IRB APPROVAL OF APPLICATION

June 8, 2020

Dear Joanne D. Stekler:

On 6/8/2020, University of Washington IRB Committee J reviewed the following application:

Type of Review:	Initial Study
Title of Study:	The GAIN (Greater Access and Impact with NAT) Study: Improving HIV Diagnosis, Linkage to Care, and Prevention Services with HIV Point-of-Care Nucleic Acid Tests (NATs)
Investigator:	Joanne D. Stekler
IRB ID:	STUDY00010387
Funding:	Name: Centers for Disease Control and Prevention (CDC), Grant Office ID: A142378, Funding Source ID: 6 U01 PS 005196-01-01
IND, IDE, or HDE:	None

IRB Approval

Under FWA #00006878, the IRB approved your activity.

- **Depending on the nature of your study, you may need to obtain other approvals or permissions to conduct your research. For example, you might need to apply for access to data or specimens (e.g., to obtain UW student data). Or, you might need to obtain permission from facilities managers to approach possible subjects or conduct research procedures in the facilities (e.g., Seattle School District; the Harborview Emergency Department).**
- **NOTE: While IRB approval for this project has been granted, the University is requiring a temporary halt of some research activities that involve in-person interaction with participants. The temporary halt will remain in effect until HSD or the Office of Research informs campus that the halt has been revised or ended. For information about which in-person activities are currently allowable, see the HSD website.**
- Your application qualified for expedited review ("minimal risk"; Categories 1, 2, 5, 6, & 7).
- Under the Revised Common Rule this IRB approval is valid until study completion. In other words, there is no expiration date and you are not required to submit Continuing Review Reports to maintain your approval. However, you are still required to (1) obtain IRB approval before making any changes (modifications) to your research, and (2) provide the IRB with any Reportable New Information such as breaches of confidentiality or unanticipated problems.
- This approval applies only to the activities described in your application (including any references to specific grant sections). It does not include other activities that may be described in your grant or contract.
- This approval applies only to the generic protocol and the UW site. You will receive a separate approval notice for each additional participating site.

- Your study automatically has a Certificate of Confidentiality (CoC), because you have CDC funding. A description of the CoC protections and responsibilities has been placed in your study's Documents section.
- If you plan to continue data collection past the expiration of your NIH funding and the CoC, contact the Human Subjects Division prior to the end of your funding. We will help you determine whether you need to apply for a CoC extension.

Determinations, waivers, and regulations

The IRB made the determinations and waivers listed in the table below. Note that any granted waivers of consent do not override a subject's refusal to provide broad consent.

Requirement	Determination or Waiver
Consent	Waived for recruiting procedures and baseline group procedures
Documentation of consent	Waived for multi-Nat and provider group procedures
HIPAA Authorization	Waived for recruiting procedures and baseline group procedures

Location of documents

Use the consent forms that were approved and stamped by the IRB. They can be downloaded from the Final column under the **Documents tab** in Zipline.

In addition, HSD has uploaded the following documents to the **Documents tab** in Zipline:

- Certificate of Confidentiality Acknowledgement Letter

Thank you for your commitment to ethical and responsible research. We wish you great success!

Sincerely,

Jenny Maki
IRB Reliance Administrator
makij2@uw.edu, 206-543-4798