University of Fort Hare
Together in Excellence

HEALTH RESEARCH ETHICS COMMITTEE

STANDARD OPERATING PROCEDURE FOR RESEARCH ETHICS APPROVAL APPLICATION PROCESS

1. DOCUMENT HISTORY

Date	Version No	Reason for revision
11 July 2018	1	Newly formulated
31 January 2022	2	Updated

2. 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:

- A first-time application for a *single study* or a *larger study* (See section 5 for definitions)
- A *sub-study application* (master's or doctoral student) under an approved *larger* study
- A systematic review
- An application for an *amendment* to an approved study
- *Monitoring report* or a request for an *extension* of an approved study.

3. SCOPE

This SOP is intended for all researchers and postgraduate students who plan to conduct studies that use human participants or impact the environment. It covers the full application process to obtain research ethics approval before research is conducted, permission for amendments, and the monitoring process during research.

4. ABBREVIATIONS AND/OR DEFINITIONS

Abbreviation/Definition	Description
HREC	Health Research Ethics Committee
UFH	University of Fort Hare
UFH HREC	University of Fort Hare Health Research Ethics Research
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 or biological samples but using a specific methodology for

	obtaining results. The methodology is not specified in the original *study*. The project leader of the other study must give permission for the use of the data or biological samples and specify its use. The study could either: 1) fulfill 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 and biological samples 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 or biological samples.
Larger study	A study involving several master's and doctoral students clearly identifies the objectives per student as well as the methodology to be used by each potential students. The extent of the data or biological samples 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 and/or biological samples have already been collected or are going to be collected. Note: 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	The entire scope of available publications or published works regarding a specific topic is methodically and critically analysed. Generally, a systematic review adheres to very specific guidelines, such as those defined by the Cochrane Collaboration or as indicated in the PRISMA statement. Systematic reviews 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. Rapid review is conducted 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 type of systematic review that is generally undertaken to inform decision-makers of a specific emergent or urgent topic. Rapid review study is conducted to provide evidence in situations where time is of the essence, and certain procedures of the

	usual systematic review process are simplified or removed in order to reduce the turnaround time of the review.
Amendment	Any change made to the originally planned proposal happens while the study is being conducted. No change may be implemented without first obtaining the necessary approval of the UFH HREC.
Monitoring	The process of observing quality and conduct of the research while in progress. *Passive monitoring* refers to the compulsory reporting required by UFH HREC (minimum on an annual basis). *Active monitoring* refers to unannounced monitoring visits conducted by UFH HREC 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	However, suppose a researcher requires an extension for a study not falling in the mentioned monitoring time frame. In that case, the extension can be requested by submitting a monitoring report to UFH HREC.

5. RESPONSIBILITIES

The primary responsibility for research ethics approval lies with the researcher, with the support of the supervisor to ensure that research ethics approval is obtained before the study; and conducted according to the approved proposal. The supervisor remains the primary accountable person for how the study obtained ethics approval and is conducted. The UFH HREC and the Ethics Office administrators communicate with the researcher or supervisor.

6. PROCEDURE(S)

The procedures define a first-time application for a single study (including an affiliated research survey to another study with previously collected data or biological samples) or a larger study with defined postgraduate student projects.

Develop the research proposal and applicable accompanying documentation and

Download the necessary documents from the Ethics Office's website

http://ufh.ac.za/healthethics

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

Obtain a letter specifying the research has been presented and approved by the relevant Departmental Research Committee attached to the application.

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

Submit the completed ethics application to the UFH HREC administration (Ethics-HRECApply@ufh.ac.za)

Attach all the required documents *separately* to the e-mail (see attachment checklist below). Attach a *covering letter* indicating:

- the title of the research;
- the researcher(s);
- the type of research ethics application ;
- which documents are attached to the application; and
- add any explanation you wish the UFH REC to take note of in your application.

Application sent by administration (five working days) to two independent reviewers (five working days for review).

The application is discussed at the UFH HREC 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 UFH HREC with attached independent reviewer reports are sent to the applicant (always the supervisor or Principal Investigator) as soon as possible

(approximately five 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 UFH HREC administrator (note that the corresponding person for UFH HREC now changes to Ethics-HRECProcess@ufh.ac.za if corrections are needed).

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 within (five 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 UFH HREC administration for research involving humans (note that the corresponding person for the UFH HREC remains Ethics-HRECProcess@ufh.ac.za during this reviewing process).

If approved, a letter of approval is sent to the researcher(s) by: the UFH HREC administrator (Ethics-HRECApply@ufh.ac.za).

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. Where interview schedules will be developed as the study unfolds. 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. 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 UFH HREC administration (Ethics-HRECProcess@ufh.ac.za).

The approved informed consent documentation as well as the translated versions of the informed consent documents must be *stamped* by the Ethics Office before they are photocopied and used in the research (Contact Dr A Okeyo x 043 704 7585 for an appointment).

If needed, send any future amendments of the proposal or the rest of the documentation to the appropriate administration

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

Monitoring of research process

For *minimal risk studies*, 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 *medium or high-risk studies*, a monitoring report must be submitted *six months* 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 the expiry* of the ethics approval of the project (see Section 4 (monitoring reports) for the 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 UFH HREC:

Document		Tick if attached	Comment
1	The 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		
2	Executive summary of the project (150 words only)		
3	Proposal approved by the Departmental Research Committee		
4	Informed consent documentation and checklist (if collaborative study, informed consent from all the centres OR if an affiliated study, the original informed consent documentation of the original study)		
5	Advertisements or recruitment materials		
6	Questionnaire(s); interview schedule for interviews or focus groups		
7	2-page narrative CVs of all the researchers in the project		
8	Proof of ethics training over the past three years for all the researchers in the project		
9	Permission letters from governing bodies to conduct the research, if applicable		
10	Any other applicable documentation, e.g. MOU, contracts with collaborators/laboratories, permits, etc.		
11	Signed UFH code of conduct for researchers for each team member		
12	Signed statistical consultation form		
13	Submitted as hard or scanned copies: Printed and signed pages of the ethics application form for the declarations by the project leader, statistical consultation services, director of the research entity		
14	Checklist of attachments		
	If applicable:		
15	Confidentiality agreement		
16	Indemnity form		

18	Permission from the project leader if a study is done as an affiliated study under another study or a sub-study under a larger study		
19	Form A for delegated ministerial consent in the case of greater than minimal risk research in children with no prospect of direct benefit to them		
20	If any non-registered medication is used, an approval letter from the Medical Control Council		
21	If radio-active substances are used, a letter from the radiation control officer		

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.).

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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.

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Submit the proposal to the *scientific/proposal committee* in your entity for scientific evaluation and approval.
Obtain a letter specifying the research has been presented and approved by the relevant Departmental Research Committee, which has to be attached to the application.

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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).

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Download the necessary documents from the Ethics Office's website:
http://health-sciences.ufh.ac.za/healthethics

Submit the new sub-study proposal and the additional required documentation either to:

UFH HREC administration for research involving humans

(Ethics-HRECApply@ufh.ac.za).

Attach all the required documents *separately* to the e-mail (see attached checklist below)

Attach a covering letter indicating:

- the title of the research
- the researcher(s)
- the type of research ethics application
- documents attached to the application

Application sent by administration (five working days) by two independent reviewers (5 working days for review).

The application is discussed at the UFH HREC 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 UFH HREC 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 either:

the UFH HREC administration (note that the corresponding person for UFH HREC now changes to Ethics-HRECProcess@ufh.ac.za if corrections are needed).

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 applications are re-sent to the same independent reviewers for the review of the corrections (five 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 either:
the UFH HREC administration (note that the corresponding person for the UFH HREC remains Ethics-HRECProcess@ufh.ac.za during this reviewing process).

If approved, a letter of approval is sent to the researcher(s) by either:
the UFH HREC administration (Ethics- HRECApply@ufh.ac.za)

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. Where interview schedules will be developed as the study unfolds.
Once the English version of the informed consent form has been finally approved, the applicants can have the form translated into 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. 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 UFH HREC administration (Ethics-HRECProcess@ufh.ac.za).

The approved informed consent documentation as well as the translated versions of the informed consent documents must be *stamped* by the Ethics Office before they are photocopied and used in the research (Contact Dr A Okeyo x 043 704 7585 for an appointment).

If needed, send any future amendments of the proposal or the rest of the documentation to the appropriate administration

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

Monitoring of research process

For *minimal risk studies involving humans*, 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 *medium or high-risk studies*, *a monitoring report must be submitted six months* 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 the expiry of the ethics approval of the project* (see Section 4 (monitoring reports) for the process). For *Category 5 studies*, a monitoring report must be submitted every *six months* 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 the expiry of the ethics approval of the project.*

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 UFH HREC:

Document		Tick if attached	Comment
1	Have the data/biological samples already been gathered, or are these in a process of longitudinal gathering, or part of an intervention?	Yes or No If Yes⇨	Make sure the larger study truly qualifies
2	Is the study clearly stated as an objective in the larger study?	Yes or No If Yes⇨	Make sure the larger
3	A 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 the 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 proposal of the larger study		
6	Original informed consent documentation of the larger study		
7	Copy of the ethics approval certificate of the larger study		
8	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/biological samples can be used* and *for what*		
9	Approval letterof the sub-study by the scientific/proposal committee		
10	New proposal of the sub-study		
11	2-page narrative CVs of all the researchers in the sub-study		
12	Proof of ethics training over the past three years for all the researchers involved in the sub-study		
13	Signed UFH code of conduct for researchers for each team member		
14	Signed statistical consultation form		
15	Submitted as hard or scanned copies: Printed and signed pages of the ethics application form for the declarations by the project leader, statistical consultation services, director of the research entity		
16	Checklist of attachments		
If applicable:			
17	Confidentiality agreement		
18	Indemnity form		
19	Form A for delegated ministerial consent in the case of greater than minimal risk research in children with no prospect of direct benefit to them		
20	Permission letter of the Chairpersons of the HREC if the study is an affiliated study or sub-study under a larger study on another campus than where the student is registered		

21	Evaluation form to see if the larger study qualifies as a larger study, completed by the project leader		

7. 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 UFH HREC.

Develop the research proposal and applicable accompanying documentation.

Download the necessary documents from the Ethics Office's website http://health-sciences.ufh.ac.za/healthethics

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

Obtain a letter specifying the research has been presented and approved by the relevant Departmental Research Committee, which has to be attached to the 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:

UFH HREC administration for research involving humans (Ethics-HRECApply@ufh.ac.za)

Attach all the required documents *separately* to the e-mail (see attachment checklist below). Attach a *covering letter* indicating:

- the title of the research
- the researcher(s)

- the type of research ethics application
- which documents are attached to the application, and
- add any explanation to clarify your application

Application sent by administration (five working days) by two independent reviewers (5 working days for review)

The application is discussed at UFH HREC

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 UFH HREC 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 UFH HREC administrator (note that the corresponding person for UFH HREC now changes to Ethics-HRECProcess@ufh.ac.za if corrections are needed).
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 (five 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 UFH HREC administration (note that the corresponding person for the UFH HREC remains Ethics-HRECProcess@ufh.ac.za during this reviewing process).

If approved, a letter of approval is sent to the researcher(s) by:
the UFH HREC administrator (Ethics-HRECApply@ufh.ac.za).
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. These conditions will be clearly stated.).

If a project has been conditionally approved, send any other outstanding documents to the administration in the Ethics Office as soon as possible (if applicable).
This documentation must be submitted to:
the UFH HREC administration (Ethics-HRECProcess@ufh.ac.za).

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

If needed, send any future amendments of the proposal or the rest of the documentation to the appropriate administration:
the UFH HREC administration (Ethics-HRECApply@ufh.ac.za)

Monitoring of research process

For *minimal risk studies involving humans*, 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 *medium or 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 Section 4 (monitoring reports) for the 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 systematic review research ethics approval applications to the HREC:

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		
2	Executive summary of the project (150 words only)		
3	Proposal approved by the Departmental Research 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	2-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 UFH code of conduct for researchers for each team member		
9	Submitted as hard or scanned copies: Printed and signed pages of the ethics application form for the declarations by the project leader, statistical consultation services, director of the research entity		
10	Checklist of attachments		

Application for an amendment to an approved 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 UFH HREC for research involving humans, through the amendments that have been made:

- the title of the research
- the researcher(s)
- 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 UFH HREC administration (Ethics-HRECApply@ufh.ac.za).

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

Application sent by administration (within five days) to two reviewers (five working days for review).

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

Aggregate individual views

Deliberation (debate) o Analogue (consensus) o 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 UFH HREC 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 either:

the UFH HREC administration (Ethics-HRECProcess@ufh.ac.za.
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 (five 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 UFH HREC administration for research involving humans (note that the corresponding person for the UFH HREC remains Ethics-HRECProcess@ufh.ac.za during this reviewing process).

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

the UFH HREC administration (Ethics-HRECApply@ufh.ac.za)

Research can continue with the amended approach and documentation as soon as the researcher has received the ethics approval letter from the UFH HREC for the

amendments.

If needed, send any future amendments of the proposal or the rest of the documentation to the administration:

the UFH HREC administration (Ethics-HRECApply@ufh.ac.za)

Checklist for attachments for an amendment to a study to the UFH HREC:

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	Adjusted proposal with highlighted changes		
3	Adjusted documentation with highlighted changes (if applicable)		
If applicable:			
4	Scientific Committee's signed letter of approval of the project		
5	Scientific Committee's signed letter of approval of the project amendment		
6	Any new/amended monitoring sheets *(to observe any undue pain and suffering, and to manage (alleviate) pain and suffering when humane endpoints are reached)*		
7	Narrative CVs of all new members of the project team *(not included in the original application)*		
8	Project head's and professional supervisor declarations forms *(as applicable to the amendment)*		
9	Other new permission letters, informed consent, permits and contracts as received from relevant governing bodies, collaborators, sponsors or owners		

8. MONITORING REPORT OR REQUEST FOR EXTENSION OF THE STUDY

A compulsory annual (in the case of minimal risk studies) and six monthly (in the case of medium and 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. The monitoring report requests a clear indication of the status of the study:

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, indicate the date, reason for termination and when HREC 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.

8.1 Monitoring report process

For minimal risk studies, an annual monitoring report must be submitted for the duration of the study until it has been completed. For medium 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. To download the necessary documents from the Ethics Office's website go to http://health-sciences.ufh.ac.za/healthethics

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:
Ethics-HRECMonitoring@ufh.ac.za for UFH HREC monitoring reports or

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

Feedback from the monitoring reports is consolidated and discussed at the appropriate Ethics Committee meeting.

Decision

Clarification o Completion o Suspended o Continuation o 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 either:

Ethics-HRECMonitoring@ufh.ac.za for UFH HREC monitoring reports

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:

Ethics-HRECMonitoring@ufh.ac.za for UFH HREC monitoring reports

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 UFH HREC meeting

The researcher can continue with the research as soon as he/she has received the letter indicating continuation.

NB Notify the administration at:

Ethics-HRECMonitoring@ufh.ac.za *for UFH HREC monitoring reports*

As soon as possible if the study is terminated unexpectedly.

Note: 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 risk studies and six monthly for a medium or 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. ADDENDA

No	Document name
1	Informed consent template and checklist
2	Confidentiality agreement
3	Declaration by the Departmental Higher Degree Committee
	See all the documents referred to in the checklists and find it on the Ethics Office's website http://www.ufh.ac.za/healthethics

10. REFERENCE DOCUMENTS

The UFH HREC adopts as its guiding reference documents the following:

- 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)
- The Declaration of Helsinki, 2013.
- The Belmont Report, 1979.
- The Singapore Statement on Research Integrity, 2010.
- The International Conference on Harmonisation – Good Clinical Practice (ICH-GCP), 1997.
- Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa (Department of Health, 2006).
- The Rules for the Management of Research Ethics at the North-West University, 2016.
- The Rules for the Management of Research Ethics at the University of South Africa, 2016.
- The Rules for the Management of Research Ethics at the University of Cape Town, 2015. Risk level descriptors for human participants and environmental impact.
- The Rules for the Management of research ethics at the University of Fort Hare, 2018.