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

Expedited Modification Approval Letter

Lisa Kuhns, MD
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: June 6, 2017

IRB EXPIRATION DATE: October 31, 2017

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 the modification to the protocol referenced above by expedited review. The modification includes the study protocol (version date 4/26/17) which includes a revised primary outcome to reflect the one month recall, increased study sample size to 150, modified inclusion criteria, revised follow-up scheduling, and procedure revisions. The participants will now be compensated in cash. Recruitment methods were revised to include flyer based marketing only. The study questionnaire was revised and the estimated duration of interviews was reduced to 60 minutes. The informed consent form was revised to reflect the changes made in this modification. The study flyer, case report forms, screening form, and the fully executed IAA with Chicago House and Social Service Agency. Amy Johnson was added to the study personnel.

The IRB approved and stamped 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.

For a full list of documents included with this submission, refer to the PDF of the Cayuse IRB application.

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