

**Summary of Proposed Changes in the ICR for 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)
OMB # 0920-1357
August 29, 2022**

Summary of Changes

We 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 requesting a non-substantial change to the schedule of study incentives by study groups, Exhibit 9-A in the SSA. Specific changes are detailed in Table 1. This change is being made to improve study implementation logistics. The original plan offered varying incentives by study group which presents operational challenges. The change provides a consistent incentive plan across the primary study groups. In addition to improving operational efficiency, this change may improve participation in the groups previously without incentives, as per the rationale in the SSA. Similar tokens of appreciation have been demonstrated to increase study participation, for example, 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).¹ 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.² The change in the schedule of incentives will have no effect on burden hours and therefore no changes to the burden table are requested. Please note that preferences by the specific clinic implementation sites (Gay City Clinic and Madison Clinic) have dictated the form of the incentives provided (gift card alone versus gift card plus food voucher) but all incentives have the same total value.

In addition, we are requesting minor changes to consent forms (Att 8_Consent form GAIN study_Testing PEP PrEP Group; Att 9_Consent form GAIN study_HIV+ Group) and the patient information sheet (Att 16_GAIN patient information sheet). Specific changes are detailed in Table 2. These changes provide additional explanation to potential participants about the possibility of a false-positive test result, including the potential for concern about that result, the possible timeline for results to return, and the reliance on FDA-approved laboratory-based test results to give the definitive answer regarding a participant's HIV status. These changes are all approved by the University of Washington Institutional Research Board (STUDY00010387). These minor changes to the language of the consent and information forms will have no effect on burden hours and therefore no changes to the burden table are requested.

¹ J. Kennet, J. Groerer, K.R. Bowman, et al. Evaluating and improving methods used in the National Survey on Drug Use and Health. Substance Abuse and Mental Health Services Administration, Rockville (MD). 2005.
https://books.google.com/books?hl=en&lr=&id=phs7YtaK3zcC&oi=fnd&pg=PA1&ots=DZ9MWKBJQp&sig=BVjJ7wXEJYSGPvt5Vb1es3GQ_as#v=onepage&q&f=false

² Turnbull AE, O'Connor CL, Lau B, Halpern SD and Needham DM. (2015). Allowing physicians to choose the value of compensation for participation in a web-based survey: randomized controlled trial. J Med Internet Res 17, 7: 1-10

Last, we are requesting a minor change to the study visit survey (Att 11_GAIN study visit survey_screenshots). Specific changes are detailed in Table 3. The change adds a question for persons who have ever taken PrEP to specify when they last took PrEP. This minor change does not affect the time to completion and will have no impact on burden hours, therefore no changes to the burden table are requested.

Table 1. Summary of changes to the schedule of study incentives by study groups, Exhibit 9-A

| Form, Page, Section, Question/Field | Change Proposed | Reason for Change Proposed |
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| Exhibit 9-A, Study Group 1, Prospective study of HIV-negative patients seeking HIV testing and/or PrEP services (Gay City) | No incentives changed to \$25 | Makes incentive plan consistent across all major study groups. |
| Exhibit 9-A, Study Group 2, Prospective study of HIV-negative patients seeking HIV testing and/or PrEP services (Madison Clinic) | No incentives changed to \$20 & \$5 food voucher | Makes incentive plan consistent across all major study groups. |
| Exhibit 9-A, Study Group 3, Prospective study of HIV-positive patients seeking STI testing (Gay City) | No incentives changed to \$25 | Makes incentive plan consistent across all major study groups. |
| Exhibit 9-A, Study Group 5, Cross-sectional comparison of several point-of-care NATs (Madison Clinic) | No incentives changed to \$20 & \$5 food voucher | Makes incentive plan consistent across all major study groups. |

Table 2. Summary of changes to consent forms (Att 8_Consent form GAIN study_Testing PEP PrEP Group; Att 9_Consent form GAIN study_HIV+ Group) and the patient information sheet (Att 16_GAIN patient information sheet)

| Form, Page, Section, Question/Field | Change Proposed | Reason for Change Proposed |
|---|---|---|
| Consent form; Testing, Att 8_Consent form GAIN study_Testing PEP PrEP Group; page 1 | Removed “in the interview” | Clarity as participants may decline to answer questions on the survey as well |
| Consent form; Att 8_Consent form GAIN study_Testing PEP PrEP Group; page 2 | Addition of “(which is about 2 teaspoons)” | Assist potential participants in understanding the quantity “10 mL” |
| Consent form; Att 8_Consent form GAIN study_Testing PEP PrEP Group; page 2 | Addition of “While the SAMBA II Qual POC NAT result is ready in 2 hours, the confirmatory laboratory HIV RNA test can take 1 week “ | Improve potential participants’ understanding of result timeline |
| Consent form; Att | Addition of “A positive SAMBA II Qual POC | Provide clarity to potential |

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| 8_Consent form GAIN study_Testing PEP PrEP Group; page 2 | NAT result does not necessarily mean that a person is HIV positive. You may experience anxiety if the test is positive and you need to wait a week for the confirmatory test result. If you have a positive SAMBA II QUAL POC NAT result we will ask you questions to assess the likelihood of a true positive result. We will recommend referral sites for urgent antiretroviral therapy if you would like to get linked to care.” And “the results of the SAMBA II Qual POC NAT will not be used in clinical decision making.” | participants about procedures following a positive NAT result and potential risks of anxiety related to testing timelines |
| Consent form; Att 8_Consent form GAIN study_Testing PEP PrEP Group; page 3 | First paragraph in Confidentiality of Research Information section, 6 months changed to 1 year and “last date of study enrollment” changed to “study closes” | Update study timeline and clarify terms |
| Consent form; Att 8_Consent form GAIN study_Testing PEP PrEP Group, page 4 | Addition of “Because the SAMBA II Qual test is not yet FDA approved, we will rely on the laboratory based tests to make a final assessment of your HIV status” | Provide clarity to potential participants about procedures following a positive NAT result |
| Consent form; Att 8_Consent form GAIN study_Testing PEP PrEP Group, page 4 | Addition of “It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you. Participants will be able to withdraw permission for use of their information at any time until the link between their identity and their study ID number is broken. This will be six years after the study closes, anticipated to be September 2030. Participants can write to Dr. Stekler at any time until this date to withdraw permission.” | Improve explanation to potential participants regarding procedures regarding future use of data |
| Consent form; Att 8_Consent form GAIN study_Testing PEP PrEP Group, page 4 | Addition of “\$20 for participating in this study . . . ” per standardization of incentive schedule | Update on changes to incentive schedule (see Table 1) |
| Consent form; Att 9_Consent form GAIN study_HIV+ Group), page 1 | Removed “in the interview” | Clarity as participants may decline to answer questions on the survey as well |
| Consent form; Att 9_Consent form GAIN study_HIV+ Group), page 1 | Addition of “(which is about 2 teaspoons)” | Assist potential participants in understanding the quantity “10 mL” |
| Consent form; Att | First paragraph in Confidentiality of Research | Update study timeline and |

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| 9_Consent form GAIN study_HIV+ Group), page 3 | Information section, 6 months changed to 1 year and “last date of study enrollment” changed to “study closes” | clarify terms |
| Consent form; Att 9_Consent form GAIN study_HIV+ Group), page 4 | Addition of “Because the SAMBA II Semi-Q test is not yet FDA approved, we will rely on the laboratory based tests to make a final assessment of your HIV status” | Provide clarity to potential participants about procedures following a NAT test result |
| Consent form; Att 9_Consent form GAIN study_HIV+ Group), page 4 | Addition of “It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you. Participants will be able to withdraw permission for use of their information at any time until the link between their identity and their study ID number is broken. This will be six years after the study closes, anticipated to be September 2030. Participants can write to Dr. Stekler at any time until this date to withdraw permission.” | Improve explanation to potential participants regarding procedures regarding future use of data |
| Consent form; Att 9_Consent form GAIN study_HIV+ Group), page 4 | Addition of “You will receive a \$25 gift card for participation in this study” | Update on changes to incentive schedule (see Table 1) |
| Information sheet; Att 16_GAIN patient information sheet, page 1 | Substitute “to complete a blood draw for the POC NATs and laboratory testing, and answer a few questions for a survey.” | Clarify study procedures |
| Information sheet; Att 16_GAIN patient information sheet, page 3 | Addition of “If you wish to stay at the clinic to obtain your result from one of the tests (the SAMBA), you may. We will not return the result of the other POC NAT (the Cepheid) to you.” | Clarify study procedures |
| Information sheet; Att 16_GAIN patient information sheet, page 3 | Addition of “Because the SAMBA II Semi-Q test is not yet FDA approved, we will rely on the laboratory based tests to make a final assessment of your viral load.” | Provide clarity to potential participants about procedures following a NAT result |
| Information sheet; Att 16_GAIN patient information sheet, page 3 | Addition of “and a \$5 food voucher” | Update on changes to incentive schedule (see Table 1) |

Table 3. Summary of change to the study visit survey (Att 11_GAIN study visit survey_screenshots)

| Form, Page, | Change Proposed | Reason for Change Proposed |
|-------------|-----------------|----------------------------|
|-------------|-----------------|----------------------------|

| Section, Question/Field | | |
|---------------------------------|---|---|
| GAIN study visit survey, page 4 | For persons who select “Yes, I have previously taken PrEP but do not use it now” as an answer to the question “Have you ever used HIV pre-exposure prophylaxis or PrEP?”, added a question, “When did you stop taking PrEP? Please enter a month and year in MM/YYYY format. If you cannot remember the month, please just enter the year.” | To best interpret the NAT results that are the focus of the GAIN study it is important to understand whether antiretroviral medications have recently been consumed. As PrEP use becomes more common this is an increasingly likely possibility. This question assesses for the possibility of recent PrEP use. |

The non-substantiative change request package includes:

- SSA: track changes
- SSA: changes accepted
- Att 8_Consent form GAIN study_Testing PEP PrEP Group_track changes_082922
- Att 8_Consent form GAIN study_Testing PEP PrEP Group_changes accepted_082922
- Att 9_Consent form GAIN study_HIV+ Group_track changes_082922
- Att 9_Consent form GAIN study_HIV+ Group_changes accepted_082922
- Att 11_GAIN study visit survey_screenshots_track changes_082922
- Att 11_GAIN study visit survey_screenshots_changes accepted_082922
- Att 16_GAIN patient information sheet_track changes_082922
- Att 16_GAIN patient information sheet_changes accepted_082922