## PROCEDURE(S) FOR ETHICS APPLICATION FOR A LARGER STUDY

**For first-time application for a <u>sub-study under an already approved larger study</u>:**

### *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.

Obtain the necessary documents from the relevant sources, e.g. the Optentia website.

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

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 administrator (Ms Yvette van der Merwe, 13128388@nwu.ac.za) via email.

Supervisors should assist students with this process.

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

The application is discussed by the Chair with the reviewers.

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 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 administrator.

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

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.

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 and chairperson.

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

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

The ethics certificate is only issued by the RERC 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 (refer to the *Amendment and Monitoring Report* on this webpage).

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 (refer to the *Amendment and Monitoring Report* on this webpage).

**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 sub-study under a larger study research ethics approval application 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:*<br><br>If *no:* | Continue<br><br>Make sure the larger study truly qualifies as a larger study by completing the attached evaluation form (Attached). |
| 2 | Is the study clearly stated as an objective in the larger study? | If *yes:*<br><br>If *no:* | Continue<br><br>Make sure the larger study truly qualifies as a larger study by completing the attached evaluation form (Attached). |
| 3 | Cover letter that indicates:<br>Title of the larger study<br>Title of the sub-study<br>Student information<br>Supervisor(s)<br>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<br>What documents are attached<br>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- | | |

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| | 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. | | |

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