

FWA #: FWA00001637
Institution: U of Cape Town
Expires: 03/08/2028

OMB No. 0990-0278
Approved for use through August 31, 2023

Federalwide Assurance (FWA) for the Protection of Human Subjects

1. Institution Filing Assurance

Legal Name: U of Cape Town
City: Cape Town State/Province: Country: SOUTH AFRICA

2. Institutional Components

List below all components over which the Institution has legal authority that operate under a different name. Also list with an asterisk (*) any alternate names under which the Institution operates.

NOTE: The Signatory Official signing this Assurance must be legally authorized to represent the Institution providing this Assurance and all components listed below.

Name of Component or Alternate Names Used	City	State (or Country if Outside U.S.)	
Groote Schuur Hospital	CAPE TOWN	SF	A
Red Cross War Memorial Children's Hospital	CAPE TOWN	SF	A
Mowbray Maternity Hospital	CAPE TOWN	SF	A
Victoria Hospital	CAPE TOWN	SF	A
Somerset Hospital	CAPE TOWN	SF	A
Vincent Palloti Hospital	CAPE TOWN	SF	A
Brooklyn Chest Hosp	CAPE TOWN	SF	A
Valkenberg Hospital	CAPE TOWN	SF	A
Desmond Tutu HIV Centre	CAPE TOWN	SF	A
Institute Infectious Disease & Molecular Medicine	CAPE TOWN	SF	A
Lentegeur Hospital	CAPE TOWN	SF	A
Alexander Hospital	CAPE TOWN	SF	A
UCT Lung Institute	CAPE TOWN	SF	A
Vanguard Clinic	Cape Town	SF	A
Children's Institute	Cape Town	SF	A
Langa Clinic	Cape Town	SF	A
Netreg Clinic (Bonteheuwel)	Cape Town	SF	A
Vanguard Drive Community Centre	Cape Town	SF	A

Brewelskloof Hosp	Cape Town	SF	A
Khayelitsha Site Two	Cape Town	SF	A
South African TB Vaccine Initiative	Cape Town	SF	A
UCT Private Hosp	Cape Town	SF	A
MRC/UCT Research Unit for Exercise Science and Sports Medicine	Cape Town	SF	A
Nolungile Clinic, Khayelitsha	Cape Town	SF	A
Groote Schuur Hospital	Cape Town	SF	A
Desmond Tutu HIV Foundation	Cape Town	SF	A
Khayelitsha Hospital	Cape Town	SF	A
Desmond Tutu Health Foundation	Cape Town	SF	A
Mitchells Plain CHC	Cape Town	SF	A
Gugulethu CHC	Cape Town	SF	A
Vuka Research Clinic	Khayelitsha	SF	A

3. Statement of Principles

This Institution assures that all of its activities related to human subjects research, regardless of the source of support, will be guided by the following statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution. (indicate below)

The Belmont Report

The Declaration of Helsinki

4. Applicability

(a) This Assurance applies whenever this Institution becomes engaged in human subjects research conducted or supported by any U.S. federal department or agency that has adopted the U.S. Federal Policy for the Protection of Human Subjects (also known as the Common Rule), unless the research is otherwise exempt from the requirements of the Common Rule or the department or agency conducting or supporting the research determines that the research shall be conducted under a separate assurance.

5. Assurance of Compliance with the Terms of the Federalwide Assurance

(a) This Institution assures that whenever it engages in research to which this Assurance applies, it will comply with the Terms of the Federalwide Assurance (contained in a separate document on the Office for Human Research Protections (OHRP) website).

(b) Non-U.S. institutions only: This Institution assures that whenever it engages in research to which this Assurance applies it will comply with the following procedural standards (please check one or more of the following):

*The current Council for International Organizations of Medical Sciences (CIOMS)
International Ethical Guidelines for Biomedical Research Involving Human Subjects*

6. Designation of Institutional Review Boards (IRBs)

This Institution assures that it will rely upon only IRBs registered with OHRP for review of research to which this FWA applies. This institution (a) designates the following internal IRB(s) for review of research under this Assurance; or (b) does not have an internal IRB and designates the following external IRB for review of all research to which this FWA applies or, if multiple external IRBs are relied upon, the following external IRB that reviews the largest percentage of research to which this FWA applies.

NOTE: Institutions designating internal IRBs do not need to designate any of the external IRBs upon which it relies.

HHS IRB Registration Number	Name of IRB as Registered with HHS	Is the IRB Internal or External to the Institution?
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IRB00001937 U of Cape Town IRB #1 - Senate Ethics in Rsch Committee I
IRB00001938 U Cape Town IRB #2 - HS Rsch & Ethics Committee I

7. Human Protections Administrator (e.g., Human Subjects Administrator or Human Subjects Contact Person)

First Name: Lyn Middle Initial: Last Name: Horn
Degrees or Suffix: MBBch, PhD Institutional Title: Director, Office of Research Integrity
Institution: University of Cape Town
Telephone: 27 21 650 1287 FAX: 27 21 448 1989 E-Mail: lyn.horn@uct.ac.za
Address: University Cape Town
 Allan Cormack House, 2 Rhodes Avenue
 Mowbray
City: Cape Town State/Province: Country: SOUTH AFRICA

8. Signatory Official (i.e., Official Legally Authorized to Represent the Institution)

I have read and agree to the Terms of the Federalwide Assurance.

I recognize that providing research investigators, IRB members and staff, and other relevant personnel with appropriate initial and continuing education and training about human subject protections will help ensure that the requirements of this Assurance are satisfied.

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure protections for human subjects as specified above. The IRB(s) that this institution relies upon will comply with the Terms of the Federalwide Assurance when reviewing research covered by this Assurance and possess appropriate knowledge of the local context in which this Institution's research will be conducted.

All information provided with this Assurance is up-to-date and accurate. I am aware that false statements could be cause for invalidating this Assurance and may lead to other administrative or legal action.

Signature: Royston Pillay

Date: 03/08/2023

First Name: Royston Middle Initial: Last Name: Pillay

Degrees or Suffix: Institutional Title: Registrar

Institution: University of Cape Town

Telephone: 27 21 650 2115 FAX: 27 21 650 2138 E-Mail: royston.pillay@uct.ac.za

Address: University Cape Town
Room 201.1 Bremner Building
Lover's Walk, Lower Campus
Rondebosch, 7701

City: Cape Town State/Province: Country: SOUTH AFRICA

9. FWA Approval

The Federalwide Assurance for the Protection of Human Subjects submitted to HHS by the above Institution is hereby approved.

Assurance Number: FWA00001637

Expiration Date: 03/08/2028

Signature of HHS Approving Official: Yi-Chiu Fan

Date: 03/08/2023

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-0278 . The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance