially operational, will be fully operational, and the 35 land borders currently closed, will remain closed. • All travellers from the African Continent and from countries outside the African Continent with a low rate of COVID-19 infection and transmission, will resume with specific provision (See amendment of regulations issued in terms of section 27(2) 18 September 2020).		interaction in close proximity, which must be conducted under strict precautionary measure, where there is not more than 2 researchers and 8 participants present for any type of *group work* in *community facilities* e.g. church hall, community centre etc. • Restricted visits by researchers to any governmental facilities e.g. correctional centres, health establishments, educational facilities e.g. school or universities, as well as to older persons' residential facilities. • Researcher has to ensure that the research team and participants have been screened for COVID-19, have masks, have used sanitiser and adhere to social distancing of at least 2 metres. • All possible risk mitigating measures should have been taken to ensure safety of the participants and the researchers. • Telephone and/or online platform interaction with human participants can continue as before. • Online quantitative research e.g. surveys, can continue as before. **Note: Please use the document "COVID-19 research risk assessment and management approach" (Greeff, version 2 of 17**
			July 2020) for details on precautionary measures.