

**MORE DETAILED INFORMATION ON HOW TO REGISTER ON THE SOUTH  
AFRICAN NATIONAL RESEARCH REGISTER**

[www.sanrr.gov.za](http://www.sanrr.gov.za)

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**"1. Background**

- *SANRR forms part of international calls to make trial info publicly available.*
- *ICMJE FROM 1 JULY 2005 WILL NOT PUBLISH TRIALS UNLESS INCLUDED ON RESEARCH REGISTER.*
- *WHO calls for public registration.*
- *Global Pharmaceutical industry released plans to make trial data publicly available.*

**2. Who is the register for?**

- *The register will enable patients, family members, health professionals, industry and the public to access information on SA based clinical research studies.*

**3. SANRR and Regulation**

- *Section 11(r) National Health Act 2004*
  - *Regulations will require:*
- *ALL RESEARCH AND CLINICAL TRIALS TO RECEIVE ETHICS CLEARANCE FROM AN ACCREDITED ETHICS COMMITTEE.*
- *ALL CLINICAL TRIALS WILL BE REQUIRED TO BE REGISTERED AND RECEIVE A REGISTER NUMBER PRIOR TO COMMENCEMENT OF THE TRIAL.*

**4. Who Registers?**

- *Sponsors are responsible for ensuring a trial is fully registered on SANRR.*
- *Unfunded trials - PI takes on the responsibility of registering.*
  - *Multi site / multi sponsor trials - lead sponsor.*
  - *Registration is done at [www.sanrr.gov.za](http://www.sanrr.gov.za)*

**5. What is to be registered?**

- *Full spectrum of clinical trials conducted in SA.*

- *ICMJE definition - "any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause and effect relationship between a medical intervention and a health outcome".*

- *'Medical intervention' refers to any intervention used to modify a health outcome including drugs, surgical procedures, devices, behavioural treatments, process of care changes.*

- *Registration requires trial has at least one prospectively assigned concurrent control or comparison group.*

**• ALL TRIALS MUST BE REGISTERED BUT TO ENSURE INNOVATION/COMPETITIVENESS IS NOT COMPROMISED PHASE I TRIAL DATA WILL NOT BE PUBLICLY RECORDED.**

#### 6. What trial information is publicly available?

- *Brief Title*
- *Recruitment Status*
- *Anticipated Start Date*
- *Anticipated End Date*
  - *Gender*
  - *Ethnicity*
  - *Age*
- *Inclusion / exclusion criteria*
  - *Contact Details*

#### 7. How to Register

**Step 1:** *The trial information required for the SANRR register is coordinated through the initial Ethics Application process. Trialists initially capture trial details on-line at [www.ethicsapp.co.za](http://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:** *Upon receiving written Ethics Approval from the relevant Research Ethics Committee or MCC, the application for a SANRR number begins:*

- Applying for a SANRR number is done at the [www.sanrr.co.za](http://www.sanrr.co.za) site.
- Trialists "Login" using their login details obtained when they registered at [www.ethicsapp.co.za](http://www.ethicsapp.co.za)
- They select the "SANRR Toolkit" button to enter Ethics Committee approval information required to request a SANRR Number.

**Step 3:** *The data is then sent to the DOH help 'desk' where the SANRR Number is allocated. Receipt of the SANRR number provides the research team with the authority to commence the study.*

- The SANRR number will be generated within two (2) working days. This will be done either by e-mail or fax and will be sent to both the relevant Research Ethics Committees and the applicant.

***Step 4: Those studies that require additional registration with the Medicines Regulatory Authority, after ethical clearance, will be entered onto both the MCC database and the SANRR.***

Confidentiality related to the regulatory process will be observed.

## 8. Role of the Ethics Committee

- *Gate Keepers to SANRR*
  - *Ensure SANRR proof of capture form is included with Ethics Application.*
- *Ethics Committees not to process application without a SANRR proof of capture form.*
- *Record SANRR number which will be automatically generated by the system.*

## 9. Updating the Register

- *Trial information can be updated at [www.ethicsapp.co.za](http://www.ethicsapp.co.za) (particularly recruitment status information).*
- *To ensure that the information available through the data bank is timely and accurate, it is asked that the sponsor/PI reviews, verifies, and updates all active protocol records on a six-monthly basis, at a minimum.*
  - *The research team must confirm the starting date of the study.*
- *Information on trials unexpectedly closed (e.g. clinical hold) should be updated within 10 days after the closing or sooner (if possible).*
- *The sponsor/PI must also inform SANRR of the trial completion date (i.e. date that analysis is concluded for the protocol), within 10 days, and provide a summary of findings within a year of study completion."*

## How to Register (summary)

### Step 1:

The trial information required for the SANRR register is coordinated through the initial ethics application process.

- Trialists initially capture trial details on-line at : (non-clinical studies)
- Industry/Pharmaceutical Co/Sponsor : (Clinical Drug Trials / Device/ Vaccine and other interventional studies )

[www.ethicsapp.co.za](http://www.ethicsapp.co.za)

- Go to ABOUT – click on HOW TO REGISTER – please read all information
- then click on the REGISTER button on the top right hand side of the screen;

- **Fill in all details and then click on the REGISTER button on the bottom middle of the screen (READ THE SCREEN \*NOTE) - Username should be generic to a company / division / department.**
- **You will receive a phone call verifying your details .**
- **If your application (registration) is authorized, you will receive notification of your access to the portal environment via email.**
- **The portal administrator will register your details on the SANRR site and notification will be sent via email of your registration on the SANRR site.**
- **You will then be able to 'login' and capture your trial on the NHREC site.**
- **Please print out the NHREC application form and submit along with your Ethics application standardization form to your accredited research ethics committee**

Step 2:

- **ONLY once Ethics / MCC approval has been received are you then required to go onto the SANRR site and register your study using your NHREC number only.**
- **The DOH – SANRR will send via email the DOH approval number**
- **Applying for SANRR number is done at [www.sanrr.co.za](http://www.sanrr.co.za) site.**
- **Trialists 'Login' using their login details obtained via the SANRR site and the portal administrator**
- **Select the "SANRR Toolkit" button to enter ethics committee approval information required to request a SANRR (DOH) Number**

Step 3:

- **The data is then sent to the DOH help "desk" where the SANRR Number is allocated.**
- **Receipt of the SANRR Number provides the research team with the authority to commence the study.**
- **The SANRR number will be generated within two (2) working days. This will be done either by e-mail or fax and will be sent to both the relevant research ethics committees and the applicant.**

Step 4:

- **Those studies that require additional registration with the Medicines Regulatory Authority, after ethical clearance, will be entered onto both the MCC database and the SANRR.**

**Confidentiality related to the regulatory process will be observed.**

**Please contact Ms H Strauss (Secretariat: Ethics Committee), Tel (051) 405-2812 if you have any enquiries.**