Ann & Robert H. Lurie
Children's Hospital of Chicago®

Expedited Modification Approval Letter

Lisa Kuhns, PhD.
Adolescent Medicine

PROTOCOL TITLE: Evaluation of TransLife Center: A Locally-Developed Combination Prevention Intervention for Transgender Women at High Risk of HIV Infection

IRB 2017-767

IRB APPROVAL DATE: September 30, 2020

IRB EXPIRATION DATE: June 30, 2021

Please Note: Due to COVID-19 restrictions, Stanley Manne Children's Research Institute leadership approval is also needed before beginning or resuming clinical or behavioral research that requires onsite visits and/or direct participant interaction. Please refer to the "Re-entry and Phased Expansion of Research Activities Guidance" disseminated on May 21, 2020 and the Lurie COVID-19 Resource Page for Healthcare Providers for more information.

Approved as Risk/Benefit Category:

45 CFR 46.404/21 CFR 50.51 Research not involving greater than minimal risk.

The Ann & Robert H. Lurie Children's Hospital of Chicago Institutional Review Board (Lurie Children's IRB) has reviewed and approved by expedited review the modification to the protocol referenced above. Refer to the PDF of the Cayuse IRB application for the details and documents reviewed with this modification. This modification includes the following as fully described in *Section M2 SubSection A*:

- Study personnel
- Updated study protocol version date 9/29/20
- Recruitment materials, verbal scripts, survey instruments, web-based instruments, questionnaires, etc. [modifications to questionnaire; addition of a study screener]

- Updated Consent Documents - The IRB approved and stamped consent document(s) for this submission is/are located in a comment in the "Supporting Documents" section of the Cayuse IRB application. Only the current Lurie Children's IRB stamped consent forms are to be used when enrolling participants into this study.

YOUR OBLIGATIONS AS PRINCIPAL INVESTIGATOR:

As the Principal Investigator, you are ultimately responsible for the conduct of the use, the protection of the rights and welfare of human subjects and adherence to the Lurie Children's IRB and hospital policies and procedures (Lurie Children's IRB Policy and Procedure Manual), including, but not limited to Section 5: Investigator Responsibilities and the following:

1. Ensure that all individuals who will work on the approved protocol are qualified, listed as Research Personnel in the Cayuse IRB application, and have completed the human subject protections education requirement.
2. Submit the renewal progress report for review and approval in advance of the expiration date.
3. Do not implement changes in the approved protocol or consent form(s) without prior IRB approval (except to eliminate apparent immediate hazards to safeguard the well-being of human subjects).
4. Obtain the legally effective written informed consent from human subjects or their legally authorized representatives as is applicable, using only the currently approved Lurie Children's IRB stamped consent form(s).
5. Report any unanticipated problems or noncompliance per IRB policies.
6. Wait until the study contract/award (if applicable) is fully executed before beginning work on the study. Contact the Office of Sponsored Programs for information about the status of the clinical trial agreement or grant award.
7. Register your study: Applicable clinical trials (i.e., interventional studies of FDA-regulated drugs, biological products, or devices) must be registered on clinicaltrials.gov by the responsible party, typically the sponsor or a PI if designated by the sponsor (refer to FDAAA 801). In addition, the International Committee of Medical Journal Editors (ICMJE) recommends that all medical journal editors require registration of clinical trials in a public trials registry at, or before, the time of first patient enrollment as a condition of consideration for publication. Their definition of a clinical trial is much broader than federal requirements. Please refer to the ICMJE recommendations Section IIIK. Your study will be listed on the Clinical and Translational Research webpage for the hospital. If you do not wish your trial to be listed on this webpage, contact Marianne Reed within 10 days of this approval letter.
8. Notify any departments providing research support of modifications to the protocol that would impact services provided (e.g., pharmacy, medical imaging, laboratory services, etc.).

Sincerely,

Institutional Review Board
Ann & Robert H. Lurie Children's Hospital of Chicago