



## PROCEDURE(S) FOR MONITORING REPORT OR AN APPLICATION FOR AN EXTENSION OF AN APPROVED STUDY

Monitoring by the BaSSREC 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 BaSSREC 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 BaSSREC Ms Yvette van der Merwe ([13128388@nwu.ac.za](mailto:13128388@nwu.ac.za)) and the BaSSREC Chair Dr Jacques Rothmann ([21081719@nwu.ac.za](mailto:21081719@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 and Chair of the BaSSREC.



The monitoring report is sent (within three working days) to two independent reviewers (10 days to review).



Feedback from the monitoring reports is consolidated and discussed by the BaSSREC chair and reviewers.

#### 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 BaSSREC 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 BaSSREC.

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

*NB Notify the Administration at the BaSSREC 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.

**Click on the Monitoring Report-link for the required documentation.**

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