Stellenbosch UNIVERSITY IYUNIVESITHI UNIVERSITEIT | forward together sonke siya phambili saam vorentoe

Health Research Ethics Committee (HREC)

SUB-FORM APPLICATION: Serious Adverse Event
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 followed by your SU password
- ⇒ 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**
- ⇒ **NB! Before creating the sub-form, please check the top of your screen for any updates. if you see a note on the top of the screen indicating "There is a newer version of the project. Update" click on update to get the latest version of your project. If there is no note please proceed to create the required sub-form.**
- ⇒ **Click on the Create Sub-form tile**
- ⇒ **Select the appropriate Sub-form to be uploaded, and once selected click the "Create" button**
  - 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 Serious adverse Event Form, click on "**Page 1**", and enter information as required
- ⇒ Once completed successfully **click on "Submit"**

What needs to be submitted for a Serious Adverse Event?

Clinical trials, Health and Student Research
Any documentation related to the SAE

Guidelines on Reporting Serious Adverse Events

SAE Report: The term Serious Adverse Event (SAE) is usually used within the context of clinical or drug trials. However an Adverse Event (AE) or SAE can occur in non-pharmaceutical research as well. Any event that can affect research participants or data integrity negatively, or that has the potential to impact negatively on members of the research team, or on the project as a whole, and that is deemed significant by the investigator, should be reported to the HREC that approved the original study. Adverse events can include a wide range of events such as breach of confidentiality, injury sustained during a procedure e.g. exercise program, assault or robbery of staff members, needle stick injuries etc. Adverse events may obviously, in certain studies also include adverse drug events.

How to report SAEs and AEs:
Investigator's site:

- Report all significant adverse events to the HREC within a maximum of 21 days.

- Report any event which, in the opinion of a reasonable and competent investigator, could have serious negative consequences for research participants, research team members, the project as a whole, or the university, within 48 hours of the investigator becoming aware of the event.
- Report any other serious study related event, which in the opinion of the investigator is significant with respect to study participants, staff or data integrity.
- Complete and submit a standard reporting form for drug related SAEs
- Attach a more detailed narrative

Other sites:

- Report all SAEs to the HREC, if deemed necessary by the investigator, i.e. significant or unexpected.
- Complete and submit a standard reporting form for drug related SAEs
- Attach a summary of adverse events in a letter

DEFINITION OF A SERIOUS ADVERSE DRUG EVENT (FDA TITLE 21 PART 312, 32): Any adverse drug experience, occurring at any dose that results in any of the following outcomes:

- Death
- A life threatening incident
- Inpatient hospitalisation or prolongation of existing hospitalisation,
- Significant or persistent disability/incapacity,
- Congenital abnormality/birth defect.
- Important medical events that may not result in death, be life threatening, or require hospitalization, may be considered a SAE when based on appropriate medical judgment; they may jeopardize the participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition e.g. allergic bronchospasm, blood dyscrasias.