

**UNIVERSITY OF CAPE TOWN**  
**INSTITUTIONAL BIOSAFETY COMMITTEE**



**Minutes**

Wednesday, 27 August 2025

On-line meeting

14h00-16h00

**Committee members**

Prof M Moshabela *ex officio*  
Prof J Murugan (acting) *ex officio*  
Prof E Ramugondo *ex officio*  
Prof B Collier-Reed *ex officio*

Prof Digby Warner (IBC Chair)  
Dr Thomas Oelgeschläger (Chair, SCI FBC & Deputy IBC Chair)  
A/Prof Suraj Parihar (Chair, FHS FBC & Deputy IBC Chair)  
Ms Bronwyn Arendze-Bailey (Scientific Officer)  
Prof Johan Burger (Community Member – Plant Expert)  
vacant (Community Member)  
Mrs Paula Saner (Acting Director: ORI)  
Ms Nzwakie Gxumisa (FHS, Health, Safety and Biosafety Manager)  
Dr Tshepo Matjila (RAF Director)  
Ms Kim Van Reenen (Environmental Risk Manager)  
Dr Sandiswa Mbewana (SCI Representative – Plant Expert)  
Dr Sarita Groenewald (Biosafety & Biosecurity Specialist)  
Prof Robert Wilkinson Co-opted committee member  
Dr Ros Chapman Co-opted committee member

**Servicing Officer**

Ms Suraya Azam  
Ms Lisa Williams (back-up)

**By invitation:**

Dr Blessing Silaigwana (FHS: RDU)  
Ms Olivia Langenhoven (FHS: RDU)  
Ms Kirshni Naidoo (Director: Occupational Health & Safety)  
Ms Thando Mdaka (Research Integrity Coordinator: Investigations)

**Attendees:**

Prof Digby Warner  
A/Prof Suraj Parihar  
Ms Bronwyn Arendze-Bailey  
Prof Johan Burger  
Mrs Paula Saner  
Ms Nzwakie Gxumisa  
Dr Tshepo Matjila  
Dr Sarita Groenewald  
Prof Robert Wilkinson  
Dr Ros Chapman  
Dr Blessing Silaigwana  
Ms Olivia Langenhoven  
Ms Kirshni Naidoo  
Ms Thando Mdaka  
Ms Lisa Williams  
Mrs Suraya Azam

**1 PRELIMINARY MATTERS**

**1.1 Welcome and Apologies**

Apologies received from Ms Van Reenen.

**2 QUORUM**

The meeting achieved quorum.

**3 DECLARATION OF INTEREST**

All members duly sent their responses.

**4 CONFIRMATION OF 2 SETS OF MINUTES FROM PREVIOUS MEETING**

The minutes from 30 July 2025 were accepted with no corrections.

**5 MATTERS ARISING FROM PREVIOUS MINUTES**

**5.1 Update on the appointment of new community members**

The Chair reported that Prof Johan Burger will retire and resign from the IBC at the end of 2025. Two new community members will therefore need to be appointed. The Chair has approached Prof Hugh Corder for advice on identifying a candidate with legal expertise and will provide an update at the next meeting.

**5.2 F/IBC Amendment Form**

The F-IBC amendment form has been accepted and approved by all members.

**5.3 Responsible Conduct of Research (RCR) training requirement**

The Chair reminded members to complete Modules 1, 2, 3, and 4 of the Responsible Conduct of Research (RCR) training. Certificates of completion must be submitted to the IBC servicing officer, who will be responsible for collating and tracking submissions and providing feedback to Internal Audit by 31 August 2025.

**6 MATTERS FOR REVIEW AND DISCUSSION**

The committee approved the following protocol amendments, noting that sufficient information had been provided to manage the associated risks:

**6.1 Protocol amendments for discussion**

**6.1.1 *IBC003-2022 - Phenotyping resistant hypertension: exploring the immune system and microbiome connection in the pathophysiology of resistant hypertension and Covid-19 with uncontrolled hypertension – Risk Group 3***

Prof Ntobeko Ntusi

This is a cross-sectional study of patients with resistant uncontrolled hypertension and patients with newly diagnosed uncontrolled hypertension in the setting of Covid-19; and how their phenotype, immune system, gut and oral microbiome compares to patients with resistant controlled

hypertension, patients diagnosed with Covid-19 in the absence of hypertension; and healthy sex and age-matched volunteers.

**6.1.2 IBC021-2021 - MTBVAC in Newborns: Randomized, Double-blind, Controlled Phase 3 Trial to Evaluate the Efficacy, Safety, and Immunogenicity of MTBVAC Administered in Healthy, HIV Unexposed and HIV Exposed Uninfected Newborns in Tuberculosis-endemic Regions of Sub-Saharan Africa – Risk Group 2**

A/Prof Michele Tameris

**6.1.3 IBC007-2024 - A Phase 2b, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of a Candidate Tuberculosis (TB) Vaccine, MTBVAC, Against TB Disease in Adolescents and Adults Aged 14-45 Years, Living in a TB Endemic Region (IAVI C113) Risk Group 2**

Honorary Professor Rodney Dawson

**6.1.4 IBC009-2024 - A Phase 2b, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of a Candidate Tuberculosis (TB) Vaccine, MTBVAC, Against TB Disease in Adolescents and Adults Aged 14-45 Years, Living in a TB Endemic Region (IAVI C113) Risk Group 2**

Professor Keertan Dheda

**6.1.5 IBC011-2024 - A Phase 2b, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of a Candidate Tuberculosis (TB) Vaccine, MTBVAC, Against TB Disease in Adolescents and Adults Aged 14-45 Years, Living in a TB Endemic Region (IAVI C113) Risk Group 2**

Dr Enid Nicolette Tredoux

**6.1.6 IBC007-2024 - A Phase 2b, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Immunogenicity of a Candidate Tuberculosis (TB) Vaccine, MTBVAC, Against TB Disease in Adolescents and Adults Aged 14-45 Years, Living in a TB Endemic Region (IAVI C113) Risk Group 2**

Professor Robert Wilkinson

**Title change:** All sites amended the study title to remove the restriction to “interferon gamma release assay positive” participants. The revised title refers broadly to “adolescents and adults aged 14–45 years, living in a TB endemic region.” This reflects the expansion of enrolment to include both IGRA-positive and IGRA-negative participants.

**Scientific rationale:** The expansion allows assessment of MTBVAC efficacy, safety, and immunogenicity in a broader population. The primary endpoint remains focused on IGRA-positive participants, with an additional secondary endpoint added for the combined study population (IGRA-positive and IGRA-negative).

**Additional protocol changes (across sites):**

- Increase in overall sample size.
- Terminology change: “subclinical TB” replaced with “asymptomatic TB.”
- Additional QuantiFERON testing of IGRA-negative participants at scheduled time points to detect conversion.
- Updated definition and management of injection site abscesses in line with WHO guidance.
- Provision for additional blood sampling at later time points (Months 24 and 36) for correlates of immune protection.
- Clarification of diary card response capture in eCRFs.
- Minor editorial changes.

**6.2 Protocols for Noting**

The committee noted the following protocols:

**6.2.1 *Fluconazole plus flucytosine vs. fluconazole alone for cryptococcal antigen-positive patients identified through screening: A phase III randomised controlled trial Acronym: EFFECT (Efficacy of Flucytosine and Fluconazole as Early Cryptococcal Treatment) – Risk Group 2***

Dr Kyla Murphy

**6.2.2 *Pathophysiology and clinical outcomes of subclinical cryptococcal meningitis short title / acronym: Subclinical Cryptococcal Meningitis in patients excluded from participation in the EFFECT Study (Sub-EFFECT) – Risk Group 2***

Dr Kyla Murphy

**6.2.3 *Investigating evolution of antibiotic resistance and association with collateral drug phenotypes - Risk Group 2***

Dr Vinayak Singh

**6.2.4 *Antenatal maternal environmental exposures, early life inflammation and neurodevelopment in a South African birth cohort – Risk Group 2***

A/Prof Pieter Naude

**7 IBC MEMBERSHIP**

The Chair informed the committee that the appointment of two community members are required, as these positions are critical to the integrity and validity of the committee and advice is being sought on appointing a community member with legal expertise. The Chair also noted the resignation of Ms Gxumisa, thanked her for her service, and confirmed that new representation from FHS will be appointed.

**8 ANY OTHER BUSINESS**

**8.1 Update of the ToR**

Members are appointed for three-year terms, with possible reappointment. Certain positions linked to office require amendment in the ToR. The Chair requested succession planning at IBC and faculty level, and stronger induction processes for new members.

The meeting ended at 14h35.

2 October 2025

---

**Date**



---

**Chair approval**