Justification for No material/Non-substantive Change
for
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)
OMB # 0920-1357
November 2, 2023

Summary of Changes

Centers for Disease Control and Prevention (CDC) and NCHHSTP are requesting a non-substantial change to the information collection request (ICR) for the GAIN (Greater Access and Impact with NAT) Study (OMB #0920-1357).

Specifically, we are re-prioritizing the aims/components of the project and adjusting the enrollment totals for the different aims accordingly. This change is made in response to changing priorities in the field of point-of-care nucleic acid (POC NAT) testing for HIV, and in light of study progress and the remaining study timeline.

To reflect prioritization of the qualitative data collection in this study, and to adjust the enrollment targets for the other study aims to levels that reflect the current clinic volumes at the study sites, we are reducing the number of persons enrolled in the following study components: 1. Prospective study of HIV-negative patients seeking HIV testing and/or PrEP services; 2. Prospective study of HIV-positive patients seeking STI testing; and 3. RCT of POC NAT or Standard of Care for HIV-positive patients. We are increasing the number of persons enrolled in the following study components: 1. POC NAT acceptability survey and 2. POC NAT acceptability survey, focus group, or interview. No change is made the following study components: 1. Baseline data collection and 2. Cross-sectional comparison of POC NATs.

The number of respondents for these study components were selected by the study team considering the current study data and survey/interview completion rates. Increasing the number of persons who complete the POC NAT survey and interview will allow us to reach saturation in our qualitative data collection and increase the quality of these important data. The collected data will inform implementation of POC NAT testing for HIV in clinical settings in the United States.

No data collection tools are included in this change request as there is not change to study materials, only the number of respondents in selected study components.

Attachment 1. Summary of Proposed Changes
Attachment 2. Estimate of Annualized Burden Hours