SOUTH AFRICAN NATIONAL CLINICAL TRIALS REGISTRY

UPDATE ON SANCTR REDEVELOPMENT

South African Clinical Trials Registry (SANCTR)

The establishment of SANCTR follows international calls for prospective registration of clinical trials to ensure greater transparency in trial conduct from the planning stages. In 2005 Department of Health (DoH) commissioned the establishment of a clinical trials register. A statement was issued in November 2005 by DoH that as from the 1st December 2005 all new clinical trials that are conducted in the country must be registered in SANCTR. Registration on SANCTR requires that a trial is approved by a Research Ethics Committee and meets the requirements of the National Regulatory Authorities, South African Health Products Regulatory Authority (SAHPRA). In meeting those requirements, SANCTR serves as a tool for approving and monitoring the conduct of clinical trials in South Africa.

"Sponsors are required to register all South African based trials on the South African Clinical Trial Register (SANCTR) managed by the Department of Health. If there is no sponsor, then it is the responsibility of the PI to register the trial. Once registered, the trial will be issued a unique study number within two working days of the application being received by the Department of Health. Trials should not commence without this number".

> The Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa, 2nd Edition (2006), section 1.5.2

What is a clinical trials register?

A trial register is a database in which key administrative and scientific information about planned, ongoing and completed trials, with enough information to identify that trial's existence, are stored.

The purpose of a clinical trials registry

The registration of all interventional trials is a scientific, ethical and moral responsibility because of the following:

- There is a need to ensure that decisions about health care are informed by all available evidence
- It is difficult to make informed decisions if publication bias and selective reporting are present
- The Declaration of Helsinki states that "Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject".
- Improving awareness of similar or identical trials will make it possible for researchers and funding agencies to avoid unnecessary duplication
- Describing clinical trials in progress can make it easier to identify gaps in clinical trials research
- Making researchers and potential participants aware of recruiting trials may facilitate recruitment
- Enabling researchers and health care practitioners to identify trials in which they may have an interest could result in more effective collaboration among researchers.

- Checking data as part of the registration process ensures that improvements in the quality of clinical trials, thus making it possible to identify potential problems (such as problematic randomization methods) early in the research process

Ethical obligation for trial registration

Clinical trial registration can assist a researcher fulfill ethical obligations by abiding to the South African Good Clinical Practice Guideline (2006). Ensuring that transparency and information dissemination (autonomy, do no harm, voluntary informed consent) as outlined by the Declaration of Helsinki. While providing public trust in the conduct of clinical research (experiments should serve the public good).

Current plans with SANCTR redevelopment

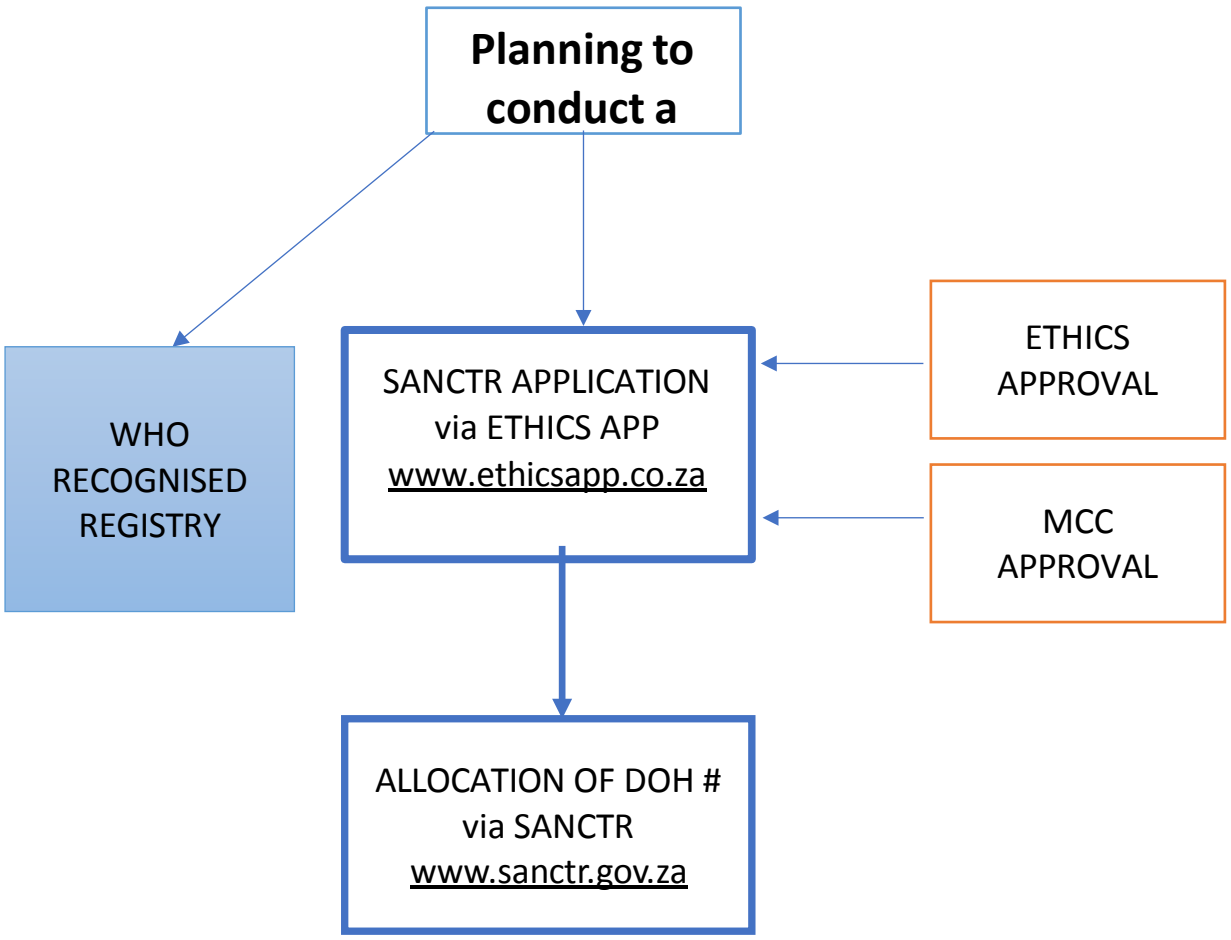
SANCTR seeks to facilitate registration of trials in accordance with the World Health Organizations (WHO) International Clinical Trials Registry Platform (ICTRP) initiative and the International Committee of Medical Journal Editors (ICMJE) both require prior registration of planned clinical trials in a public registry as a condition for publication. In accordance with section 1.6 in The Guidelines for Good Practice in the Conduct of Clinical Trials with Human Participants in South Africa, (2006), 2nd edition. We proposed a process flow in which we received scientific guidance on the process, we initiated a steering group (**Table 1**).

The SANCTR database will align with the Pan African Clinical Trials Registry (PACTR) which is a WHO Primary Registry for the African continent. SANCTR will become a Partner Register to PACTR and eligible records will be transferred from SANCTR to PACTR and eventually to WHO-ICTRP. As a Primary Registry, PACTR sends clinical trial records monthly to WHO's ICTRP. ICTRP is a platform facilitating registration of a minimum 24-item data set in a harmonised and standardized format while providing a searchable one-stop portal for registered clinical trials.

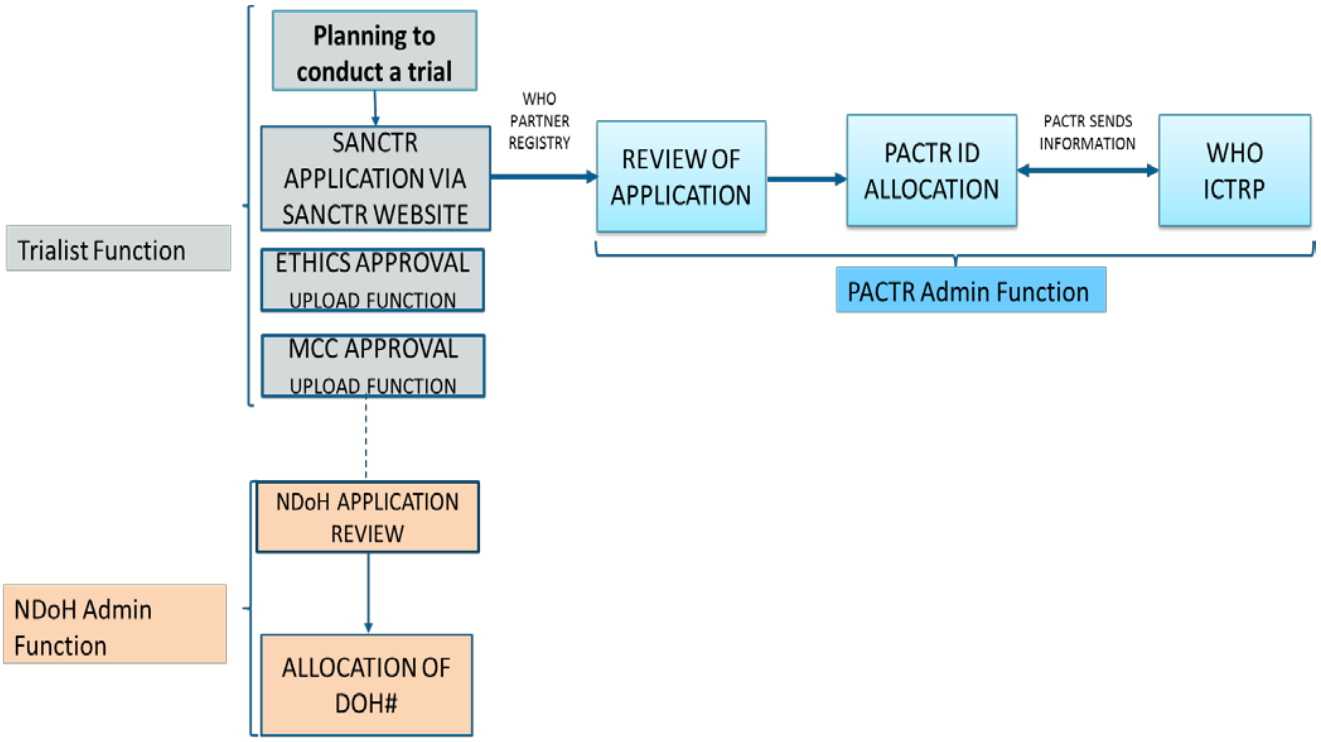
SANCTR was initially developed by the Wits Health Consortium (WHC) with grant funding and there is a process underway to move the database to the South African Medical Research Council (SAMRC) as requested by DoH back in 2015. The SANCTR redevelopment process includes the following activities:

- Data exploration and migration of registered trials from WHC to SAMRC
- Enhancing the process flow of registration in SANCTR with stakeholder input
- Stakeholder consultation at each step to ensure that SANCTR meet the needs for the country while conforming to the international standards for registries

Current process for acquiring a DoH number:



Proposed process for acquiring a DoH number



GOVERNANCE

Table 1: List of Steering Committee Members

Surname	Name	Institution
Zondi	Thulile	NDoH
Muthivhi	Tshilidzi	NDoH
Nkambule	Portia	NDoH
Spotose	Thozama	NDoH
Kgasi	Mpho	NDoH
Kredo	Tamara	PACTR and Cochrane South Africa
Pienaar	Elizabeth	PACTR and Cochrane South Africa
Ndwandwe	Duduzile	PACTR and Cochrane South Africa
Charls	Patrick	SAMRC IT
Ross	Keith	SAMRC IT

For more information or to share suggestions on the redevelopment of SANCTR please contact:

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