



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

DATE: July 08, 2021

TO: Arachu Castro, PhD, MPH

FROM: Tulane University Social-Behavioral IRB

STUDY TITLE: COVID-19 in Latin America and the Caribbean: Impact on health services for women, children, and adolescents (ISLAC Project)

REF #: 2020-910

SUBMISSION TYPE: Amendments

ACTION: **EXEMPT**

On July 06, 2021, the Tulane University Social-Behavioral IRB provided a review and exempt determination for the changes to this research. This research continues to be exempt from the requirements of the Common Federal Rule in accordance with the appropriate regulations.

The requested changes were as follows:

- Addition of Annie Preaux, Tulane doctoral student, as co-investigator.
- Update the online surveys to 2021.

The following items were submitted as part of the submission:

- 210628 Translation attestation.pdf (Certification of Translation)
- ISLAC 2020 Cuestionario - Espan~ol with marked deletions.pdf (Amendment/Modification)
- ISLAC 2020 Questiona´rio - Portugue^s with marked deletions.pdf (Amendment/Modification)
- ISLAC 2020 Questionnaire - English with marked deletions.pdf (Amendment/Modification)
- ISLAC 2021 Cuestionario - Espan~ol.pdf (Data Collection Tool)
- ISLAC 2021 Cuestionario - Spanish with highlighted additions.pdf (Amendment/Modification)
- ISLAC 2021 Questiona´rio - Portugues.pdf (Data Collection Tool)
- ISLAC 2021 Questiona´rio - Portuguese with highlighted additions.pdf (Amendment/Modification)
- ISLAC 2021 Questionnaire - English with highlighted additions.pdf (Amendment/Modification)
- ISLAC 2021 Questionnaire - English.pdf (Data Collection Tool)

Exempt studies are subject to institutional oversight including reviews and audits by the Human Research Protection Program. Please submit any proposed changes to the research that could potentially change the exempt status prior to implementation, unless a change is necessary to avoid immediate harm to subjects. If subject safety becomes an issue, please notify the HRPO as soon as possible.

Please submit a Study Closure form once the research has been completed.

Please do not hesitate to contact our office with any questions or concerns.

We encourage investigators and research staff to provide feedback about the IRB review process, our website, and any other aspects of the HRPP that will help us to identify improvements we can make. You can complete this form in an anonymous manner at [HRPO/IRB Feedback Survey](#).

Sincerely,

Tulane University Human Research Protection Office

Please note that the actual signature by the IRB Chair(s) is not required for this document to be effective. IRBManager generates this letter 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 notices to sponsors and others of approval, disapproval or other IRB decisions. Please refer to Tulane's Electronic Signatures and Records Policy by visiting the HRPO website at <https://research.tulane.edu/hrpo>.