

South African National Clinical Trial Registry (SANCTR) and National Health Research Ethics Committee (NHREC)

NHREC: <http://www.ethicsapp.co.za>

SANCTR: <http://www.sanctr.gov.za>

How to register: <http://www.sanctr.gov.za/Investigatorbrnbsplnformation/Howtoregister/tabid/180/Default.aspx>

The SANCTR Registry informs the public with updated information on clinical trials via the NHREC system on human participants being conducted in South Africa. The Register provides the general public with information on a trials purpose; who can participate, where the trial is located, and contact details.

Registration Process:

Step 1: The trial information required for the South African National Clinical Trials Register is coordinated through the initial ethics application process. Trialists/ Investigators will initially capture trial details on-line at www.ethicsapp.co.za where after a proof of capture form is printed and submitted with the ethics application pack to the relevant accredited research ethics committee

Step 2: You apply for your unique trial number via the www.sanctr.gov.za site where you can "Login" using your login details obtained when you registered at www.ethicsapp.co.za. Select the "SANCTR Toolkit" button to enter regulatory authority approval information required to request a SANCTR Number.

Step 3: The data is then sent to the Department of Health 'desk' where the SANCTR Number is allocated. Receipt of the SANCTR number via fax or email, provides the research team with the authority to commence the study pending all other relevant regulatory clearances have been granted. (this should not take more than 3 days)- you can now commence with your study procedures.

Step 4: Once you receive your SANCTR number return to www.ethicsapp.co.za to update the NHREC form with your approval dates, print and send the completed document to regulatory authorities (MCC and HREC) (TAT of 2 days)

Step 5: Within one year of study completion please ensure that study close out date is updated on www.ethicsapp.co.za