

## Health Research Ethics Committee (HREC)

### SUB-FORM APPLICATION: Protocol Deviation 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**
- ⇒ **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 if you see a note on the top of the screen indicating "There is a newer version of the project.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. Please do not create a REC Protocol Deviation Form.**
- ⇒ **Click on the Create Sub-form tile**
- ⇒ **Select the appropriate Sub-form to be uploaded, and once selected click on create**
  - **HREC Protocol Deviation Form**
  - HREC Documentation Form
  - HREC Protocol Amendment Form
  - HREC Annual Progress /Final Report for Clinical Trial/Health/Student Research
  - HREC Serious Adverse Events( SAE)
- ⇒ Under the HREC Protocol Deviation Form, close to Section 1, select page 1 and enter information as required
- ⇒ Once completed successfully click on submit.

#### What needs to be submitted for a Protocol Deviation acknowledgement letter?

Clinical trials:		Health and student research:
Cover letter		Cover letter
Documents related to submission		Documents related to submission