

REPUBLIC OF RWANDA/REPUBLIQUE DU RWANDA



NATIONAL ETHICS COMMITTEE / COMITE NATIONAL D'ETHIQUE

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Ministry of Health

P.O. Box. 84

Kigali, Rwanda.

FWA Assurance No. 00001973
IRB 00001497 of IORG0001100

November, 2015

No342/RNEC/2015

Timothy Rutland Walsh
Principal Investigator

Your Project title "**Burden of Antibiotic resistance in neonates from developing societies**" has been evaluated by the Rwanda National Ethics committee.

Name	Institute	Involved in the decision		
		Yes	No (Reason)	
			Absent	Withdrawn from the proceeding
Dr.Jean-Baptiste MAZARATI	Biomedical Services (BIOS)	x		
Prof. Eugène RUTEMBESA	University of Rwanda	X		
Dr.Laetitia NYIRAZINYOYE	University of Rwanda (school of public Health)		x	
Prof.Alexandre LYAMBABAJE	University of Rwanda	X		
Ms.Françoise UWINGABIYE	Lawyer at Musanze	X		
Dr. Egide KAYITARE	University of Rwanda	X		
Sr.Domitilla MUKANTABANA	Kabgayi Nursing and Midwife school	X		

Mr. David K. TUMUSIIME	Kigali Health institute	X		
Dr. Lisine TUYISENGE	Kigali Teaching Hospital	X		
Dr. Claude MUVUNYI	Biomedical Services (BIOS)		x	

After reviewing your protocol during the RNEC meeting of October 10, 2015 where quorum was met, and revisions made on the advice of the RNEC submitted on 10 November, 2015, **Approval letter has been granted to your study.**

Please note that approval of the protocol and consent form is valid for **12 months**. You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrollment of participants
3. All consent forms signed by subjects should be retained on file. The RNEC may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the RNEC in a timely fashion and before expiry of this approval.
5. Failure to submit a continuing review application will result in termination of the study.
6. Notify the Rwanda National Ethics committee once the study is finished.

Sincerely,



Dr. Jean- Baptiste MAZARATI
Chairperson, Rwanda National Ethics Committee.

Date of Approval 10 November 2015
 Expiration date: 9 November, 2016
 Rwanda National Ethics Committee
 Approval Date: ... 10.11.2015
 Expiration Date: 10.11.2016