



BaSSREC APPLICATIONS

MONITORING AND AMENDMENT REPORTS PROCEDURES

The following procedures inform the ethics application process for **the monitoring of existing studies, amendments made to or extensions of approved projects/studies:**

Monitoring reports:

1. All approved ethics applications are monitored by the BaSSREC annually. This is clearly stated on the official BaSSREC ethics approval letter.
2. Applicants and their supervisors/promoters are expected to complete the official BaSSREC monitoring report (available on the BaSSREC web page) and submit to the BaSSREC administrator or via InfoED one month before the lapse of the yearlong approval granted to the study. If the applicant fails to do so, the BaSSREC approval will be revoked.
3. In addition to this passive monitoring process, the BaSSREC chairperson may select at least one approved BaSSREC study for active monitoring per semester, i.e. they will randomly monitor the ethics process of applications approved by BaSSREC. This could include asking to see the stored consent forms, and/or asking to speak with study participants about their experience of being part of the study, etc. This will be done in accordance with the Protection of Personal Information Act (POPIA).

Amendments to or extension of existing studies:

1. All applications/requests for amendments to or extensions of already approved projects must be submitted in writing (via email) to the BaSSREC administrator. The written application must include the existing ethical clearance certificate, the original ethics application and informed consent documents, and a letter tabulating all the proposed changes with explicit comment on the ethical implications of each change. If the changes imply the need for re-consent, the adapted informed consent documents must be included.

2. For preparation of the next meeting, the BaSSREC administrator will email the application/request for evaluation to the BaSSREC chairperson as soon as all the relevant information has been received.
3. The BaSSREC administrator will include the application/request on the agenda for the next relevant meeting. The remaining steps/processes are exactly the same as for new project/single study applications.