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

Expedited Initial Review 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: November 8, 2016

IRB EXPIRATION DATE: October 31, 2017

This protocol was approved under the following risk/benefit determination as described in 45 CFR 46, Subpart D/21 CFR 50, Subpart D:

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) reviewed and approved as authorized by 45 CFR 46.111/21 CFR 56.111 and via expedited review as authorized by 45 CFR 46.110/21 CFR 56.110 the above-named protocol.

The IRB approved and stamped documents for this submission are located in a comment posted by ORIC staff in the section titled **"Supporting Documents"** 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.

This research was reviewed and approved under expedited review **category #2 (a)**: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection many not occur more frequently than 2 times per week

This research was reviewed and approved under expedited review **category #3**: Prospective collection of biological specimens for research purposes by noninvasive means.

This research was reviewed and approved under expedited review **category #5**: Research involving materials (data, documents, records, or specimens) that has been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

This research was reviewed and approved under expedited review **category #6**: Collection of data from voice, video, digital, or image recordings made for research purposes.

This research was reviewed and approved under expedited review **category #7**: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

The IRB also **waives the requirement of obtaining a signed consent form** for this study in accordance with 45 CFR 46.117(c): (1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or (2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

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

Federal regulations require that an IRB conduct continuing review of research not less than once per year, regardless of whether initial approval was via full board or expedited procedures. Please note the expiration date for your current IRB approval and be aware that you must submit a progress report for IRB review prior to the expiration in order to obtain IRB approval for the next approval period. If the current approval expires and you do not obtain approval for another approval period, research on this study, including subject enrollment, must cease until you regain approval. If you have questions about your obligations as principal investigator, please contact the ORIC staff as listed on the ORIC website:
https://www.luriechildrens.org/en-us/research/management/toolkit/Pages/research-directory.aspx

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.

Sincerely,

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