Wits Reproductive Health and HIV Institute

REGULATORY SUBMISSIONS

MTN STAKEHOLDERS MEETING

26 March 2019

Thabile Msomi

University of the Witwatersrand
WITS RHI

2 MAIN REGULATORY AUTHORITIES IN SOUTH AFRICA THAT A PROTOCOL NEEDS TO BE APPROVED BY

1. South African Health Products Regulatory Authority- SAHPRA

SAHPRA
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

2. Research Ethics Committee
3. [Wits RHI submits to Wits Human Research Ethics Committee (Medical)]

University Of the Witwatersrand, Johannesburg

A PROTOCOL GOES THROUGH THE FOLLOWING BEFORE BEING IMPLEMENTED:

1. Wits RHI Internal Review Committee (RRC) [*for Wits RHI Sites*]
2. National Health Research Ethics Committee (NHREC) (online)
3. Wits Human Research Ethics Committee (Wits HREC)
4. South African Health Products Regulatory Authority-SAHPRA
5. Department of Health Gauteng Provincial Research Committee (online)

AFTER RECEIVING THE APPROVED PROTOCOL FROM THE PROTOCOL TEAM

STEP 1. Research Review Committee (RRC)

- Committee meets monthly, excl. December
- Ethics Application Form, Protocol & informed consent forms submitted to the review committee
- Comments, questions are raised by the committee and responded to by the principal investigator (PI) and/ or the protocol team
- Approval received from RRC and Prof Helen Rees (Wits RHI Executive Director) signs off on the form

HREC APPLICATION FORM (MEDICAL) - 2019

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG

APPLICATION [1] TO THE HUMAN RESEARCH ETHICS COMMITTEE: (MEDICAL) - FOR CLEARANCE OF RESEARCH – for Pharmaceutical / Grant / Donor Sponsored Clinical Trials involving Drugs / Devices

THIS APPLICATION MUST BE TYPED
Please complete ALL investigators' details involved in the Study as requested below (including item 6.3):

SECTION 1

1 PRINCIPAL INVESTIGATOR PER SITE
NAME: Prof/Dr/Mr/Miss/Ms

- PROFESSIONAL STATUS (If student, year of study)
- UNIVERSITY DEPARTMENT
- DETAILS OF SITE WHERE STUDY WILL BE CONDUCTED / (SYNDICATE NAME):
- HOSPITAL / INSTITUTION WHERE EMPLOYED
- FULL-TIME OR PART-TIME: HPCSA NO:
- TELEPHONE NO: FAX NO:
- CELL: EMAIL:

OR

1.1 **NON-WITS SITE / INSTITUTION** ***(if no association of any type with the University)*** e.g. *Private Research Site; Laboratories;*

- DETAILS OF SITE WHERE STUDY WILL BE CONDUCTED
  Full Address
- TELEPHONE NO: FAX NO:
- CELL: EMAIL:

GOOD CLINICAL PRACTICE (GCP)
GCP TRAINING: Please list Principal and all Sub-Investigators GCP Training
Please indicate DATE AND NAME of GCP Course attended (dd/mmm/year)
(Investigators meetings do not qualify as GCP training)
(Please attach study specific CV's AND Declarations in the required format.)

- Full Name:_____
- GCP Course Name: _____
- Date of GCP course: day/month/year: _____
  (the date is important for database process– please insert full date)

STEP 2. National Health Research Ethics Committee/ South African Clinical National Clinical Trials Register

- National database of all research done in South Africa (NHREC, SANCTR)
- http://www.ethicsapp.co.za/ / http://www.sanctr.gov.za/
- Online application, copy of NHREC application to be sent with HREC and SAHPRA submissions
- Both databases updated once approvals are received from both entities

NHREC

South African Human Research Electronic Application System

Welcome

Welcome to the online ethics application system of the South African National Human Research Ethics Council.

The Registration of Clinical Trial Information is important to enable applicants to submit proof of registration to relevant Ethics Committees and the study information is automatically uploaded to the South African National Clinical Trials Register **(SANCTR)** system via the NHREC registration number. sequential processes for applicants are described below.

- Applicants register and enter clinical trial registration information on the 'Ethicsapp' site (www.ethicsapp.co.za). The system generates the NHREC application/registration number.
- Once Ethics or MCC approval is obtained applicants enter these regulatory approval numbers us the NHREC number on the SANCTR site utilising the SANCTR Toolkit - (www.sanctr.gov.za).
- The DOH then issues the National Register Number.

For further information on the process of registering clinical trials please refer to www.sanctr.gov.za.

The Registration of all Clinical Trials on the SA National Clinical Trial Register is required by law - (reference to the appropriate legislation will be supplied when issued).

Please Register before using the system by selecting the register button in the top right hand corner, alternatively go to 'How to Register' under the 'About' section for a more detailed explanation.

- It is advisable to select User names that are generic to Company / Academic Department / Research Unit.

health

Department:
Health
REPUBLIC OF SOUTH AFRICA

South African National Clinical Trial Register

Welcome to SANCTR

The South African National Clinical Trials Register provides the public with updated information on clinical trials on human participants being conducted in South Africa. The Register provides you with information on a trials purpose; who can participate, where the trial is located, and contact details.

The South African National Clinical Trials Register forms part of international calls for making trial information publicly available. The International Committee of Medical Journal Editors, which includes peer reviewed journals from around the world, recently made a statement that from 1 July 2005 no trials will be considered for publication unless they are included on a research register. The World Health Organisation has begun the push for clinical trial registration with the initiation of a Clinical Trials Register platform. Similarly, the global pharmaceutical industry has recently released plans to make trial data more publicly available.

The benefits of a central publicly accessible clinical trial register are numerous. They include:

- Serves to promote collaboration among researchers, the private sector and the community through the sharing of research information;
- Assists people to identify clinical trials they can participate in;
- Decreases publication bias; reduce duplication of research efforts;
- Promotes best use of limited research resources; and
- Contributes to global efforts to reduce / eliminate disease.

STEP 3. Wits Human Research Ethics Committee

- Committee meets monthly excl. December
- Site collates documents for the assessor/ reviewers
- Comments/ queries from assessors are sent to site
- Queries addressed by principal investigator and/ or protocol team
- Final ethics approval received

STEP 4. South African Health Products Regulatory Authority (SAHPRA)

- Previously MCC- Medicines Control Council
- Committee meets quarterly, submissions done before 3 months before
- Comments/ queries raised and sent to site
- Queries addressed by PI and/ or protocol team
- Final approval received

MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

APPLICATION TO CONDUCT CLINICAL TRIALS

STEP 5. National Health Research Database (NHRD)

- After Ethics and SAHPRA approval
- Complete online form, upload Protocol, approvals
- NHRD administrator distributes the protocol to the relevant district research committees.
- District research committees review the protocol and provide recommendations to the provincial committee
- Approval granted after recommendations from the district committees, then recruitment can start
- District Research Committees meet monthly

https://nhrd.hst.org.za/

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The National Health Research Database

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Provincial Department of Health Research Days

The following provinces are hosting their annual Research Days soon. For more information, see the attached PDF docun

Why do protocols go through all these submissions? Is it necessary?

1. **Ethics Committee:** Oversees the safety, rights and welfare of human participants in research. Committee comprises of doctors who specialise in a variety of fields (e.g paediatrics, obstetrics & gynaecology, psychiatry cardiovascular etc) there are lawyers, social workers, community representatives, priests, social workers. This ensures that all rights of the participant are taken into account.

2. SAHPRA:

Regulates

- everything related to Medicines and Related Substances,
- Medical Devices.
- Regulations relating to the Labelling, Advertising and Composition of medicines and cosmetics.
- Product recalls.

There is a board comprises of individuals with expertise in the fields of medicine, medical devices, *in vitro* diagnostic medical devices (IVDs), vigilance, clinical trials, good manufacturing practice, public health. SAHPRA has different units/ directorates, we deal with the Clinical Evaluation & Trials Unit. All clinical trials who are doing research on medicines, new dose, different use need to be approved by SAHPRA.

3. NHREC/ SANCTR: database of all research conducted in SA, helps with seeing areas of research that may be available.

4. NHRD: streamlines recruitment efforts for sites. They check if the health facilities requested for recruitment meet the criteria of the protocol requirements.

Timelines

1. **MTN042B**
Protocol received, currently preparing for RRC submission due on 01 Apr 2019

2. **MTN 042**
Awaiting final protocol

3. **MTN 043**
Awaiting final protocol

Thank You!!

Questions?