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# South African Medical Research Council Clinical Trials Unit (MRC CTU)

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Project Number	Former Number	Contact PI/Project Leader	Awardee Organization
<b>SUM1AI069422-13</b>	<b>1UM1AI108549-01</b>	<b>GOGA, AMEENA Other PIs</b>	<b>MEDICAL RESEARCH COUNCIL OF SOUTH AFRICA</b>

## Description

### **Abstract Text**

DESCRIPTION (provided by applicant): Durban, KwaZulu Natal, South Africa is the epicenter of the global HIV **pandemic**, where a large number of people infected with HIV are also co-infected with TB. The MRC Clinical Trials Unit (MRC CTU) is internationally renowned for conducting large scale trials of HIV prevention including microbicides, vaginal diaphragm, and oral Pre-Exposure Prophylaxis (PrEP); HIV therapeutic trials, and socio-behavioral studies. Six well-established clinical research sites (CRSs) are located in the greater Durban area, where HIV incidence among young women ranges from 5.1/100PY (in earlier research) to 16.4/100PY (in 2012). Lack of effectiveness in earlier trials was due to multiple factors, including poor adherence. The current understanding of the epidemic suggests a need for an integrated approach to HIV and TB prevention, treatment, and linkage to care. The MRC CTU's primary goal is to integrate site operations, community partnerships, and responses to adherence challenges/behavioral research by partnering with 4 Networks to meet the following aims: AIM 1: Conduct HIV prevention trials of long-acting microbicides and oral PrEP and HIV vaccines in at-risk populations. We hypothesize that long-acting formulations in this population may circumvent adherence challenges. AIM 2: Conduct therapeutic trials of novel, safe, effective, and robust regimens. We hypothesize that cost-effective, third-line treatment regimens will be needed in the foreseeable future in our setting. AIM 3: To undertake RCTs of HIV-associated comorbidities. There are critical gaps in TB treatment that we propose to address by developing and participating in trials using molecular diagnostics to determine treatment duration and optimize drug regimens for multidrug-resistant TB. AIM 4: Integrated strategies to address the epidemic. No single HIV prevention option will address the epidemic. We hope to participate in trials testing integrated strategies of HIV prevention, as well as those integrating prevention and treatment of both HIV and TB, with effective linkage to care. The MRC CTU has access to the population at-risk, a well-developed and centralized CRS infrastructure, and the experience and expertise of international consultants to undertake and deliver on the proposed research aims. RELEVANCE: This comprehensive attempt to address the dual HIV/TB **pandemic** in Durban, South Africa through an integrated approach of testing novel HIV prevention strategies, novel HIV therapeutics agents for future options, and addressing HIV co-morbidity with TB with appropriate linkage to care, will provide the empirical data to guide future real-world development and implementation of effective HIV and TB strategies.

### **Public Health Relevance Statement**

This comprehensive attempt to address the dual HIV/TB pandemic in Durban, South Africa through an integrated approach of testing novel HIV prevention strategies, novel HIV therapeutics agents for future options, and addressing HIV co-morbidity with TB with appropriate linkage to care, will provide the empirical data to guide future real-world development and implementation of effective HIV and TB strategies.

### **NIH Spending Category**

Antimicrobial Resistance	Behavioral and Social Science	Clinical Research
Clinical Trials and Supportive Activities	Emerging Infectious Diseases	HIV/AIDS
Infectious Diseases	Orphan Drug	Prevention
Vaccine Related (AIDS)	Women's Health	Rare Diseases
		Tuberculosis
		Immunization
		Vaccine Related

### **Project Terms**

AIDS prevention	Address	Adherence	Adult	Area	Barrier Contraception	Behavioral
Behavioral Research	Caring	Clinical Research	Clinical Trials	Clinical Trials Unit	Communities	
Comorbidity	Couples	Data	Development	Diagnostic	Drug resistance	
Drug resistance in tuberculosis	Effectiveness	Epidemic	Failure	Formulation	Future	Goals
HIV	HIV prevention trial	HIV vaccine	HIV/TB	Health Personnel	Healthcare	
Home environment	Incidence	Individual	Infrastructure	International	Intervention	
Knowledge	Link	Medical Research	Multidrug-Resistant Tuberculosis	Nucleosides	Oral	
Outcome	Participant	Pharmaceutical Preparations	Phase	Policies	Policy Maker	

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5UM1AI069422-13	1UM1AI108549-01	GOGA, AMEENA <a href="#">Other PIs</a>	MEDICAL RESEARCH COUNCIL OF SOUTH AFRICA

SPECIALIST SCIENTIST [bcastillo@niaid.nih.gov](mailto:bcastillo@niaid.nih.gov)Contact  
[Ameena.Goga@mrc.ac.za](mailto:Ameena.Goga@mrc.ac.za)

### Organization

Name	Department Type
MEDICAL RESEARCH COUNCIL OF SOUTH AFRICA	Unavailable
City	Organization Type
CAPE TOWN	Unavailable
Country	
SOUTH AFRICA (SF)	

State Code  
Congressional District

### Other Information

FOA	Administering Institutes or Centers	Project Start Date	
<a href="#">RFA-AI-12-018</a>	<b>NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES</b>		<b>01-March-2007</b>
Study Section	DUNS Number	Project End Date	
<a href="#">ZAI1-JBS-A(S3)</a>	635909489		<b>30-November-2020</b>
	CFDA Code	Budget Start Date	
	855		<b>01-December-2018</b>
Award Notice Date		Budget End Date	
12-November-2018			<b>30-November-2019</b>
Fiscal Year			
2019			

### Project Funding Information for 2019

Total Funding	Direct Costs	Indirect Costs
\$3,525,766	\$3,264,598	\$261,168

Year	Funding IC	FY Total Cost by IC
2019	NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	\$3,525,766

### NIH Categorical Spending

[Click here for more information on NIH Categorical Spending](#)

Funding IC	FY Total Cost by IC	NIH Spending Category
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	\$542,335	Vaccine Related (AIDS); Women's Health;
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	\$1,084,670	Antimicrobial Resistance; Behavioral and Social Science; Clinical Research; Clinical Trials and Supportive Activities; Emerging Infectious Diseases; HIV/AIDS; Immunization; Infectious Diseases; Orphan Drug; Prevention; Rare Diseases; Tuberculosis; Vaccine Related;
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	\$1,220,548	Vaccine Related (AIDS) Women's Health
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES	\$2,441,096	Antimicrobial Resistance; Behavioral and Social Science; Clinical Research; Clinical Trials and Supportive Activities; Emerging Infectious Diseases; HIV/AIDS; Immunization; Infectious Diseases; Orphan Drug; Prevention; Rare Diseases; Tuberculosis; Vaccine Related;

### Sub Projects

No Sub Projects information available for 5UM1AI069422-13

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Leader

GOGA, AMEENA

[Other](#)[PIs](#)

Awardee Organization

MEDICAL RESEARCH

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### [Outcomes](#)

No Outcomes available for 5UM1AI069422-13

### [Clinical Studies](#)

No Clinical Studies information available for 5UM1AI069422-13

### [News and More](#)

#### Related News Releases

No news release information available for 5UM1AI069422-13

### [History](#)

No Historical information available for 5UM1AI069422-13

### [Similar Projects](#)

No Similar Projects information available for 5UM1AI069422-13

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