Tulane University
Human Research Protection Program

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

DATE:	January 09, 2018
TO:	Emily Harville
FROM:	Tulane University Biomedical IRB
STUDY TITLE:	Addressing the Rise of Congenital Syphilis
IRB REFERENCE #:	1118637
SUBMISSION TYPE:	Initial Submission
ACTION:	**APPROVED**
APPROVAL PERIOD:	January 09, 2018 - January 08, 2019

Thank you for your recent New Project 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:

- Consent pregnant.doc (Application Form)
- Cover-Sheet-Letter-TemplateIRBChoice_TU_PI.docx (Application Form)
- Initial Expedited and Full Board Submission Checklist.doc (Application Form)
- Pregnant Protocol-Template.doc (Application Form)
- Woman's LOS.pdf (Letter of Support)
- Healthy Start Letter of Support - Congenital Syphilis and Mealth care providers 2017.pdf (Letter of Support)
- CDC MOD Flyer.docx (Flyer)
- Syphilis Bio Application Part 2 pregnant.docx (Application Form)
- Application Part 1 from IRBNet.pdf (Application Form)
- Investigator CITI Certificate from IRBNet.pdf (Training Certificate)
- PI CITI Certificate from IRBNet.pdf (Training Certificate)
- Determination Letter (Decision Letter)
- Supplemental Forms (A-O).doc (Application Form)

On November 3, 2017, the Tulane University Biomedical IRB made a determination of Conditions Required for Approval for the initial submission for this minimal risk study in accordance with 45 CFR 46.110 (b)(1), research category 7.

On January 9, 2018, the Tulane Investigator's response, along with the revised and requested study documents were reviewed and it was determined that the stipulations have been met.

Criteria for IRB approval of this research is met in accordance with 45 CFR 46.111.

This study is approved for the local enrollment of 40 subjects. An Amendment must be submitted, reviewed, and approved before exceeding this number. The Tulane University IRB approved and stamped Consent documents are to be utilized when enrolling subjects.

This study is granted an approval period of January 9, 2018 – January 8, 2019.

Proposed changes to the research study, including enrollment of additional study participants, must be submitted to the IRB for review and approval prior to implementation, unless a change is necessary to avoid immediate harm to subjects.

Please remember that informed consent is a process beginning with a description of the study and assurance of participant understanding followed by a signed consent form. Informed consent must continue throughout the study with dialogue between the Investigator and research participant. Federal regulations require each participant to receive a copy of their signed consent form unless this requirement has been waived by the IRB.

Any unanticipated problems involving risk to subjects or others, deviations from the approved research, non-compliance, and complaints must be reported to the IRB in accordance with Tulane HRPP policies and procedures. If this study includes ongoing oversight by a Data Safety Monitoring Board (DSMB) or

other such committee, reports generated by the DSMB or oversight committee must be submitted to the IRB.

Continuations must be submitted in accordance with Tulane HRPP policies and procedures. 45 CFR 46.109(e) states that an IRB must conduct a continuing review of research at intervals appropriate to the degree of risk, but not less than one year. The federal regulations provide for no grace period. Failure to obtain approval for continuation of your study prior to the expiration date will require discontinuation of all research activities for this study, including enrollment of new subjects.

When all study activities and data analysis have been completed, please notify the IRB within 30 days of such completion by submitting a Study Closure Form.

This research study will expire on January 08, 2019. As per federal regulations and Tulane HRPP policy, this study will be administratively closed 30 days after the expiration date, if approval for continuation of this study has not been granted.

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

Sincerely,
Tulane University Human Research Protection

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 IRBManager 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.