

## RePORT South Africa



**Mark Hatherill**  
**University of Cape Town**  
**RePORT International Meeting-Rio Brazil Sept 2017**

## *RePORT SA*

- Agreement for RePORT SA between SAMRC and NIAID/NIH signed April 2015
- RePORT SA initiated in 2016
- Funding provided through the South African Medical Research Council (**SAMRC**), with funds from the South African Department of Health (**NDoH**), and National Institute of Allergy and Infection Diseases (**NIAID**) and National Institute of Health (**NIH**) & **PEPFAR**
- Bio-repository for specimen storage is hosted by the HIV Prevention Research unit (**HPRU**), a unit of the SAMRC located in Durban, SA- funded by SAMRC
- The statistical and data management center is hosted by the Perinatal HIV Research Unit (PHRU) located at Chris Hani Baragwanath Hospital in Johannesburg, SA-funded by SAMRC

# RePORT SA: Funded Projects

TB RePORT SA				
Proposal Title	SA PI	SA Institute	US PI	US Institute
The Clinical Research Unit (CRU) for Advancement of Tuberculosis (TB) Biomarker-Targeted Interventions	Mark Hatherill	University of Cape Town (SATVI)	Jerrold Jay Ellner	Boston University Medical Campus
TB in hot and cold spots in South Africa: researching index cases and their households.	Neil Martinson	Wits Health Consortium (PHRU)	Richard E. Chaisson	John Hopkins University
Highly sensitive cartridge-based nucleic acid amplification testing for the diagnosis of pulmonary tuberculosis in children	Mark Nicol/ Heather Zar	University of Cape Town	Jeffrey Starke	Baylor College
Quantifying infectiousness of undiagnosed tuberculosis cases and impact of enhanced community-based active case finding strategy using novel diagnostic tools – a randomized controlled trial	Keertan Dheda	University of Cape Town	Tawanda Gumbo	Baylor Research Institute
Identifying Innovative Bacterial and Host-Mediated Biomarkers of Treatment Response to Tuberculosis Chemotherapy	Alexander Pym	Africa Health Research Institute	Timothy Sterling	Vanderbilt University

# *RePORT SA: RICC RFA's & Cross Consortium*

- RePORT Paediatric RFA
  - Lala: EDICT study- Enhancing diagnostics and improving outcomes in childhood TB
    - Ethics & hospital approval obtained awaiting district approval
  - Nicol/Zar: Oral swab testing nested in RePORT study
    - 124 children tested; single swabs per child from 84 children; two swabs per child from 40 children.
- TB-Diabetes Cross-consortium project
  - Martinson: Ethics to be submitted in Sept
  - Pym, Andrade, Sterling: Prospective profiling of eicosanoid and inflammatory balance in TB-diabetes and TB-HIV

# *RePORT SA: Scientific projects & Publications*

- Other scientific projects linked to RePORT
  - CORTIS trial; PREDICT trial; ACTTIS study
  - Steyn (AHRI): Physiochemical and Bioenergetics Dynamics within the Spectrum of Human TB:
    - agreement under review for final execution
  - Martinson
    - Digital x-ray collection to allow mathematical algorithm to diagnose TB
    - Validate sputazol to liquefy sputum allowing ease of separation-Martinson
- Publications/presentations resulting from RePORT
  - Diagnosis Of Pulmonary Tuberculosis In HIV-Infected And Uninfected Children Using Xpert Mtb/rif Ultra. H. J. Zar, L. Workman, M. Nicol. Am J Respir Crit Care Med 2017;195:A7610. Abstract from ATS 2017
  - TB, HIV, Diabetes Mellitus and Early TB Treatment Response in Durban, South Africa- Farina Karim, Fernanda Maruri, Khadija Khan, Sashen Moodley, Day Munatsi, Alexander S. Pym, Timothy R. Sterling, Yuri F. van der Heijden- Poster @ RePORT International Meeting, Rio Brazil, Sept 2017
  - Accuracy of Ultra for the diagnosis of pulmonary tuberculosis in children- Poster presentation @ RePORT International Meeting, Rio Brazil, Sept 2017

# RePORT SA: Site locations

## Site locations in SA ★

### Western Cape

- Klipfontein (Dheda)
- Mitchells Plain (Dheda)
- Red Cross Childrens Hospital (Nicol/Zar)
- Ravensmead (Walzl)
- Khayelitsha (Wilkinson)
- UCT Lung institute (Dawson)
- Worcester (Hatherill)

### Eastern Cape

- Dora Nginza (Nicol/Zar)

### Kwazulu-Natal

- Kwadabeka (Pym)

### North West

- Klerksdorp (Martinson)

### Limpopo

- Polokwane (Martinson)

### Gauteng

- Chris Hani Baragwanath Hospital (Lala)
- Pretoria (Nchabeleng/Fourie/Hatherill)



## Common Protocol Status: Cohort A

Site name	Date started enrollment	# Enrolled/ target (%)	Completing 6 mo/24 mo follow up (%)	LTFU* at 6 mo/24 mo (%)	Known endpoints? (failures, relapses)
Nicol/Zar	March 2016	240/450 (53%)	22%/0%	0%	2 relapse
Pym	Dec 2016	64/75 (85%)	3%/0%	0%	None yet
Dheda	March 2017	4/60 (7%)	0%/0%	0%	None yet
Martinson	May 2017	22/300 (8%)	0%/0%	0%	None yet
Hatherill**	pending ethics approval	0/50 (0%)	N/A	N/A	N/A

*\*LTFU = lost to follow-up*

*\*\*Supplementary funding from SAMRC March 2017*

## Common Protocol Status: Cohort B

Site name	Date started enrollment	# Enrolled/ target (%)	Completing 6 mo/24 mo follow up (%)	LTFU* at 6 mo/24 mo (%)	Known endpoints? (failures, relapses)
Dheda	March 2017	3/150 (2%)	0%/0%	0%	None yet
Martinson	May 2017	23/1200 (2%)	0%/0%	0%	None yet
Hatherill	June 2017	50/225 (22%)	0%/0%	0%	None yet

*\*LTFU = lost to follow-up*



## *Common Protocol Sample updates*

### ***Cohort A = 344 (30%)***

<b>Sample type</b>	<b>Aliquots</b>
Paxgene	258
QGIT	280
Whole Blood (DNA)	138
PBMC	41
Plasma	731
Urine	832
Saliva	200
Sputum	566
MTB Isolate	272

### ***Cohort B = 76 (4%)***

<b>Sample type</b>	<b>Aliquots</b>
Paxgene	70
QGIT	528
Whole Blood (DNA)	29
PBMC	204
Plasma	216
Urine	579
Saliva	288

\*Excludes Nicol/Zar sample storage

## *RePORT SA: Future Data or Sample Sharing*

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- Data/sample-sharing issues for discussion:
  - Data Sharing agreement under review by RICC
  - Need for a country-level consortium agreement
- Are there any definite or planned RePORT-based projects you would like to propose for discussion?
  - None yet
- Laboratory issues for discussion?
  - Standardization of FBS for PBMC's

# *Cape Town, South Africa*

