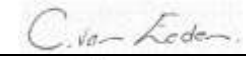
FACULTY OF HUMANITIES

Standard Operating Procedure:
SOP_HSSREC_2.4

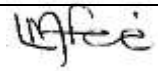
SOP for the research ethics approval application process

	Standard Operating Procedure		
Title	SOP for the research ethics approval application process		
SOP No	SOP_HSSREC_2.4	**Version No**	2
Date of approval		**Revision date**	April 2023
Web address		**Page No**	

1 COMPILATION AND AUTHORISATION

Action	**Designated person**	**Signature**	**Date**
Revised by:	Prof. C. van Eeden		7 April 2021
Checked by:	Prof. J. Rothmann		22 April 2021
Authorised by:	Prof. M. Nel		28 Sep. 21

2 DISTRIBUTION

Department/Unit	**Name**	**Signature**	**Date**
HSSREC	Prof. M. Heyns		27/4/21
Faculty of Humanities: Faculty Board	Prof. LM Fourie		29 Sept 2021
Committee for Research, Innovation and Higher Degrees	Prof. M. Nel		28 Sep. 21

3 DOCUMENT HISTORY

Date	**Version No**	**Reason for revision**
9 March 2018	1	Revision of 2015 SOP in line with NHREC audit of 30 November 2017. Based on the SOP of the NWU: HREC.
27 April 2021	2	Revision of 2018 SOP in line with NHREC requirements. Based on the SOP of the NWU: HSSREC: 2018.
29 October 2021	3	Final approval of HSSREC SOP documentation by Faculty Board and Deputy Dean Research and Innovation, Faculty of Humanities.

4 PURPOSE OF THE SOP

The purpose of this SOP is to provide researchers with a clear systematic procedure to follow when applying for one of the five options for ethics approval:

4.1 A first-time application for a *single study* or a *larger study* (See 6 for definitions).

4.2 A *sub-study application* (master's or doctoral student) under an approved *larger* study.

4.3 A systematic review.

4.4 A narrative literature review.

4.5 An application for an *amendment* to an approved study.

4.6 An application for an extension of an approved research project.

4.7 Monitoring report.

5 SCOPE

Scope of research ethics evaluation and approval by the NWU-HSSREC:

- Studies within the broad field of humanistic disciplines that research human functioning in social, political, institutional, cultural and historical environments and developmental contexts (excluding health sciences).
- Other studies in the Faculty of Humanities that involve vulnerable populations or medium to high risk levels.
- Delegated power to consent to research involving minors: DELEGATION OF POWER TO CONSENT TO RESEARCH INVOLVING MINORS AS PRESCRIBED BY SECTION 71 (3)(a)(ii) OF THE NATIONAL HEALTH ACT No.61 OF 2003 TO HEALTH RESEARCH ETHICS COMMITTEES REGISTERED WITH THE NATIONAL HEALTH RESEARCH ETHICS COUNCIL.

This SOP is intended for all researchers and postgraduate students of the NWU: Faculty of Humanities who plan to conduct studies in human social science fields that use human participants. It covers the full application process to obtain research ethics approval before research is conducted, permission for amendments and the monitoring process during research.

6 ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/definition	**Description**
HSSREC	Human Social Sciences Research Ethics Committee
NWU	North-West University
SCRE	Senate Committee for Research Ethics
Single study	A study consisting of one or more researchers not intending to involve master's or doctoral students, or for the purpose of a single master's or doctoral study. OR A single study could also be *affiliated* with *another study* not approved as a larger study by using the other study's previously collected data, but using a specific methodology for obtaining results. The methodology is not specified in the original *other study*. The project leader of the other study

	must give permission for the use of the data and specify its use. The study could either: 1) fulfil one of the previously stated objectives not yet achieved, or 2) work on secondary data analysis. OR A study intending to run over several years, collecting data to be used with the described methodology focusing more on data collection. Follow-up studies will use various methodologies to obtain results from the originally collected database.
Larger study	A study planning to involve several master's and doctoral students and that clearly identifies the objectives per student as well as the methodology to be used by each of the potential students. The extent of the data is more extensive in nature and can accommodate several students. The objective(s) should indicate whether it is for a master's or a doctoral student. The inclusion of this type of study is to simplify the research ethics application process for future master's and doctoral students that will be working in this study.
Sub-study	A sub-study that has been identified as a potential master's or doctoral study in the objectives of an ethically approved larger study by covering a *specific stated objective(s)* of the larger study, using *identical methodology* or section(s) of the methodology as the larger study. It could be that data have already been collected or are going to be collected. NB: The sub-study can add **no new methodology** that was not covered in the larger study. If the latter is needed, the larger study should be amended first.
Systematic review	A systematic review is a study wherein the entire scope of available publications or published works regarding a specific topic is methodically and critically analysed. Generally, a systematic review is done according to very specific guidelines, such as those defined by the Cochrane Collaboration or as indicated in the PRISMA statement. Systematic reviews can be done on their own, or may also include a meta-analysis of the published results to provide a summary decision regarding the evidence for or against a specific topic.
Rapid review	A rapid review is a type of systematic review that is generally undertaken to inform decision makers of a specific emergent or urgent topic. As the reason for doing a rapid review is to provide evidence in situations where time is of the essence, certain procedures of the usual systematic review process are simplified or removed in order to reduce the turnaround time of the review.
Narrative literature review	A narrative review summarises the key findings of a specific topic and may follow a less structured analysis of all published outputs available than in the case of a systematic review. The summation of the data is generally more qualitative than quantitative in nature.
Amendment	Any change made to the originally approved study and that happens while the study is being conducted. No change may be implemented without first obtaining the necessary approval of the HSSREC.
Monitoring	Monitoring refers to the process of observing quality and conduct of the research while in progress. *Passive monitoring* refers to the compulsory reporting required by the HSSREC (minimum on an annual basis). *Active monitoring* refers to unannounced monitoring visits conducted by

	the HSSREC to research sites or where data is stored. A study is approved on a year-by-year basis, based on the submission and positive outcome of the review of the annual monitoring report and written confirmation that the study may continue for another year.
Extension	If a researcher requires extension for a study's ethics approval not falling in the mentioned monitoring time frame, extension can be requested by submitting a monitoring report to the HSSREC.

7 RESPONSIBILITIES

The responsibility lies with the researcher (employee/student of the University) or supervisor to ensure that research ethics approval is obtained in time before a study is started and that the study is conducted according to the ethics guidelines and the approved proposal. The supervisor remains the primary accountable person for the way in which the study obtained ethics approval and is conducted. The HSSREC communicates with the researcher or supervisor and not the student. The latter is the responsibility of the supervisor.

8 PROCEDURE(S)

8.1 For first-time application for a single study (including an affiliated study to another study with previously collected data) or a larger study with defined postgraduate student projects:

Process:

Conceptualise the research study (observing problems, reading literature, discussion, etc.)

Develop the research proposal and applicable accompanying documentation and enter into negotiations with potential authorities to ensure that they will be open for the research to be conducted.

Obtain the necessary documents from the relevant sources, i.e. the HSSREC Website.

Submit the proposal to the *scientific/proposal committee* in your research entity for scientific evaluation and approval.

Obtain a letter of approval from them, which has to be attached to the ethics application.

Once the proposal has been approved by the scientific/proposal committee, submit the title registration request through the Faculty office (this is a process that runs parallel to the research ethics application process).

Submit the completed ethics application to the HSSREC administration, by means of the InfoEd system (Teresa.Smit@nwu.ac.za or Nkosinathi.Machine@nwu.ac.za) and via email to the HSSREC Administrator (Yvette van der Merwe; 13128388@nwu.ac.za). Refer to the HSSREC Website for further information in this regard.

Supervisors should assist students with this process.

Application sent by InfoEd to the HSSREC administrator who will, in consultation with the chairperson, send the application to reviewers.

The application is discussed at the HSSREC meeting.

Decision process

- Aggregate individual views
- Deliberation (debate)
- Analogue (consensus)
- Vote, if necessary: Decision
- Approved
- Approved with minimal/several changes
- Deferred (too many changes and further committee deliberation needed)
- Disapproved (have to go back to the drawing board).

Formal letter of decision of the HSSREC with attached independent reviewer reports are sent to the applicant (always the supervisor or PI) as soon as possible (approximately three working days) after the meeting by the appropriate administrator.

Corrections are done by the applicant and are sent back as soon as possible to the HSSREC administrator.

A rebuttal letter should be included indicating *what, how* and *where* in the documentation the corrections were addressed. (Corrections should be highlighted in the various documents as well.)

The *total set* of new documentation should be included as this will then be the set used for monitoring purposes as required by the NHREC.

The updated application is re-sent to the same independent reviewers for the review of the corrections (three working days).

Corrections are either approved by reviewers or further corrections are requested.

If additional corrections are requested they should be corrected (as previously indicated) and re-submitted by the applicant to the HSSREC administration.

If approved, a letter of approval is sent to the researcher by the HSSREC administrator.

The letter will either indicate *final approval* or *conditional approval.* (Conditional approval is given when there are certain processes that have to occur before final approval can be given. E.g. approval of a study from the Department of Health (DoH) can only be applied for after the HSSREC gives approval. However, the HSSREC cannot approve the study without receiving the permission letter from the DoH therefore, *conditional approval* is granted. Where interview schedules will be developed as the study unfolds, the same could apply. The conditions required for final approval will be clearly stated.)

Once the English version of the informed consent form has been finally approved, the applicants can have the form translated into the culturally relevant languages. This is to ensure that the applicants only have to translate the informed consent documentation once it has been approved. Translations have to be done professionally by a registered translator and according to the NWU policy.

If a project has been conditionally approved, any other outstanding documents, e.g. permission letters from authorities or gatekeepers (e.g. Department of Health) that could only be obtained after ethics approval was obtained, must be sent to the HSSREC administration as soon as possible.

If the *conditions associated with the approval are process-linked,* e.g. development of an interview schedule for phase two of a project is based on the results obtained during phase one of the project, then the research can continue until that point, e.g. the end of phase one, after which the applicant must submit the required documentation for approval before the study can continue.

This documentation must be submitted to the HSSREC administration.

For human social sciences research involving humans, the approved informed consent documentation as well as the translated versions of the informed consent documents after HSSREC approval, must be stamped by the HSSREC and signed by the chairperson before they are photocopied and used in the research.

Note: The translation of documents as indicated above, should be discussed by the HSSREC and the Committee for R&I of Faculty.

Research can begin as soon as the researcher has received the ethics approval letter.

The ethics certificate is only issued by the SCRE once all conditions are met.

If applicable, send any future amendments of the study or the rest of the documentation as agreed, to the HSSREC administration (see 8.4).

For ***minimal and medium risk studies*** *involving the human social functioning*, an ***annual monitoring report*** must be submitted for the duration of the study *at least two months before expiry* and annually until it has been completed. For ***high-risk studies***, **a *monitoring* report must be submitted *six monthly*** for the duration of the study. Ensure that the monitoring report submitted for the end of the annual term is submitted *at least two months before expiry* of the ethics approval of the project (see 8.5)

Note: Ethics approval of projects, due to legal requirements, have to be confirmed annually after a monitoring process.

It must be indicated in the monitoring report whether the study is *completed or not*. If the study is completed, the monitoring report acts as a *final report*. If the study is not complete, the monitoring report acts as a request to *extend the study*.

NB: If a study is terminated, immediately notify the appropriate administration.

Research dissemination/publication.

Checklist for attachments for a single study research ethics approval application to the HSSREC:

	Document	Tick if attached	Comment
1	Cover letter that indicates the title, researcher(s), the type of research ethics application, which documents are attached and that adds any explanations to clarify your application (If necessary and if not submitted through InfoEd).		
2	Executive summary of the project (150 words only).		
3	Proposal approved by a scientific/proposal committee.		
4	An ethics application form to provide additional information not covered in the proposal.		

5	Informed consent documentation and checklist (if collaborated study, informed consent from all centres OR if an affiliated study, the original informed consent documentation of the original study).		
6	Advertisements or recruitment materials.		
7	Questionnaire(s), interview schedule for interviews or focus groups, full description of other data collection methods e.g. written, constructed or drawn material.		
8	Approval letter of the study by the scientific committee.		
9	Two-page narrative CVs of all the researchers in the project.		
10	Proof of ethics training over the past three years for all the researchers in the project.		
11	Permission letters from governing bodies to conduct the research where applicable.		
12	Goodwill permission letters, e.g. from community leaders, where applicable, etc.		
13	Any other applicable documentation, e.g. contracts with collaborators, permits, etc.		
14	Signed NWU code of conduct for researchers for each team member.		

8.2 A research ethics approval application for a sub-study under an approved larger study

Process:

Conceptualise the sub-study and how it will fall within the approved larger study (observing the specific problems, reading focused literature, discussion, etc.).

Enter into negotiations with the project leader of the larger study, to ensure that he/she will be open for the sub-study to be conducted under the larger study.

Develop the research proposal for the sub-study and get the applicable accompanying documentation ready.

- Please see the process description under 8.1 and follow the same steps for your application.

Checklist for attachments for a sub-study under a larger study: Research ethics approval applications to the HSSREC:

	Document	Tick if attached	Comment
1	Have the data already been gathered, or are these in a process of longitudinal gathering, or part of an intervention?	If *yes:* If *no:*	Continue Make sure the larger study truly

			qualifies as a larger study by completing the attached evaluation form (Attached as Addendum 5).
2	Is the study clearly stated as an objective in the larger study?	If *yes:* If *no:*	Continue Make sure the larger study truly qualifies as a larger study by completing the attached evaluation form (Attached as Addendum 5).
3	Cover letter that indicates: Title of the larger study Title of the sub-study Student information Supervisor(s) What the sub-study is about and how it fits into the larger study; the objective(s) it intends to fulfil from the original study What documents are attached Detailed description of any outstanding issues of the larger study identified during the evaluation of the larger project (see evaluation form below) done by the project leader and how it will be addressed. *(Note: This should be handled as a separate amendment to the larger study if it involves changes that will still take place in future and should be done before the sub-study is submitted for ethics approval).*		
4	Executive summary of the sub-study (150 words only).		
5	Original informed consent documentation of the larger study.		
6	Copy of the ethics approval certificate of the larger study.		
7	Letter from the project leader clearly indicating *which objective(s) will be covered* as a sub-study under the larger project, as well as clearly specifying *what part of the previously collected data can be used* and *for what purpose.*		
8	Approval letter of the sub-study by the scientific/proposal committee.		
9	New proposal of the sub-study.		
10	Two-page narrative CVs of all the researchers in the sub-study.		
11	Proof of ethics training over the past three years for all the researchers involved in the study.		
12	Signed NWU code of conduct for researchers for each team member.		
13	Evaluation form to see if the larger study qualifies as a larger study (attached), completed by the project leader.		

8.3 Systematic review

In the case of a systematic review it may or may not have ethical implications when the study involves research with humans, e.g. deciding on an intervention or leading to guidelines. When a minimal risk (or higher) exists, ethics approval is required. **In some cases, the journal expects an ethics approval number. To obtain such a number, the research proposal needs to be evaluated by HSSREC beforehand, i.e. no retrospective approval will be given for the purpose of article submissions and/or publications**.

Process:

Conceptualise the research study (observing problems, reading literature, discussion, etc.).

Develop the research proposal and applicable accompanying documentation.

- Please see the process description under 8.1 and follow the same steps for your application.

Checklist for attachments for a systematic review: Research ethics approval applications to the HSSREC:

Document		Tick if attached	Comment
1	Cover letter that indicates the title, researcher(s), the type of research ethics application, which documents are attached, and that add any expectations to clarify your application (If necessary and if not submitted through InfoEd).		
2	Executive summary of the project (150 words only).		
3	Proposal approved by a scientific/proposal committee.		
4	A systematic review ethics application form to provide additional information not covered in the proposal.		
5	Approval letter of the study by the scientific committee.		
6	Two-page narrative CVs of all the researchers in the project.		
7	Proof of ethics training over the past three years for all the researchers in the project.		
8	Signed NWU code of conduct for researchers for each team member.		

8.4 Application for an amendment to an approved study

All changes to a research protocol and amendments to an HSSREC-approved ethics application must be reported in writing to the HSSREC.

Failure to do so may lead to immediate withdrawal of ethics clearance given to the study.

Process:

Decide what the required amendments are for the present study (*It may be that amendments require speedy approval*).

Review and update the proposal and any other study documentation and indicate clearly where the possible changes have been made in order to amend the existing study (using yellow highlight).

Formulate a clear and systematic cover letter guiding the HSSREC through the amendments that have been made, by stating:

- The title of the research;
- the researcher(s) involved in the study;
- that it is an amendment request;
- the nature of the amendment (indicating what changes have been made and where);
- which documents are attached to the application, and
- add any explanation to clarify your application.

Submit the amended ethics application to the HSSREC administration.

Attach all the required documents separately to the e-mail (see document checklist below).

Application sent by HSSREC administration (within three days) to the chairperson, deputy chairperson and independent reviewers.

The application is handled as expedited (changes not of a large nature) or discussed at the next HSSREC meeting (if large changes are made).

Decision process

- Aggregate individual views.
- Deliberation (debate).
- Analogue (consensus).
- Vote, if necessary: Decision.
- Approved.
- Approved with minimal/several changes.
- Deferred (too many changes and further committee deliberation needed).
- Disapproved (have to go back to the drawing board).

Formal letter of decision of the HSSREC with feedback is sent to the applicant (always the supervisor or PI) as soon as possible (approximately three working days) after the meeting by the appropriate administration, or sooner if expedited.

Corrections are done by the applicant and are sent back to the HSSREC administration.

A rebuttal letter should be included indicating *what*, *how* and *where* in the documentation the corrections were addressed (corrections should be highlighted in the various documents as well).

The *total set* of new documentation should be included as this will then be the set used for monitoring purposes as required by the NHREC.

The updated application is re-sent to the same independent reviewers for the review of the corrections (three working days).

Corrections are either approved by reviewers or further corrections are requested.

If additional corrections are requested they should be corrected (as previously indicated) and re-submitted by the applicants to the HSSREC administration.

If approved, a letter of approval is sent to the researcher(s) by the HSSREC administration.

Research can continue with the amended approach and documentation as soon as the researcher has received the ethics approval letter from the HSSREC for the amendments.

If needed, send any future amendments of the study or the rest of the documentation to the appropriate administration of the HSSREC.

Checklist for attachments for an amendment to a study:

	Document	Tick if attached	Comment
1	Cover letter that indicates the title, researcher(s), the nature of the amendment and what has been changed within the various attached documents (NB highlighted).		

2	The updated ethics application form.		
3	Amended project proposal (as approved by the Scientific Committee) with highlighted changes.		
If applicable:			
4	Scientific Committee's signed letter of approval of the project.		
5	Scientific Committee's signed letter of approval for the project amendment.		
6	Any new/amended monitoring sheets.		
7	Narrative CVs of all new members of the project team *(not included in the original application).*		
8	Proof of ethics training for all new members during the last 3 years.		
9	Project head's and professional supervisor declaration forms *(as applicable to the amendment).*		
10	Other new permission letters, informed consent, permits and contracts as received from relevant governing bodies, collaborators, sponsors or owners.		

8.5 Monitoring report or request for extension of the study

Monitoring by the HSSREC of compliance to conditions stated for ethics clearance by researchers, is required by the NHREC.

A compulsory annual (in the case of minimal and medium risk studies) and six monthly (in the case of high risk studies) monitoring report of approved projects is required. This should be submitted at least *two months before the expiry date* of the study. Failure to submit the monitoring report, may lead to immediate withdrawal of the study's ethics clearance.

The monitoring report requests a clear indication of the status of the study:

Status of the study	**Yes**	**No**	**NA**
Has the study been completed and does this serve as your final report?			
Has this project been terminated? If so, indicate the date, reason for termination and when the HSSREC was notified:			
Does the project have to continue in the following year?			

If the study has not been completed, an *extension* will automatically be granted for the project if the monitoring report is approved.

Note: Should you require an extension for the study at a time which does not fall within the required monitoring report period, you can use the same process to request for an extension by completing the monitoring report. A cover letter should clearly indicate that this is what you require.

Monitoring report process:

For minimal and medium risk studies, an annual monitoring report must be submitted for the duration of the study until it has been completed. For or high-risk studies, a monitoring report must be submitted six monthly for the duration of the study.

Two months before the end of the ethics approval period indicated for the different risk level studies, the researcher needs to complete a monitoring report. The documents can be obtained from the Administrator of the HSSREC (yvette.vandermerwe@nwu.ac.za).

Complete the monitoring report ensuring that all appropriate sections are completed.

It must be indicated in the monitoring report whether the study is *completed or not*. If the study is completed, the monitoring report acts as a *final report*. If the study is not complete, the monitoring report acts as a *request to extend the study*.

Submit your completed monitoring report to the Administrator of the HSSREC.

The monitoring report is sent (within three working days) to two independent reviewers (5 days to review).

Feedback from the monitoring reports is consolidated and discussed at the HSSREC meeting, e.g.

Decision:

- Clarification
- Completion
- Suspended
- Continuation
- Termination

A formal letter of decision is sent to applicants as soon as possible by the administration.

If any clarification or feedback is requested, the applicants should send the required information within a week to the HSSREC Administrator.

Clarifications are sent back to the same independent reviewers.

Clarifications are either approved by reviewers or further clarification is requested.

If additional clarification is requested, it should be corrected (as indicated) and re-submitted within a

week by the applicant to the Administrator of the HSSREC.

A letter will be sent to the applicant stating the status of the research. If it is a continuation, it will state the date for the next monitoring report.

The decision is ratified at the next HSSREC meeting.

The researcher can continue with the research as soon as they have received the letter indicating continuation.

NB Notify the Administration at the HSSREC as soon as possible if the study is terminated unexpectedly.

Extension request not falling in the monitoring report cycle:

If a researcher wants to extend an approved research project at any time other than the compulsory monitoring times, i.e. annually for minimal and medium risk studies and six monthly for a high-risk study, the researcher can do so by submitting the same monitoring report with a very clear cover letter indicating that extension is requested that falls outside the monitoring cycle.

9 REFERENCE DOCUMENTS

The National Health Act, No 61 of 2003.

Regulations Relating to Research with Human Participants, 19 September 2014.

Ethics in Health Research: Principles, Processes and Structures (Department of Health, 2015).

Risk level descriptors for human participants and environmental impact.

The Rules for the Management of research ethics at the North-West University, 2016.

Standard Operating Procedures of the HREC of the NWU.

10 ADDENDA

No	Document name
1	Informed consent template and checklist
2	Confidentiality agreement
3	Monitoring reports
4	Ethics review checklist
5	Evaluation form to evaluate whether the study qualifies as a larger study
	See all the documents referred to in the checklists and find it on the InfoEd system, the HSSREC website or from the HSSREC Administrator.

HSSREC Stamp

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT:

REFERENCE NUMBERS:

PRINCIPAL INVESTIGATOR:

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 **Human Social Sciences Research Ethics Committee (HSSREC) 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 Declaration of Helsinki 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 will be conducted .....and will involve.....*
- *The researchers have been trained to use the methods mentioned in the previous sentence.*
- *Approximately X 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 …*
- *You will be excluded if …*

What will your responsibilities be?

- *You will be invited to …*

Will you benefit from taking part in this research?

- *The direct benefits for you as a participant will probably be …*
- *The indirect benefit will probably be …*

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

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

Probable/possible risks/discomforts	***Strategies to minimize risk/discomfort***
[E.g., Because you will spend about three hours completing the questionnaires, it is possible that you will become tired]	[E.g., The researchers facilitating your completion of the questionnaire, will give you a15-minute break, with some refreshment (a juice and a piece of fruit) about halfway through]
[E.g., Because the researcher will ask you questions about what has been hard for you in your life, you will need to think about difficult times in your life. This could make you feel uncomfortable.]	[E.g., The researcher has a list of local mental health organizations/practitioners (add specific examples/names of organizations/practitioners who know about research and are willing to support participants) whom you can contact for one counselling session of 50 minutes.]
Etc.	

- *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?

- *Anonymity (that is, in no way will your results be linked to your identity) will .....*
- *Confidentiality (that is, I/we assure you that we will protect the information we have about you) will be ensured by .....*

- *Reporting of findings will be anonymous by..... Only the researchers and..... Data will be kept safe and secure by locking hard copies in locked cupboards in the researcher's office and for electronic data it will be password protected.*
- *Audio-recorded data will be sent to a transcriber who will sign a confidentiality clause (i.e., she will not be allowed to talk to anyone about any aspect of the data). As soon as data has been transcribed it will be deleted from the recorders. The transcripts will be stored on a password-protected computer. All co-coders will sign confidentiality clauses.*
- *Data will be stored for 5 years in …*

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 (e.g., your address or the name of your school).

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 refreshments will be..... 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.

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 ...

Is there anything else that you should know or do?

- You can contact (*researcher)*..... at ..... if you have any further queries or encounter any problems.
    - You can contact the chair of the Human Social Sciences Research Ethics Committee (HSSREC) (Prof Jacques Rothmann) at 018 299 1595 or 21081719@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:

I declare that:

- I have read and understood this information and consent form and it is written in a language with which I am fluent and comfortable.
- 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 understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- 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 may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

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

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

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 researcher **Signature of witness**

Declaration by researcher and participant

Personal face-to-face interviews during Covid-19 restrictions

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**

ADDENDUM 2

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

HUMAN SOCIAL SCIENCES RESEARCH ETHICS COMMITTEE

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 make 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*)

ADDENDUM 3

HSSREC ANNUAL MONITORING REPORT

Period: January – December

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 stored biological samples or data that had already been collected (i.e., analysis of an existing data set).

SECTION A: GENERAL INFORMATION AND PROGRESS

Name and surname of person completing report:

Role in project:

1. Project Head Details

Surname			Initials		Title	
School & focus area						
Position				E-mail		
Telephone	Work		Cell		Fax	

2. Details of approved proposal/protocol

Title				Approval number	
Approval date		Start date		End date	

3. Funding details (Where do you receive your funding from?)

Internal				Other (if yes, explain briefly)	
Industry		International grant			
Were you able to fund your project as initially intended (Indicate Yes/No/NA)?					
If not, please indicate in what way it has changed:					

4. Summary of progress to date

Shortly describe the overall progress to date of the project (maximum 500 words):	
Please describe any ethical issues (both minor and/or major) that may have arisen during the course of the monitoring period – please include comments about any participants who needed psychological/counselling intervention (maximum 500 words):.	
Has the level of risk to the participants changed since the original application (Indicate Yes/No/NA)?	
If yes, please explain:	
Has any new conflict of interest occurred since the original approval was obtained (Indicate Yes/No/NA)?	
If yes, please explain:	
Have the research records produced (both hard and soft copies) been correctly maintained and secured as stated in the original application (Indicate Yes/No/NA)?	
Please explain any changes:	

SECTION B: QUANTITATIVE STUDIES

5. Enrolment of Participants

Total number of participants to be included in the project.	
Number of participants enrolled to date (with written informed consent).	
Number of participants enrolled since previous HSSREC monitoring report (if applicable).	
Number of participants withdrawn (were enrolled but either chose not to or were not able to complete the study).	
Please provide reasons for participant withdrawal:	
Number of participants lost to follow-up (if appropriate).	
Please provide reasons:	
Number of participants no longer taking part for reasons not listed above	

Please provide reasons:

6. Adverse events in quantitative studies (if applicable)

Please list and explain serious adverse events (both expected and unexpected) that have occurred during the study, highlighting causal links (if any) to your research:
Please indicate any changes that have had to be made to the informed consent form or proposal/protocol because of these adverse events (these changes can only be implemented once they have been approved by the HSSREC):
Please indicate the treatment/follow-up/referral implemented for individuals that experienced an adverse event e.g. abnormal or incidental findings, distress, or anxiety:

7. Monitoring

Is there an external incident monitoring group/advisory panel in place, to provide ongoing oversight and impartial analysis of unanticipated incidents (Indicate Yes/No/NA)?	
If yes, is a copy of their report attached (Indicate Yes/No/NA)?	
Please explain the membership and functioning of this committee:	

SECTION C: QUALITATIVE ANALYSES

8. Methods used

Please give an overview of the methodology used to determine the data saturation of your study:	
Has data saturation been reached in this project (Please indicate Yes/No/NA)?	
How many participants have been enrolled to date (with written informed consent)?	
Number of participants enrolled since previous HSSREC monitoring report (if applicable).	
Number of participants withdrawn (were enrolled but either chose not to or were not able to complete the study e.g. withdrawn by PI).	
Please provide reasons for participant withdrawal:	

9. Incidents in qualitative studies (if applicable)

Please list and explain the incidents (both expected and unexpected) that have occurred during the study, highlighting if any causality could be determined with the intervention or research procedures implemented:

Please indicate any changes that have had to be made to the informed consent form or proposal/protocol because of these events occurring (these changes can only be implemented once they have been approved by the HSSREC):
Please indicate the follow-up/referral implemented for individuals that were involved in the incident e.g. distress or anxiety:

10. Monitoring

Is there an external incident monitoring group/advisory panel in place, to provide ongoing oversight and impartial analysis of unanticipated incidents (Indicate Yes/No/NA)?	
If yes, is a copy of their report attached (Indicate Yes/No/NA)?	
Please explain the membership and functioning of this committee:	

SECTION D: SECONDARY DATA ANALYSES

11. Biological sample analysis (if applicable)

Total number of previously collected samples to be used.	
How many samples have been examined?	
Have any ethical issues arisen which will require further attention e.g. incidental or clinically relevant findings:	
How have/will these ethical issues been/be dealt with:	

12. Databases (if applicable)

Was the database you received anonymised (Indicate Yes/No/NA)?	
Was the database you received correctly curated (Indicate Yes/No/NA)?	
Was the database you received password protected (Indicate Yes/No/NA)?	
Have the statistical analyses for this project been completed (Indicate Yes/No/NA)?	
Will the results of the analyses in any way stereotype/malign the original participants? Comment on how you intend to address this.	

SECTION E: PROJECT AMENDMENTS AND EXTENSIONS

13. Amendments

Has the original proposal/protocol been amended or changed (Indicate Yes/No/NA)?	No

Has the original proposal/protocol previously been amended and have these amendments been approved (Indicate Yes/No/NA)?	
Please indicate the date that these amendments were approved.	
If new amendments or changes to the proposal/protocol are to be approved, please indicate them in the box below and attach the amended documentation (Please highlight the changes in the amended documentation).	

14. Extensions

Has the original approval been extended (Indicate Yes/No/NA)?	
If so, please indicate the date on which the extension was approved.	
Please indicate the current completion date of the project.	

15. Termination

Has this project been terminated (Indicate Yes/No/NA)?	
If so, please indicate the date on which it was terminated.	
Please indicate the reason for the termination of the study:	

16. Signature

By signing this document, I certify that the information provided is accurate and complete.			
Signature by researcher/student completing report		**Date**	
Signature by PI/study leader		**Date**	

This document has been adapted from similar HREC documentation of the University of Stellenbosch and the University of the Cape Town.

17. For Office Use Only

Summary of reviewer's findings: **The study has thus far proceeded according to the HSSREC ethics recommendations made. Data gathering adhered to all ethics parameters and no unforeseen matters arose that required HSSREC attention.**					
Please indicate the feedback to be given to the researcher: **The study has thus far proceeded according to the HSSREC ethics recommendations made. Data gathering adhered to all ethics parameters and no unforeseen matters arose that required HSSREC attention.**					
Can the researcher continue with their research (Please indicate Yes/No)?					
If not, please indicate the reasons for your decision: **N/A**					
Date of next monitoring report					
Reviewer name		**Reviewer Signature**		**Date**	
HSSREC Chair name		**HSSREC Chair Signature**		**Date**	

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

Faculty of Humanities

ETHICS REVIEW CHECKLIST

Instructions for completion:

- Select the section applicable to you and complete the appropriate checklist.
- If you have **any yes answers** in your applicable section, you will have to apply for ethical approval.
- Should you have **only no answers** it means you do not require ethical approval. This will be confirmed by the scientific/proposal committee reviewing your proposal.
- Attach the completed and signed list with your application to the scientific/proposal committee.

INTRODUCTION

This checklist is for the use of researchers in the Faculty of Humanities. It also guides researchers not doing human social sciences research but doing research with vulnerable participants or that are medium and high risk level studies.

Research with **human participants** can never have a *"no risk level"* and if it is human social sciences research, it will always require ethics approval from a National Health Research Ethics Council (NHREC) registered research ethics committee (REC) for research studies of both academics and students.

The World Health Organization defines **health** as *"a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity".*

In this context **research** refers to *"a range of activities conducted by many disciplines that may use different methodologies and explanatory frameworks to extend knowledge through disciplines or systematic investigation"* (Ethics in health Research: Principles, Processes and Structures. Second edition. Department of Health, 2015). Further referred to as DoH, 2015.

Human social sciences research refers to any research conducted by disciplines about topics or participants within the fields of social, political, institutional, cultural and historical environments and developmental contexts, or investigating or striving to improve the human social functioning of participants. Health Sciences do not fall within this framework.

SECTION A: FOR RESEARCHERS IN THE FACULTY OF HUMANITIES

1. Research making use of human participants

All research with human participants (or their data) require ethics review (*all minimal to high* risk level studies).

The exceptions, however that do not require ethical clearance are:

- Research that relies exclusively on publicly available information or that is accessible through legislation or regulation. This does not mean that ethical considerations are irrelevant to the research.
- Research involving observation of people in public places and natural environments, provided:
  - the researcher does not interact directly with individual groups;
  - the researcher does not stage any intervention;
  - the individuals or groups do not have a reasonable expectation of privacy;
  - dissemination of research findings does not identify any individual or groups.
- Quality assurance and quality improvement studies, programme evaluation activities and performance reviews *not intended for publication.*

Note: Should *publication be envisaged* for the above mentioned research and ethics approval may be requested (e.g. required by sponsor or journal), prospective ethics approval should be obtained before the research activity, because RECs may not and cannot grant retrospective ethics approval.

2. Other scenarios not using humans for research purposes that might require ethics approval

- Systematic reviews that have direct impact on human intervention studies.
- Risk to the researcher due to the research.

3. Checklist to be used by researchers in the Faculty of Humanities:

Items	Yes	No
Does the study involve human participants?		
Does the study use previously collected data of human participants?		
Is the study a systematic review that has a direct impact on interventions with humans?		
Does the journal to which the publication is to be sent, require an ethics approval number?		
Does the study pose a risk to the researcher?		
Does the study pose a risk to the name of the NWU?		

Note: If the answer is **"Yes"** to any of the above, ethics review is required.

SECTION B: FOR RESEARCHERS FROM OTHER FACILITIES MAKING USE OF THE HSSREC

Research with **human participants** can never have a *"no risk level"* and will always require ethics approval from a REC for research studies of both academics and students.

Research conducted in other Faculties than the Faculty of Humanities that does **human social sciences research** with **human participants** whether *minimal, medium or high risk level* research, require ethics approval from a NHREC-registered REC.

Note: Human social sciences research refers to any research conducted by disciplines about topics or participants within the fields of social, political, institutional, cultural and historical environments and developmental contexts, or investigating or striving to improve the human social functioning of participants. Health Sciences do not fall within this framework.

Checklist to be used by researchers in other Faculties than the Faculty of Humanities doing social sciences research:

Items	Yes	No
Is the research about human social sciences?		
If the answer to the first question is "Yes", please continue:		
Does the study involve human participants?		
Does the study use previously collected data of human participants?		
Is the study a systematic review that has a direct impact on interventions with humans?		
Does the journal to which the publication is to be sent, require an ethics approval number?		
Does the study pose a risk to the researcher?		
Does the study pose a risk to the name of the NWU?		

Note: If the answer is **"Yes"** to any of the above, ethics review by the HSSREC is required.

SECTION C: CHECKLIST FOR RISK LEVELS ABOVE MINIMAL RISK LEVEL RESEARCH

The following checklist helps you to assess whether your research is above the minimal risk level.

Items	Yes	No
Does the study involve vulnerable human participants where there is a diminished ability to fully safeguard their own interests in the context of the research to be conducted, e.g. staff members, students, patients, aged, prisoners, mentally disabled people, participants from low socio-economic groups, people in dependent/ power relationships, ethnic and religious minorities?		
Does the study involve specifically children even if only observing them?		
Does the study involve participants in interviews with sensitive questions e.g. related to personal information, personal socio-economic information, sexual preference or activity, drug use, crime, violence, etc.?		

Is the research topic considered as sensitive e.g. personal in nature like finances, sexuality, illness or confidential topics, etc.?		
Does the study involve participants in focus groups with sensitive questions e.g. related to personal information, personal socio-economic information, sexual preference or activity, drug use, crime, violence, religious activities or choices, etc.?		
Is there the possibility of a loss of privacy and/or confidentiality e.g. collect information with personal identifiers (names, student numbers, etc.)?		
Does the study involve a psychological, physical, educational or socio-economic intervention?		
Will the study involve potentially harmful activities e.g. sharing confidential information, involved in focus groups on sensitive topics?		
Will the participants be misled/deceived in any way?		
Will any personal data of a human participant be used?		
Could the study induce more than negligible stress or emotional reactions (e.g. trauma, embarrassment, stigma, devaluation of values and beliefs) beyond those encountered in very day life?		
Could the wider community be linked to the research and suffer harm e.g. community stigma, stigmatization due to religious choices?		
Is there the possibility that the research may cause varying degrees of harm to any participant?		
Does the risk of harm include several identified risks (e.g. physical, psychological, educational, social, legal, socio-economic, dignitary or community)?		
Are there no precautionary measures available for some of the identified risks of harm?		
Does the study have the possibility of adverse or serious adverse events (e.g. undesirable or unintended responses or occurrences from a research participant during research that is related or not related to the research), occurring during the study?		
Are there any conflicts of interest e.g. a researcher's individual interests or responsibilities that have the potential to influence the carrying out of his/her role or professional obligations during the research?		
Does the research investigate illegal activities e.g. involving illegal immigrants or people engaged in illegal activities, etc.?		
Will the researcher (or research team) be placed at any risk of harm (e.g. dangerous sites, breaking of law by performing research activities such as investigating gang activities or the possession of illegal firearms)?		
Is there a possibility that the research may reveal information requiring mandatory action by the researcher or the university that could place the participant or others at risk e.g. researching child victims of abuse, victims of domestic violence, etc.?		
Is there a risk to the name of the NWU?		
Is there a potential risk to the environment?		

Researcher/Student	
Name and surname	
Signature	
Date	

Supervisor	
Name and surname	
Signature	
Date	

Chairperson of the scientific/proposal committee	
Name and surname	
Signature	
Date	

Acknowledgement to the developer:

Prof. Minrie Greeff
Head of the Faculty of Health Sciences Ethics Office

7 April 2017

ADDENDUM 5

NORTH-WEST UNIVERSITY
YUNIBESITI YA BOKONE-BOPHIRIMA
NOORDWES-UNIVERSITEIT
VAAL TRIANGLE CAMPUS

EVALUATION FORM TO EVALUATE WHETHER THE STUDY QUALIFIES AS A LARGER STUDY

#	**Criteria for evaluation**	**Yes**	**No**	**If no, please comment**
1	Is there an approved and detailed original proposal available?			
1.1	Is there a clear and well-defined problem statement indicating the gap that this research is filling and motivating the larger study?			
1.2	Are there clear aims/objectives for the study?			
1.3	Is the methodology well-defined?			
1.4	Is there a clearly stated research design?			
1.5	Has sampling been clearly described (type and process)?			
1.6	Are there clear inclusion and exclusion criteria?			
1.7	Has the recruitment process been described?			
1.8	Has the informed consent process been clearly described?			
1.9	Does the informed consent form comply with the latest requirements? (See checklist for informed consent)			
1.10	Is it clear how the research team and fieldworkers were trained?			
1.11	Has the method/s and process of data gathering clearly been described?			
1.12	Is data analysis clearly described and appropriate (statistical consultation if applicable)?			
1.13	Are the ethical aspects of the project described in the proposal? • When and from whom ethical approval was obtained • Anticipated risks and precautions • Benefits • Privacy and confidentiality throughout the research process • Anonymity and respect • Justice (fair recruitment and burden evenly distributed) • Management of vulnerability			
2	Is there a clearly identified project leader/principle investigator?			
3	Has the research team been well described?			
4	Are you still within the ethics approval time frame?			
5	Has the title been registered?			
6	Is there valid informed consent documentation available at the appropriate language level? If necessary is there translated informed consent			

	forms available?			
7	Is the required supplementary information such as questions, interview schedules and/or questionnaires available?			
8	If applicable is the advertisement available?			
9	Are the necessary contracts available (e.g. collaborators, sponsors)?			
10	Are confidentiality agreements available (e.g. fieldworkers, transcribers)?			
11	Is proof of authority/power of attorney of signatories to agreements available? (If applicable)			
12	Is the process of data storage fully described?			
13	Is the process of research monitoring clearly described?			
14	Is it clearly stated how results will be made known?			
15	Is there a budget available?			
16	**Is there a clear outline of how many possible Masters and Doctoral sub-studies can be accommodated within the project and specifically what each student will be doing?**			
17	Are there any other current sub-studies running under the larger project?			How many? Indicate the names of the running sub-studies and the students involved.
18	Were there any amendments made to the project?			If yes: How many? When?
19	Were there any extensions granted for the project?			If yes: Until when?

Final comments by the project leader:

Recommendation by the reviewers	**Yes**	**No**	**If yes, please comment**
Qualifies as a larger study and can continue			
Continuation as a larger study with revision			
Discontinue			

Name of reviewer 1	Signature of reviewer 1	Date
Name of reviewer 2	Signature of reviewer 2	Date

Used with acknowledgement of the HREC Ethics Office.