Tulane University
Human Research Protection Program

Tulane Human Research Protection Program
Institutional Review Boards
Biomedical
Social Behavioral
FWA00002055

DATE:	December 17, 2014
TO:	James Robinson, M.D. and Robert F. Garry, Ph.D.
FROM:	Tulane University Biomedical IRB
STUDY TITLE:	[140674-16] Roles of Protective or Pathogenic B Cell Epitopes in Human Lassa Fever and Ebola Virus Disease (09-00419)
IRB REFERENCE #:	09-00419
SUBMISSION TYPE:	Amendment/Modification
ACTION:	APPROVED
EFFECTIVE DATE:	**December 16, 2014**
EXPIRATION DATE:	**June 11, 2015**
REVIEW TYPE:	Expedited Review
PROJECT RISK LEVEL:	Minimal Risk

Thank you for submitting the Amendment/Modification for the above referenced study. The Tulane IRB approved your submission including:

- Amendment/Modification - B Cell_Amendment_Dec 2014 (UPDATED: 12/11/2014)
- Application for Human Subjects Research, Part 1 - Application for Human Subjects Research, Part 1 (UPDATED: 12/11/2014)
- Child Assent - B Cell Assent_SL_track changes (UPDATED: 12/16/2014)
- Child Assent - B Cell Assent_SL_clean (UPDATED: 12/16/2014)
- Child Assent - B Cel_Assent SCript_SL (UPDATED: 12/16/2014)
- Consent Form - B Cell Consent_SL_track changes (UPDATED: 12/16/2014)
- Consent Form - B Cell _Consent_SL_clean (UPDATED: 12/16/2014)
- Consent Form - B Cell_Consent Script_SL (UPDATED: 12/16/2014)
- Cover Sheet - B Cell_Cver Sheet_Dec 2014 (UPDATED: 12/16/2014)
- Other - Emergency Contact Cards (UPDATED: 12/12/2014)
- Other - ICIDR Grant Application (UPDATED: 12/11/2014)
- Protocol - B Cell_Protocol_Dec2014_clean (UPDATED: 12/12/2014)
- Protocol - B Cell_Protocol_Dec2014_track changes (UPDATED: 12/12/2014)

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The Tulane University Biomedical IRB has conducted an expedited review and has granted a CONDITIONAL APPROVAL of an amendment to the research titled, "Roles of Protective or Pathogenic B Cell Epitopes in Human Lassa Fever and Ebola Virus Disease," in accordance with 45 CFR 46.110(b)(1). The amendment to the protocol includes:

1. The addition of a new funding source from NIH;

2. A revision to the consent process to allow for obtaining verbal consent, using a consent script, to support strict infection control practice, due to the circulation of Ebola Virus in Sierra Leone;

3. Revisions to the protocol to address requirements from the new funding source. Serology analysis and auditory evaluation for hearing loss are now included in the protocol, as well as the revised consent/assent documents and scripts.

Please provide the Tulane University Biomedical IRB with the approval letter from the Sierra Leone Ethics and Scientific Research Committee, prior to implementing the amended procedures.

Criteria for approval continues in accordance with 45 CFR 46.111(a)(1-7). Children may be enrolled in research not involving greater than minimal risk in accordance with §46.404. The permission by parents or guardians and for assent by children in accordance with §46.408.

This study is approved for the enrollment of 5,300 patients; 2,500 from Nigeria and 2,800 from Sierra Leone which includes 300 Ebola patients. The Investigator reports that 2,355 patients have been enrolled.

IRB approval for this study will expire June 11, 2015.

This approved protocol is supported by NIH grant HHSN272200900049C (Roles of protective or pathogenic B cell epitopes in human Lassa fever) with funding pending under grant opportunity 1 U19 AI115589-01 (International Collaboration in Infectious Disease Research on Lassa Fever and Ebola).

The most recent IRB approved and stamped informed consent/assent form(s) are to be used when enrolling subjects.

If there are any pending approvals from any other institutions or other research oversight committees, the research cannot commence until all such approvals have been obtained, and the PI is to provide to the Tulane IRB via IRBNet a copy of all approval letters as received. This includes Tulane Institutional Biosafety approval (when applicable), Tulane Radiation Safety Committee approval (when applicable), and any other committee approval required by the University. Additionally, for sponsored research, the research cannot commence until the sponsored research agreement has been fully executed.

If you have any questions, please contact the HRPO at (504) 988-2665 or irbmain@tulane.edu.

Sincerely,
Tulane University Human Research Protections Office
1440 Canal St, Suite 1705, TW-36
New Orleans, LA 70112

Please note that the actual signature by the IRB Chair(s) is not required for this document to be effective since it is generated by IRBNet pursuant to the IRB Chair's electronic signature and approval. This process is consistent with Federal Regulations and Tulane standard operating policies with respect to the IRB and Human Research Protection Office, which consider electronically generated documents as official notice to sponsors and others of approval, disapproval or other IRB decisions. Please refer to the HRPO website at http://tulane.edu/asvpr/irb to refer to Tulane's Electronic Signatures and Records Policy.

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GOVERNMENT OF SIERRA LEONE
Office of the Sierra Leone Ethics and Scientific Review Committee
Directorate of Training, Non-Communicable Diseases and Research
Connaught Hospital
Ministry of Health and Sanitation

2nd December, 2014

To: Dr. John S. Schieffelin
Departments of Pediatrics and Internal Medicine
Tulane University School of Medicine
1430 Tulane Avenue TB - 8
New Orleans, Louisiana 70112

Study Title: Development of a Recombinant Antigen Diagnostic for Ebola Zaire Antigen Detection
Committee Action: Expedited Review
Approval Date: 2nd December, 2014
Submission Type: Initial Protocol Approval Version 1.0 of 9th November, 2014

The Sierra Leone Ethics and Scientific Review Committee (SLESRC) having conducted an expedited review of the above study protocol and determined that this protocol presents minimal risk to subjects, hereby grants ethical and scientific approval for the study to be conducted in Sierra Leone. The approval is valid for the period, 2nd December 2014 – 1st December, 2015. It is the responsibility of an investigator to obtain re-approval for any ongoing research prior to its expiration date. The request for re-approval must be supported by a progress report.

Review Comments:

- To use written informed consent with witness signature (for illiterate participants) for blood, saliva, breast milk and urine sample collections. Provide contact 076629251, for SLESRC Secretariat. Augustine Gobba's mobile non-responsive.
- Amendments: Intended changes to the approved protocol such as the informed consent documents, study design, recruitment of participants and key study personnel, must be submitted for approval by the SLESRC prior to implementation.
- Termination of the study: When study procedures and data analyses are fully complete, please inform the SLESRC that you are terminating the study and submit a brief report covering the protocol activities. Individual identifying information should be destroyed unless there is sufficient justification to retain, approved by the SLESRC. All findings should be based on de-identified aggregate data and all published results in aggregate or group form.

Professor Hector G. Morgan
Chair

Email: Personal Info

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DATE:	November 14, 2014
TO:	John Schieffelin, MD
FROM:	Tulane University Biomedical IRB
STUDY TITLE:	[682862-1] Development of a Recombinant Antigen Diagnostic for Ebola Zaire Antigen Detection
IRB REFERENCE #:	14-682862
SUBMISSION TYPE:	New Project
ACTION:	APPROVED WITH CONDITIONS
APPROVAL DATE:	**November 14, 2014**
EXPIRATION DATE:	**November 13, 2015**
REVIEW TYPE:	Expedited Review
PROJECT RISK LEVEL:	Minimal Risk

Thank you for your recent initial submission. The Tulane University Institutional Review Board has approved your submission.

This approval is based on an appropriate risk/benefit ratio and a study design where the risks have been minimized. All research must be conducted in accordance with this approved submission.

The following items were included in this submission:

- Application for Human Subjects Research, Part 1 - Application for Human Subjects Research, Part 1 (UPDATED: 11/13/2014)
- Application Form - ReEBOV Application part 2 (UPDATED: 11/13/2014)
- Consent Form - EBOV RDT Consent Script (UPDATED: 11/11/2014)
- Cover Sheet - Cover SHeet_EBOV RDT_Initial (UPDATED: 11/11/2014)
- CV/Resume - Schieffelin_CV (UPDATED: 11/11/2014)
- Other - Information Card (UPDATED: 11/13/2014)
- Other - routing sheet (UPDATED: 11/11/2014)
- Other - Package Insert (UPDATED: 11/11/2014)
- Proposal - R44 (UPDATED: 11/11/2014)
- Protocol - ReEBOV Protocol_v1 (UPDATED: 11/13/2014)

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