

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 if you see a note on the top of the screen indicating "There is a newer version of the project.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
 - o 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