

## PROCEDURE(S) FOR ETHICS APPLICATION FOR AMENDMENTS TO AN APPROVED STUDY

### For 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 name(s) of 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 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 vice-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.		
<b>If applicable:</b>			
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 <u>new</u> members of the project team ( <i>not included in the original application</i> ).		
8	Proof of ethics training for all <u>new</u> members during the last 3 years.		
9	Project head's and professional supervisor declaration forms ( <i>as applicable to the amendment</i> ).		
10	Other <u>new</u> permission letters, informed consent, permits and contracts as received from relevant governing bodies, collaborators, sponsors or owners.		