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Health Research Ethics Committee (HREC)

SUB-FORM APPLICATION: Amendments
Guidance and instructions for researchers

The Health Research Ethics Committee (HREC) uses an electronic ethics review management system, *Infonetica*©, to manage the application and review process.

- ⇒ To access the electronic submission platform for your HREC e-form application, please click to our HREC website: **Electronic Application Process**
- ⇒ **To login**, type in your SU username followed by @sun.ac.za
- ⇒ Should log in be unsuccessful please verify your Sun ID account with your home department and try again at a later stage.
- ⇒ **Locate your specific project** and then **click on the Create Sub-form tile**
- ⇒ **Select the appropriate Sub-form to be uploaded, and once selected click on create**
  - o HREC Documentation Form
  - o *HREC Protocol Amendment Form*
  - o Annual Progress /Final Report for Clinical Trial/Health/Student Research
  - o HREC Serious Adverse Events(SAE)
- ⇒ Under the Amendment Section 1, select page 1, and enter information as required
- ⇒ Once the form is completed successfully click on submit.

What needs to be submitted for an amendment?

Clinical trials, Health and Student Research		Biobank, Case Report and Case Series
Revised Amendment Documents		Revised Amendment Documents

APPLICATION FOR APPROVAL OF A MAJOR STUDY AMENDMENT: GUIDELINE

Health Research Ethics Committee has the discretion to decide whether or not a proposed amendment is substantial and requires ethical review. Principal investigators and sponsors should seek advice from the HREC if in doubt.
The HREC must be notified of ALL amendments and approval for these must be granted before ANY of the changes are implemented. Amendments may not be implemented without HREC approval unless patient safety is at stake and the issues have been discussed with the HREC Chair or Manager.

1. ***Minor amendments*** *do not change the risk benefit profile of the study in any way.*

Examples of typical minor amendments:

a) Additional investigators or study sites
b) Small changes in the Informed Consent
c) Change in background information or update of literature review
d) Extension of period of study
e) Other changes that do not affect study design and will not affect study outcomes or results
f) Administrative changes

g) Stricter inclusion or exclusion criteria

2. Major or substantive amendments** require a change(s) to the study methodology or procedure that **may result in an alteration of the risk benefit profile of the study.

Examples of typical major or substantive amendments:

a) Change in study aims, objectives or design
b) Resulting changes to consent documents
c) Additional study procedures
d) Easing of inclusion or exclusion criteria