The Greater Access and Impact with NAT (GAIN) Study: Improving HIV Diagnosis, Linkage to Care, and Prevention Services with HIV Point-of-Care Nucleic Acid Tests (NATs)

Reinstatement With Changes

OMB No. 0920-1357

Section A: Supporting Statement

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- **Goals of the study:** GAIN is an implementation study to assess the feasibility and acceptability of point-of-care (POC) HIV nucleic acid tests (NAT) in community and clinic settings.
- **Intended use:** These data will be analyzed and disseminated to describe the real-world clinical effectiveness and performance of POC NAT testing technology. This study will develop functional models to integrate POC NAT testing technology into HIV testing, prevention, and treatment services.
- **Methods to be used to collect data:** Participants will complete quantitative surveys. Interviews and focus groups will be conducted with a subset of study participants. Test results and other clinical data will be extracted from electronic health records. Clinic data will be used to assess the feasibility and cost of implementing POC NAT.
- **The subpopulation to be studied:** Persons seeking HIV/STI testing, prevention, treatment services at the Gay City and the Madison clinics in Seattle, WA. Providers of HIV testing, prevention and treatment services at these facilities will also be recruited.
- **How data will be analyzed:** Quantitative analyses will be conducted to evaluate the impact of POC NAT on 1) PrEP-related clinical outcomes, 2) HIV care continuum outcomes, and 3) time to virologic suppression. Qualitative analyses will be conducted to assess the acceptability and feasibility of POC NAT among clients and providers.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention's (CDC) Division of HIV Prevention (DHP) requests a Reinstatement of the research study entitled "The Greater Access and Impact with NAT (GAIN) Study: Improving HIV Diagnosis, Linkage to Care, and Prevention Services with HIV Point-of-Care Nucleic Acid Tests (NATs), OMB# 0920-1357, for a period of 36 months. This project is funded under Cooperative Agreement #U01PS005196, Department of Health and Human Services, Centers for Disease Control and Prevention.

In 2022, human immunodeficiency virus (HIV) infection was diagnosed in more than 38,000 people in the United States, with 70% of these diagnoses among gay, bisexual, and other men who have sex with men (MSM). Among MSM, Black or African American (Black) (34%) and Hispanic or Latino (Latino) (36%) MSM were disproportionately affected.[1] Preexposure prophylaxis (PrEP) can prevent HIV acquisition among persons at risk.[2] To prevent the emergence of drug-resistant HIV strains, prior to initiating PrEP, persons must be tested for HIV to ensure that they are not infected. Current rapid point-of-care (POC) technologies do not reliably detect the earliest HIV infections and lab-based testing can introduce delays while patients wait for test results. During this time, patients can drop out of care and are still at high-risk to become HIV infected. Direct molecular detection of HIV through nucleic acid tests (NATs) can identify early HIV infections, which have high potential for transmission. NATs that are used at the point-of-care (POC NAT) can provide results in 60 to 90 minutes. Obtaining timely molecular test results from a POC NAT in clinics or community settings can expand prevention as well as HIV treatment services, improve our reach into disproportionately affected populations, and provide opportunities to approach the goal of no new HIV infections.[3-4]

In 2015, the U.S. Food and Drug Administration (FDA) licensed the NAT systems to be used for screening plasma donors for HIV and HCV (hepatitis C virus)[5]. Outside of the U.S., several POC NAT platforms are approved for HIV diagnosis and viral load quantification. However, in the United States (U.S.), available POC testing with FDA-approved tests can only detect HIV p24 antigen and antibodies. The earliest an antigen antibody test can detect HIV is 18 days after infection. However, NATs are able to detect HIV within 10 days of infection, making this an important tool for early diagnosis and ending the HIV epidemic. In the future, it is anticipated that the FDA will approve HIV POC NATs to diagnose and monitor HIV infections in the U.S.; until then, these tests can be used in a research capacity in community and clinical settings.

In PrEP clinics, systematic use of an HIV POC NAT to test at-risk persons, regardless of whether they have symptoms of acute HIV infection or not, would facilitate the identification of uninfected individuals who would benefit from initiating PrEP within a single care visit. To expedite PrEP initiation, rapid creatinine tests could also be implemented to assess renal function (a recommended safety test). HIV POC NATs could also facilitate more expedient treatment for persons diagnosed with an HIV infection.

Community-based settings can reach populations at disproportionate risk for HIV, such as Black and Hispanic MSM, who may not regularly access HIV testing in clinical settings. The use of HIV POC NATs may reduce the time between testing and PrEP initiation among persons at high risk and may reduce the time between testing and treatment initiation or re-engagement for those who are diagnosed with HIV. Further, an HIV POC NAT to detect viral load at the time of diagnosis may provide information on the risk of progression of disease, and for transmission to sex and drug-sharing partners, that might improve motivation to link to HIV treatment.

1A. Status of the GAIN Information Collection

The GAIN Information Collection (0920-1357) was approved by the Office of Management and Budget on December 3, 2021. In 2024, CDC approved an extension to the Cooperative Agreement #U01PS005196 so that the GAIN project could continue work into 2025. GAIN Project Officers at CDC also planned to submit an Extension ICR with OMB in 2024; however, as a result of an unplanned staffing change at CDC, a key deadline was missed and the 6-month window for submitting an Extension ICR closed and OMB approval for GAIN expired on December 31, 2024. The GAIN project has been successful in meeting several project goals and has shared study information through manuscripts published in scientific journals and presentations at scientific conferences.[6-7] GAIN is on track to reach remaining enrollment targets and successfully conclude this important information collection if the study is reinstated.

The GAIN study has five objectives:

- Aim 1 evaluates the impact of POC NAT on pre-exposure prophylaxis (PrEP) uptake and persistence among persons testing HIV-negative
- Aim 2 evaluates the impact of HIV RNA POC NAT on HIV clinical care outcomes among persons testing HIV-positive
- Aim 3 implements a POC NAT-tailored behavioral intervention to evaluate impact on time to virologic suppression among persons living with HIV (PLWH) receiving antiretroviral therapy (ART)

- Aim 4 will quantify the acceptability and feasibility of implementation of POC NAT in community and clinical settings.
- Aim 5 compares the sensitivity, specificity, and agreement of multiple POC NATs over a range of HIV RNA levels.

Since the OMB approved the GAIN data collection in December 2021, the project has succeeded in meeting several goals. Enrollment for Aims 1, 2, and 3 was completed at the Gay City study location. Enrollment for Aims 1 and 2 was completed at the Madison Clinic. Aim 5 was also completed.

Study objectives completed prior to study expiration:

- Aim 1 enrollment was completed at both study locations
- Aim 2 enrollment was completed at both study locations
- Aim 3 enrollment was completed at the Gay City location
- Aim 5 was completed

GAIN has successfully met many study goals and there are a limited number of data collection activities to be completed; therefore, the burden hours needed to complete this study are greatly reduced from the initial, new ICR. We estimate it will take 49 annual burden hours (135 total burden hours across the three-year collection) to complete all remaining data collection for the GAIN study. The annualized burden hours are detailed in Exhibit 12.1. The study activities that remain to be completed are listed below.

Study activities to be completed following reinstatement:

- Aim 3 enrollment at Madison Clinic
- Study visit survey and acceptability survey collection at Madison Clinic
- Focus groups or interviews among a subset of Madison client participants
- Interviews with Madison Clinic health care providers
- Follow up phone calls to Gay City participants
- Medical record data collection at Gay City and Madison Clinic

GAIN was awarded an extension to Cooperative Agreement #U01PS005196 to complete the critical data collection described above. This information is necessary for CDC to understand the implementation of point-of-care NATs; therefore, we request a reinstatement so that we may successfully complete this information collection.

To reduce burden and improve data quality, we will use a combination of previously approved, revised, and new data collection instruments to complete these study activities. Data collection instruments GAIN study stakeholders noted several opportunities to improve our understanding of POC NAT performance and acceptability by refining existing tools and collecting additional data; therefore, we propose non-substantive revisions to four study instruments and the addition of three new study instruments. Details about the changes to study instruments can be found in **Attachment 10 Detail of Changes to Data Collection Instruments**.

The study consent form and all data collection instruments have been approved by the University of Washington (UW) Institutional Review Board (IRB) (**Attachment 6a and 6b**).

2. Purpose and Use of the Information Collection

The purpose of this information collection is to determine the acceptability and feasibility of POC NAT implementation in clinical and community settings. POC NATs have the potential to help address some of the remaining challenges to ending the HIV epidemic in the United States by assisting with early detection of acute HIV infection and by providing a more efficient viral load monitoring tool for people living with HIV. This study is the first of its kind in the US and is critical to understanding the utility of POC NAT and provider and patient perspectives on its use in the US.

Data collected during this study will be used to evaluate the performance of POC NAT and associated clinical outcomes, patient and provider perspectives regarding acceptability and feasibility, and implementation science outcomes. The GAIN study will develop, implement, and evaluate models for use of POC NAT among HIV-negative persons seeking HIV testing, PEP, and PrEP and HIV-positive persons in community and clinical settings. Study findings will be disseminated through community forums, academic and community conference presentations, and peer-reviewed publications.

This project is in alignment with the following goals and objectives of the National HIV/AIDS Strategy (2022-2025)[8]:

- Goal 1: Prevent New HIV Infections
  - Objective 1.2: Increase knowledge of HIV status
  - Objective 1.4: Increase the diversity and capacity of health care delivery systems, community health, public health, and the health workforce to prevent and diagnose HIV
- Goal 3: Improve HIV-related health outcomes of people with HIV
  - Objective 2.4: Increase the capacity of the public health, health care delivery systems, and health care workforce to effectively identify, diagnose, and provide holistic care and treatment for people with HIV

This project is also in alignment with the Prevent strategy of the U.S. Department of Health and Human Services (HHS) Ending the HIV Epidemic in the U.S. (EHE) initiative. The initiative aims to reduce new HIV infections in the U.S. by 90% by 2030 by scaling up four key HIV prevention and treatment strategies: Diagnose, Treat, Prevent, and Respond Quickly.[9] The aim of this research is to develop an implementation model for using HIV POC NATs to reduce time between HIV testing and linkage to HIV prevention and HIV treatment and care.

This project will involve interaction with human participants and intends to collect new individually identifiable data and biospecimens from the participants. This project is considered human subjects research and will be covered by the Paperwork Reduction Act.

The following section of the U.S. Federal Code is relevant to this data collection: 42 USC 241, Section 301 of the Public Health Service Act authorizes conduct of “research, investigations,

experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man." (**Attachment 1**)

3. Use of Improved Information Technology and Burden Reduction

Participant surveys (study visit survey and post-visit acceptability survey) will be delivered using computer-assisted self-administered instruments. Using computer-assisted technology to conduct the assessments will allow the study to build in computer-generated skip patterns, significantly cutting down on respondent burden. In addition, data collected through computer application can be used to automatically generate the study database, reducing data entry burden and potential interviewers and data coding errors. Computer assisted surveys also evoke a greater sense of privacy than surveys that involve personal interviewing, thereby encouraging participants to answer more sensitive personal questions. Participant surveys will be conducted during in-person visits and study staff will be available to assist them or answer questions. The study will provide laptops for participants to complete the assessments. Participants will have the option to complete the follow up call survey either by telephone or virtual call (Zoom), This will allow participants to complete the follow up survey at a place and time that is most secure and convenient to them.

The GAIN study will use Research Electronic Data Capture (REDCap), a secure, HIPAA compliant, web-based survey application hosted by the awardee (University of Washington), to support direct electronic data capture for research studies, providing user-friendly web-based case report forms, real-time data entry validation (e.g., for data types and range checks), audit trails, and a de-identified data export mechanism to common statistical packages. All REDCap accounts are role-based, and password protected.

Respondents (patient and providers) will have the option to complete the study focus groups or interviews either in-person or virtually (via Zoom). This will allow respondents to complete the collection in a setting and time that is most comfortable and convenient to their schedules. All interviews will be audio-recorded. This limits burden on the interviewer (the interviewer does not have to take handwritten notes), allows researchers to accurately capture participant responses, and allows the interviewer or focus group moderator to concentrate on building and maintaining rapport with the respondent.

4. Efforts to Identify Duplication and Use of Similar Information

Due diligence was applied to identify duplication of study objectives and planned data collection. HIV POC Nat tests are not yet approved by the FDA for clinical use outside of a research capacity in community and clinical settings. The need for these data drove the development of the study objectives. The awardee, University of Washington, was not collecting these data for other purposes prior to study initiation, the data will be collected to address the study's unique objectives.

The Agency believes no other survey data collection effort has been conducted or has been planned to collect similar information for this population. CDC conducted a review of similar studies prior to the issuance of the Cooperative Agreement[10] and determined that this study is

collecting unique information from the population. Therefore, our evaluation requires the collection of this new primary data.

5. Impact on Small Businesses or Other Small Entities

This collection request does not involve burden to small businesses or other small entities.

6. Consequences of Collecting the Information Less Frequently

This study will provide the quantitative and qualitative data needed to assess the feasibility and acceptability of point-of-care nucleic acid HIV tests in community and clinic settings. Data will be collected over a three-year period. Screen and Link data (**Attachment 4a**) and the Release of Information (**Attachment 4b**) will be collected once. Data from the Study Visit Survey (**Attachment 4c**) and the Acceptability Survey (**Attachment 4d**) will be collected once. The Follow Up Phone Call Survey (**Attachment 4f**) is conducted three times after the study visit. The purpose of the survey is to determine the outcome of the study visit. Conducting this information less frequently would not allow us to determine the immediate, short- and longer-term effects of the visit. Data from the participant focus group or interview (**Attachment 4e Participant Focus Group and Interview Guide**) is collected once. Provider Interviews will be conducted three times with health care providers at the Madison Clinic (**Attachment 4g Provider Interview Guide**). The purpose of the provider interviews is to understand how providers perceive the feasibility and acceptability of POC NAT testing. This perception may change over time with different clients and changing needs. Collecting this interview data less frequently would limit our ability to assess the impact of POC NAT on the provider experience over time and in varying clinical scenarios. Health record data will be collected from Madison Clinic every other month to capture health data from newly enrolled participants at the clinic (**Attachment 4h Madison Clinic Data Collection**). Health record data will be collected biannually from Gay City in order to complete the collection of health record data from participants who were enrolled in the study at Gay City immediately prior to the study expiration (**Attachment 4i Gay City Data Collection**). Collecting data less frequently would limit our ability to monitor the impact of POC NAT on 1) PrEP uptake and persistence among person testing HIV-negative, 2) time from testing to linkage to care among persons testing HIV-positive, and 3) time to virologic suppression among PLWH receiving anti-retroviral therapy (ART). The number of collections is the minimum required to ensure timely and accurate information capture, analysis, and interpretation.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances. The message testing activities fully comply with the regulations and guidelines in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A 60-Day Federal Register Notice to solicit public comments was published on 01/08/2025, Vol. 90, No. 5, page 1501 (**Attachment 2a**). CDC received no comments during the 60-day notice period.

In addition to CDC staff, University of Washington was involved in the development of this study in 2020 and 2021. There were no unresolved issues associated with the development process.

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9. Explanation of Any Payment or Gift to Respondents

Following reinstatement, GAIN will enroll 61 PLWH from Madison Clinic to complete Aim 3 of the study. Upon enrollment and completion of the study visit survey, client participants will receive $40 and a $5 food voucher redeemable at the Harborview Medical Center cafeteria adjacent to Madison Clinic. Participants will also receive a $10 Amazon gift card upon SSA completion of the acceptability survey. A subset of participants (N=12) will be selected to participate in a 60-minute focus group or interview. These respondents will receive $40 for their participation. GAIN will also engage 18 health care providers from Madison Clinic to participate in an interview. Health providers will receive a $5 gift card for each interview and may complete up to three interviews for a total of $15.

GAIN Incentives for Health Providers

Data collection activity	Incentive amount	Total number of times administered	Maximum incentive
Provider Interview	$5	3	$15

GAIN Incentives for Client Participants

Data collection activity	Incentive amount	Total number of times administered	Maximum incentive
Study Visit Survey	$45*	1	$45
Acceptability Survey	$10	1	$10
Total for survey group (N=49)			$55
Participant Focus Group or Interview	$40	1	$40
Total for survey and interview (N=12)			$95

*$40 and a $5 food voucher

The proposed incentives for the Acceptability Survey and Participant Focus Group or Interview were approved by the Office of Management and Budget (OMB) on December 3, 2021 (**Attachment 7**). The incentive for enrollment and completion of the Study Visit Survey was approved by OMB in the amount of $25. We are requesting to increase this incentive to $45 following reinstatement. We are proposing this increase due to low enrollment among Aim 3 participants at Madison Clinic prior to study expiration. Upon reinstatement, GAIN will focus efforts to enroll Aim 3 Madison participants in order to complete our proposed data collection and achieve our scientific goals. The health provider interview is a new proposed data collection activity, and the incentive amount ($5) has not yet been reviewed by OMB. All incentives were approved by the University of Washington (UW) Institutional Review Board (IRB) (**Attachment 6**).

Similar tokens of appreciation have been demonstrated to increase study participation, as in the National Survey on Drug Use and Health, conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), where participants receiving no token of appreciation had a participation rate of 69%, compared to 79% among those receiving $20, and 83% among those who receiving $40 (OMB No. 0930-0110, exp. 10/31/2022).[11] Additionally, a randomized controlled trial demonstrated that offering nominal tokens of appreciation (<$50) to persons recruited to complete online surveys yielded greater response rates and decreases response time compared to no tokens of appreciation.[12]

Remuneration has been used in other similar HIV-related CDC data collection efforts including the National HIV Behavioral Surveillance (OMB 0920-0770, exp. 5/31/2014), the Expanding PrEP in Communities of Color (EPICC) study (OMB 0920-1423, exp. 12/31/2026), the mChoice: Improving PrEP Uptake and Adherence study (OMB 0920-1428, exp. 1/31/2027), and the Understanding HIV/STD Risk and Enhancing PrEP Implementation Messaging study (OMB 0920-1421, exp. 11/30/2026), all of which included hard-to-reach populations and had a similar length of time for completing the client interview as in this proposed research. In each of these projects, tokens of appreciation helped to increase and maintain participation rates.

In his memorandum for the president's management council dated January 20, 2006, the Administrator of the Office of Information and Regulatory Affairs of the Office of Management and Budget wrote, "Incentives are most appropriately used in Federal statistical surveys with hard-to-find populations or respondents whose failure to participate would jeopardize the quality of the survey data (e.g., in panel surveys experiencing high attrition), or in studies that impose exceptional burden on respondents, such as those asking highly sensitive questions…"[13] The use of tokens of appreciation in the proposed research is appropriate according to this guidance. The primary goal of the project is to develop and assess the potential impact of POC NAT technologies on persons seeking HIV and STI testing, and persons receiving HIV treatment and care. This study seeks to recruit, enroll, and follow a stigmatized population, while also asking highly sensitive questions about issues such as PrEP use, HIV and STIs, and HIV status and care. Moreover, offering tokens of appreciation is critical when recruiting historically underrepresented groups in research.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

The CDC National Center for HIV, Viral Hepatitis, STD, and TB Prevention (NCHHSTP) Associate Director for Science Office has reviewed this project. A Privacy Impact Assessment has been conducted (**Attachment 8**).

The awardee, University of Washington University, will be responsible for collecting all data for this study. Personally identifiable information will not be shared with CDC.

The terms of the CDC Cooperative Agreement authorizing data collection require the grantee to maintain the privacy of all information collected. Section 301(d) of the Public Health Service (PHS) Act, as amended by Section 2012 of the 21st Century Cure Act, P.L. 114-255 (42 U.S.C. 241(d), states that the Secretary shall issue Certificates of Confidentiality to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. This study meets those requirements. The Certificate of Confidentiality further protects the privacy of subjects by limiting the disclosure of identifiable, sensitive information. With this Certificate, the research team cannot be forced (for example, by court subpoena) to disclose identifying information from study participants for any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

To minimize risks to confidentiality, we will provide study data with all appropriate physical and operational security protections. All identifiable data collected regarding study participants will be maintained separately from all other information, including screen and link responses, study visit, acceptability and phone surveys, focus group and interview data, and medical record data. All participants will be assigned a unique identification (ID) number which will be unrelated to the participants' name or other uniquely identifying information. Documents containing personally identifying information (PII) and the document linking PII and the study ID number will be maintained separately from study data in password protected files stored within a restricted folder on a secured server. These confidential files will only be accessible only to the Principal Investigator, Study Manager, and other staff who will undergo training in data security procedures.

All web survey data will be collected using REDCap, a HIPPA-compliant, secure, encrypted electronic platform maintained by the University of Washington. Study data stored by REDCap are maintained on a dedicated secure server. Data collected via REDCap are automatically encrypted, with the coded access only available to the Project Director and the PIs. All data will be secured during transmission by using a 256-bit SSL encryption or higher, and the SSL certificate will be from a reputable provider (e.g., VeriSign).

All electronic files and records will be maintained in a firewall-protected, encrypted server at University of Washington. Access to printed or electronic data will be on a role-based standard; only those study staff who require access to identifying data to complete their study-related roles will be allowed access. All study staff will be trained in security and confidentiality procedures and will sign a confidentiality agreement before receiving access to any participant data.

The study will rely on the HIPPA-compliant Zoom video chat service to conduct in-depth interviews and focus group discussions. Zoom provides end-to-end encryption using Advance Encryption Standard (AES) 256-bit algorithm, or similar. Session keys are generated with device unique hardware ID to avoid data being read from other devices. This ensures that the consultation cannot be eavesdropped or tampered with. These qualitative assessments will be recorded and retained on the secure study server. The recordings from the qualitative assessments will be transcribed and during the transcription process all uniquely identifying information will be removed.

Study staff will be trained to follow regulations for mandatory reporting of breaches in confidentiality or adverse events. All study personnel will have completed human research protections (CITI) training. All study staff will be trained to recognize, document, and report any unusual events or circumstances that occur during data collection immediately to the Principal Investigator (PI) and the University of Washington IRB. If an adverse event appears to be research-related, it will be reported to the Office for Human Research Protections along with summaries of discussions concerning the event. CDC will be informed of any IRB action taken concerning any adverse event. The Principal Investigators and Project Manager will monitor staff closely. Study staff will be closely monitored for adherence to the protocols and procedures that maintain participant privacy and confidentiality and staff who are deficient in any aspect of performance will be re-trained or terminated.

University of Washington (UW) will follow UW Institutional Review Board (IRB) procedures for handling personal information. Six years after the study is completed, all study ID numbers will be de-linked from personally identifying information. De-linked study data will be retained for a period in accordance with all applicable state and federal laws and regulations relating to the preservation and destruction of information created and received by the University and University policies including the University's General Records Retention Schedule.

CDC will store de-identified data on a secure server that is accessible through the Division of HIV Prevention, HIV Research Branch for six years; after which time, the data will be archived according to guidance set forth by CDC Records Management Policy, Policy # CDC-GA-2005-07 (updated 9/14/2021). De-identified, summary data may be used in manuscripts, presentations and reports that highlight the activities and successes of this program.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

The study protocol, the data collection instruments, and all accompanying documents have been reviewed and approved by University of Washington IRB. GAIN receive initial IRB approval in June 2020 (**Attachment 6a)** and has received annual continuation approvals since that time. The most recent IRB approval from UW IRB was received in August 2024 (**Attachment 6b**).

Sensitive Questions

This study is designed to collect information about PrEP use and adherence and HIV treatment and care. As such, our study entails the collection of sensitive information. All study staff will be

trained to provide respondents with referrals to sources of prevention and care, such as mental health organizations, as needed. Sensitive questions will be asked about PrEP use, HIV care, and substance use. We will inform all participants that they may skip any question or end their participation in the study at any time for any reason.

12. Estimates of Annualized Burden Hours and Costs

12A. Estimates of Annualized Burden Hours

The requested data collection period is 36 months. Upon reinstatement, GAIN will enroll a total of 61 PLWH seeking or receiving care at Madison Clinic. We will also interview 18 health providers at the Madison Clinic. In addition, 100 clients who were previously enrolled at Gay City prior to study expiration (12/31/2024) will participate in up to three brief, five-minute telephone surveys. Finally, one employee each at the Madison Clinic and Gay City Center will be engaged to collect electronic health record data.

For PLWH participants, we anticipate that 50% of participants screened will be eligible and choose to enroll in the GAIN study; therefore, we expected to screen 41 respondents annually. Eligibility screening will occur once and is anticipated to take five minutes (**Attachment 4a**). Following enrollment, each year up to 21 participants will complete a Release of Information which will take five minutes to complete (**Attachment 4b**); a study visit survey (**Attachment 4c**) which will take approximately 15 minutes to complete; and an acceptability survey (**Attachment 4d**) which is estimated to take 20 minutes to complete. A subset of enrolled clients (12 total, 4 annually) will take part in a focus group or interview (**Attachment 4e**), both of which are estimated to take 60 minutes to complete. Upon reinstatement, GAIN will also conduct follow up telephone surveys (**Attachment 4f**) with participants enrolled at the Gay City Center prior to study expiration (100 total, 34 annually). The telephone surveys are estimated to take five minutes to complete, and participants may be contacted up to three times. Annually, six health providers at from the Madison clinic, will take part in 45-minute interviews (**Attachment 4g**). Each provider may complete up to three interviews over the course of the study. Finally, one clinic employee at each of the two study sites will be engaged to collect electronic medical record data. The Madison Clinic data collection (**Attachment 4h**), an automated data collection, is estimated to take five minutes to complete and data will be collected once every two months (six times annually). The Gay City data collection (**Attachment 4i**), a manual data pull, is estimated to take 60 minutes and data will be collected once every six months (twice annually).

There are no costs to the participant other than their time. The total number of burden hours (rounded up to the nearest whole hour) is 135 across three years of data collection. The total estimated annualized burden hours are 49. Annualized burden was calculated by dividing the total burden hours for each data collection activity by three and working back to calculate the number of respondents and responses needed to arrive at the annualized amount equal to one-third of the total burden. Total number of respondents are rounded up to the nearest whole number. Total burden hours for each activity are rounded up to the nearest whole hour.

Exhibit 12.1: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. of Responses	Average Burden Per	Total Burden

			Per Respondent	Response (in Hours)	Hours
General Public-Adults	Screen and Link (Att. 4a)	41	1	5/60	4
General Public-Adults	Release of Information (Att. 4b)	21	1	5/60	2
General Public-Adults	Study Visit Survey (Att. 4c)	21	1	15/60	6
General Public-Adults	Acceptability Survey (Att. 4d)	21	1	20/60	7
General Public-Adults	Participant Focus Group and Interview Guide (Att. 4e)	4	1	60/60	4
General Public-Adults	Follow Up Phone Call Survey (Att. 4f)	34	3	5/60	9
Health Practitioners	Provider Interview Guide (Att. 4g)	6	3	45/60	14
Health Practitioners	Madison Clinic Data Collection (Att. 4h)	1	6	5/60	1
Health Practitioners	Gay City Data Collection (Att. 4i)	1	2	60/60	2
				Total	**49**

A detailed description of the changes proposed by this reinstatement ICR to the original annualized burden hours can be found in **Attachment 11 Detail of Changes to Annualized Burden Hours**.

12B. Estimated Annualized Burden Costs

The annualized costs to the respondents are described in Exhibit 12.2. The United States Bureau of Labor Statistics' employment and wages estimates from May 2023 (http://www.bls.gov/oes/current/oes_nat.htm) were used to estimate the hourly wage rates for the for the purpose of this request. The estimated annualized burden cost is $1,771.77. This cost represents the total annual burden hours of respondents multiplied by the average hourly wage rate for each respondent type (General Public – Adults, $31.48; Healthcare Practitioners and Technical Occupations, $49.07; and Medical Records Specialists, $25.81).

Exhibit 12.2: Estimated Annualized Burden Costs

Type of Respondent	Form Name	Burden Hours	Hourly Wage Rate	Respondent Costs
General Public-Adults	Screen and Link (Att. 4a)	4	$31.48	$125.92
General Public-Adults	Release of Information (Att. 4b)	2	$31.48	$62.96
General Public-Adults	Study Visit Survey (Att. 4c)	6	$31.48	$188.88
General Public-Adults	Acceptability Survey (Att. 4d)	7	$31.48	$220.36
General Public-Adults	Participant Focus Group and Interview Guide (Att. 4e)	4	$31.48	$125.92
General Public-Adults	Follow Up Phone Call Survey (Att. 4f)	9	$31.48	$283.32
Health Practitioners	Provider Interview Guide (Att. 4g)	14	$49.07	$686.98
Health Practitioners – Medical Record Specialists	Madison Clinic Data Collection (Att. 4h)	1	$25.81	$25.81
Health Practitioners – Medical Record Specialists	Gay City Data Collection (Att. 4i)	2	$25.81	$51.62
				Total $1,771.77

A detailed description of the changes proposed in this reinstatement ICR to the estimated annualized burden costs can be found in **Attachment 12 Detail of Changes to Annualized Burden Costs.**

13. Estimates of Other Total Annual Cost Burden to Respondents and Record Keepers

There are no other costs to respondents for participating in this survey.

14. Annualized Cost to the Federal Government

The annual cost to the government for the data collection is estimated to be $346,459 (Exhibit 14.1).

Exhibit 14.1: Annualized Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to	CDC, Project Officer (GS-14, 0.30 FTE)	$39,507

the Federal Government[14]	CDC Data Analyst (GS-13, 0.20 FTE)	$22,288
	CDC Project Coordinator/Data Manager (GS-12, 0.30 FTE)	$28,115
	Subtotal, Direct Costs	**$89,910**
Cooperative Agreement Costs	**Annual Cooperative Agreement #U01PS005196 Costs**	**$256,549**
	ANNUALIZED COST TO THE GOVERNMENT	**$346,459**

A detailed description of the changes proposed in this reinstatement ICR to the annualized cost to the government can be found in **Attachment 13 Detail of Changes to Annualized Cost to Government.**

15. Explanation for Program Changes or Adjustments

This is a request for reinstatement with changes for OMB 0920-1357, exp. 12/31/2024.

16. Plans for Tabulation and Publication and Project Time Schedule

Data collection will occur over a period of 36 months, beginning immediately after reinstatement. If OMB approves this request for reinstatement by June 2025, analysis and report writing will be carried out from March to September 2028. We are requesting approval for three (3) years of data collection. The project timeline is detailed in exhibit 16.1.

Exhibit 16.1: Project Time Schedule

Activity	**Time Schedule**
OMB Approval (New ICR)	December 3, 2021
Data Collection	December 2021 - 2024
ICR Expiration	December 31, 2024
Reinstatement submitted	September 2025
Recruitment	1 month after OMB Approval
Data Collection	1-36 months after OMB Approval
Data analysis finalized and report drafted	33-39 months after OMB Approval
Final de-identified data set submitted to CDC	39 months after OMB Approval

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We do not seek approval to eliminate the expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exemptions to the certification.

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