Expanding PrEP in Communities of Color (EPICC)
OMB # 0920-1423

Summary of Changes

We are requesting a non-substantive change request to the information collection request (ICR) Expanding PrEP in Communities of Color (EPICC, OMB #0920-1423). The requested changes do not impact the burden table and do not result in an overall change in the scope of data collection. Changes are being made to bolster study enrollment and strengthen data collection efforts which are critical to the final analyses and study outcomes. Changes will also further harmonize this study with the mChoice Study (OMB 0920-1428); both are funded through PS-21-003, PrEP Choice: Increasing the Use of HIV Pre-exposure Prophylaxis in an Era of Choices, and their data will be combined for analysis.

Finally, we are updating the race and ethnicity questions to reflect the new standards announced by the Office of Management and Budget (OMB) on 03/29/2024 (Revisions to OMB's Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, 89 FR 22182).

Study Inclusion Criteria

A change is being requested to harmonize this study's inclusion criteria with the mChoice Study (OMB 0920-1428). This change will specify that non-binary persons, including persons that identify as gender nonconforming and genderqueer are eligible to participate in the study. Making this change will help ensure that we are fully inclusive of the population sought for this study and benefit the overall PrEP Choice Study which will analyze data across both studies to gain deeper insight on PrEP use (i.e. PrEP medications used, adherence and persistence). Current CDC HIV pre-exposure prophylaxis (PrEP) guidelines were informed by studies that included few or no non-binary people[1]. The PrEP Choice Study will add to the limited data on PrEP use among non-binary persons and provide information needed to develop more comprehensive PrEP guidance. This change does not impact burden hours or the overall scope of data collection.

Sexual History Screening Question

The change to the study inclusion criteria necessitates a change to the sexual history screening question. Specifically, we will change "sex with a man" to "sex with a person with a penis." Removing gender will be more inclusive to a broader range of gender identities for a participant's sexual partners. Removing gender from the question and replacing it with the anatomical term penis, will also bring the question in line with current language guidance from the Adolescent Medicine Trials Network for HIV/AIDS Interventions[2]. The changes will better acknowledge and respect how participants define themselves and their relationships.

We also propose removing 'anal sex' from the sexual history screening question and replacing it with 'sex'. Current CDC PrEP guidelines note that that patients often do not disclose stigmatized sexual behaviors to their health care providers [3-7]. We believe that some of our respondents may be reluctant to disclose what may be perceived as stigmatizing sexual behavior and, as a result, they are not eligible to participate in the study. Therefore, we propose using the more general term 'sex' in order to minimize any perceived stigma and mitigate any reluctance to respond.

We also propose removing the 12-month time frame from the sexual history screening question in order to bring the question into line with the proposed change to the inclusion criteria described above. Expanding the timeframe in which a participant may have been sexually active will allow us to

be more inclusive of persons who may be in different stages of their lives and sexual relationships. This change will also benefit participants as they will not have to rely on memory in order to respond to a question with a strict timeline. These changes do not impact burden hours or the overall scope of data collection.

Blood Collection Instructions

Next, we propose adding the question 'Have you switched your PrEP medication within the last 3 months of collecting this blood sample?' to the Blood Collection Instructions for dried blood spot (DBS) specimens. This question is needed as some participants may choose to switch PrEP types within the three months prior to completing their DBS collection. If participants did change their PrEP medication during that period, and we were not aware of the change, it could make analysis of the DBS samples more difficult to interpret. The half-life of tenofovir-diphosphate in whole blood is approximately 17 days, thus concentrations reflect the average number of doses taken over the last 6-12 weeks, while the half-life of emtricitabine-triphosphate is shorter (approximately 62 hours), thus reflecting doses taken over the past week[8]. Being aware of any recent switches will help us ensure the accuracy of our analysis. This change does not impact burden hours or the overall scope of data collection.

Tokens of Appreciation (ToA)

We are requesting increases to the Tokens of Appreciation (ToA) for cohort participation in the study. Since implementing the EPICC study, the study team has experienced difficulties getting participants to collect and return DBS specimen kits and complete the full complement of enrollment activities. The change in ToAs more appropriately compensates participants for these study activities that require more time and effort.

To encourage more participants to complete and return DBS kits, we propose increasing the ToA for participants who return baseline and 6-month kits from $25 to $50. We also propose a $50 bonus token for participants who successfully return the first three DBS kits (baseline, 6-month, and 12-month). Lastly, we propose increasing the ToA for the final, 18-month DBS kit from $50 to $75. These amounts are slightly higher than the incentives offered in the Prepared, Protected, emPowered (P3) study, which began enrollment in 2019[9]. P3 study DBS retention rates at 3 and 6 months were 63.4% and 66.3% respectively. The main outcome for the EPICC study is based on the analysis of DBS samples; therefore, it is essential that our DBS retention rates exceed the rates in the P3 study.

To encourage participants to complete all enrollment activities, we propose offering a $50 ToA for attending the optional study onboarding visit. Since implementing the EPICC study, the study team has found that participants were opting out of the onboarding visit instead choosing to complete onboarding activities on their own. As a result, some participants did not fully complete all required onboarding activities and were the never fully enrolled. We anticipate that offering a ToA for completing the onboarding visit will increase visit attendance thereby reducing the number of people who begin, but never fully complete, enrollment activities. These changes do not impact burden hours or the overall scope of data collection.

Sexual Orientation and Gender Identity (SOGI)

We have also revised the SOGI questions on the Provider Pre Focus Group Survey (Att 4p) so that they match the SOGI questions on the Cohort Screener (Att 4f Aim 2a Cohort Screener). The SOGI revisions to the Cohort Screener were approved by OMB on 02/16/2024. The revisions to the SOGI questions on the Provider Pre Focus Group Survey were inadvertently omitted from that request, therefore, updating now. Study stakeholders have recommended that the SOGI questions be harmonized

throughout the study for consistency. Updating the framing of these questions aligns with "Recommendations on the best practices for the collection of sexual orientation and gender identity data on federal statistical surveys" released by the White House in January 2023.[10] This change does not impact burden hours or the overall scope of data collection.

Other Changes

In addition to the proposed changes detailed above, we are also revising the SSA and SSB to reflect changes in CDC project staff. We are revising the list of participating clinics to reflect the departure of two clinics from the study and we specify satellite clinic locations for existing study clinics. We are also correcting a few omissions and grammatical and mathematical errors. These changes do not impact burden hours or the overall scope of data collection.

The proposed changes affect the following attachments, and are included with this request:

- Att 4f_Aim2aCohortScreener (English/Spanish; Tracked and Clean)
- Att 4l_Aim2aCohortBloodCollectionInstructions (English/Spanish; Tracked and Clean)
- Att 4p_Aim 2b Provider Pre-Focus Group Survey (Tracked and Clean)
- Att 5b_Aim2aCohortConsent (English/Spanish; Tracked and Clean)
- SSA (Tracked and Clean)
- SSB (Tracked and Clean)

References

1. Centers for Disease Control and Prevention: US Public Health Service: Preexposure prophylaxis for the prevention of HIV infection in the United States—2021 Update: a clinical practice guideline. https://www.cdc.gov/hiv/pdf/risk/prep/cdc-hiv-prep-guidelines-2021.pdf.
2. Easterling, L, and Byram, J. Shifting language for shifting anatomy. Using inclusive anatomical language to support gender and nonbinary identities. The Anatomical Record. 2022: 305(4), 983-981. https://doi.org/10.1002/ar.24862
3. Qiao S, Zhou G, Li X. Disclosure of same-sex behaviors to health-care providers and uptake of HIV testing for men who have sex with men: A systematic review. Am j Mens Health. 2018;12(5):11971214.
4. Petroll AE, Mosack KE. Physician awareness of sexual orientation and preventive health recommendations to men who have sex with men. Sex Transm Dis. 2011;38(1):63. 22. U.S. Preventive Services Task Force. Screening for Illicit Drug Use. Accessed 20 August 2013, http://www.uspreventiveservicestaskforce.org/uspstf08/druguse/drugrs.htm#summary
5. McDonell MG, Graves MC, West II, et al. Utility of point of care urine drug tests in the treatment of primary care patients with drug use disorders. Journal Addict Med. 2016;10(3):196.
6. Chasnoff IJ, Landress HJ, Barrett ME. The prevalence of illicit-drug or alcohol use during pregnancy and discrepancies in mandatory reporting in Pinellas County, Florida. N Engl J Med. 1990;322(17):1202-1206.
7. White D, Rosenberg ES, Cooper HL, et al. Racial differences in the validity of self-reported drug use among men who have sex with men in Atlanta, GA. Drug Alcohol Depend. 2014;138:146-153.
8. Anderson PL, Liu AY, Castillo-Mancilla JR, Gardner EM, Seifert SM, McHugh C, et al. Intracellular Tenofovir-Diphosphate and Emtricitabine-Triphosphate in Dried Blood Spots following Directly Observed Therapy. Antimicrob Agents Chemother. 2018;62.
9. LeGrand S, Knudtson K, Benkeser D, et al. Testing the Efficacy of a Social Networking Gamification App to Improve Pre-Exposure Prophylaxis Adherence (P3: Prepared, Protected, emPowered): Protocol for a Randomized Controlled Trial. JMIR Res Protoc 2018;7:e10448

Table 1. Summary of Changes to Data Collection Instruments	
Att 4f_Aim2aCohortScreener (English and Spanish)	
Summary of Changes	**Reason for Change Proposed**
Page 2: Screener text was revised to include non-binary persons, including gender nonconforming, and genderqueer.	This change was made in response to recommendations to harmonize inclusion criteria across PrEP Choice studies (i.e., mChoice Study- OMB 0920-1428) and specify the broad array of gender identities eligible for the study.
Pages 5-6: Race and ethnicity questions were updated to the new OMB race/ethnicity standard.	This change was made to align the project's race and ethnicity questions with the new race/ethnicity data collection standards announced by OMB in March 2024.
Page 6: Grammatical error was corrected; 'English and/or Spanish' was changed to 'English or Spanish'.	Grammatical error corrected.
Page 10: 'Anal sex' was revised to 'sex (as a top or bottom, insertive or receptive)' was added. The 12-month time frame was removed and the text 'with a person who has a penis' was added.	'Anal sex' was revised to 'sex' reduce perceived stigma and mitigate any reluctance to respond. Language was added to clarify the types of sex. Time frame was removed to be more inclusive of persons who may be in different stages of their sexual relationships. A description that included anatomical terminology was added to be more inclusive of a broader range of gender identities. These changes are consistent with the mChoice Study- OMB 0920-1428.
Pages 11, 12: Pediatric Specialty Clinics (Cook County Health) and Bliss Healthcare Services were removed; satellite clinics for remaining clinics are specified for clarity.	Two clinics (Pediatric Specialty and Bliss Healthcare) were removed from the study because they were no longer able to participate in the study. We added the names of the satellite clinics that are part of the remaining study clinics. The number of study participants and burden remains unchanged.
Page 12: Participant instructions were updated to include language about: the importance of a valid email address and the privacy and security of a participant's contact information, as well as to let a participant know what happens next in the screening process.	This change was made in response to recommendations from key stakeholders to better inform participants about their eligibility and the next steps in the enrollment process.
Att 4l_Aim2aCohortBloodCollectionInstructions (English and Spanish)	
Summary of Changes	**Reason for Change Proposed**

Page 4: The ToAs for completing each specimen kit were added to the blood collection instructions. The total ToA amount for 12-month participants was changed from $350 to $500. The total token of appreciation amount for 18-month participants was changed from $475 to $650.	Key stakeholders have recommended these changes be made to compensate participants more appropriately for their time and effort to collect and return the DBS specimen kits, as this data is critical to interpreting study outcomes. We have added the ToAs to the blood collection instructions to encourage participants to complete this recurring study activity.
Page 6: A new question about medication switching was added to the Blood Collection Instruction form. "Have you switched your PrEP medication within the last 3 months of collecting this blood sample? For example: switched from daily oral Truvada to daily oral Descovy; switched from daily oral Truvada to injectable PrEP; switched from daily oral Truvada to intermittent oral Truvada."	This question was added to identify participants who may choose to switch PrEP types during the course of the study. Due to differences in the half-life of PrEP medications, the specimens are more difficult to interpret if analysts are unaware the participant switched medications. The addition of this question will help to ensure the accuracy of the analysis.
Att 4p_Aim2bProviderPreFocusGroupSurvey	
Summary of Changes	**Reason for Change Proposed**
Pages 1, 2: The race and ethnicity questions were updated to conform to the new OMB race and ethnicity standards	This change was made to align the project's race and ethnicity questions with the new race/ethnicity data collection standards announced by OMB in March 2024.
Page 4: The sexual orientation and gender identity question was updated to match the responses in the cohort screener.	The SOGI questions were updated to match the responses in the Cohort Screener (Att 4f Aim2a Cohort Screener). The SOGI revisions to the cohort screener were approved by OMB on 02/16/2024. The revisions to the SOGI questions on this document were accidentally omitted from that request.

Table 2. Summary of Changes Other Study Documents (Consent, SSA, SSB)	
Att 5b_Aim2aCohortConsent (English and Spanish)	
Summary of Changes	**Reason for Change Proposed**
Pages 2, 3, 7: The summary in the consent form was updated to include information about the study onboarding visit.	We have revised the consent form to include previously omitted information about attending the study onboarding visit.
Pages 2, 3: The consent form was updated to include non-binary persons, and language describing sex partners was therefore revised to be more inclusive of sexual partners with different gender identities.	This change harmonizes eligibility criteria with mChoice Study (OMB 0920-1428). It specifies that the study eligibility criteria is inclusive of non-binary persons. Similarly, we have also revised the language describing sex partners to reflect this change.

Page 6: Text regarding the clinical trials website was removed.	This text was removed because this study was not required to register with clinicaltrials.gov.
Page 7: Text to describe the proposed ToA for the study onboarding visit was added and the total token amount was revised.	These revisions were made in response to recommendations from key stakeholders to strengthen data collection efforts, especially study onboarding which is critical to study enrollment.
Page 8: ToA for the completion of baseline and 6-month blood specimen kits were increased to $50. The ToA for the 18-month blood specimen kit was increased to $75. A $50 bonus token was added for participants who complete all 3 initial specimen kits.	The EPICC study is experiencing challenges in getting participants to return DBS specimen kits. Key stakeholders have recommended that the study increase ToAs to compensate participants more appropriately for their time and effort to collect and return DBS specimen kits, we propose increasing the ToA. DBS data is critical to interpreting study outcomes.
SSA	
Summary of Changes	**Reason for Change Proposed**
Page 1, 11: CDC Project Officer's contact information updated, as well as Point of Contact.	CDC staffing for this project has changed. Katrina Byrd is replacing Mary Tanner. Carla Galindo is the new point of contact.
Pages 4 and 6: Non-binary persons were added to the SSA. We also revised language for the description of sexual activity to "sex with persons with a penis."	This change harmonizes eligibility criteria with mChoice Study (OMB 0920-1428). It specifies that the study eligibility criteria is inclusive of non-binary persons. To align with this change, we have also revised the language describing sex partners to be more inclusive of sexual partners with different gender identities.
Pages 4, 6, 7, 8, 12, 15: The number of study clinics changed from nine to seven. This change is reflected throughout SSA.	Two clinics (Pediatric Specialty and Bliss Healthcare) were removed from the study because they were no longer able to participate. The number of study clinics changes from nine to seven. The number of study participants remains unchanged.
Pages 11 and 12: A $50 ToA for attending the app setup (study onboarding) visit was added. The total amount was updated to reflect the new token amount.	We are proposing this new ToA in response to recommendations from key stakeholders to strengthen data collection efforts, especially study onboarding which is critical to study enrollment.
Page 12: ToA for the completion of baseline and 6-month blood specimen kits were increased to $50. The ToA for the 18-month blood specimen kit was increased to $75. A $50 bonus token was added for participants who complete all three initial specimen kits. The total amount of compensation for blood specimens was increased to $275 and for completing all study activities was increased to $600 to reflect the new amounts.	The EPICC study is experiencing challenges in getting participants to return DBS specimen kits. Key stakeholders have recommended that the study increase ToAs to compensate participants more appropriately for their time and effort to collect and return DBS specimen kits, we propose increasing the ToA. DBS data is critical to interpreting study outcomes.

Page 12: Information about the exit Interviews was added.	This information was erroneously omitted from the original SSA. This addition corrects that error.
Page 15: The total number of participants was corrected (changed from 487 to 478).	This edit corrects a previous error (typo).
SSB	
Summary of Changes	**Reason for Change Proposed**
Page 1 (title page): Contact name, mailstop, zip code, phone number, and e-mail address were updated. **Page 11:** CDC Staffing change was made.	CDC staffing for this project has changed. Katrina Byrd is replacing Mary Tanner. Carla Galindo is the new point of contact.
Pages 3, 4, 5: Non-binary (including gender non-conforming and genderqueer) persons were added to the SSB. To align with this change, we revised language for the description of sexual activity to "sex with persons with a penis" and "Report ever having sex with a person with a penis."	This change harmonizes eligibility criteria with mChoice Study (OMB 0920-1428). It specifies that the study eligibility criteria is inclusive of non-binary persons. To align with this change, we have also revised the language describing sex partners to be more inclusive of sexual partners with different gender identities.
Pages 3,4: The number of study clinics has changed from nine to seven and the study locations reflect this change. Remaining clinics' satellite locations are specified for clarification.	Two clinics (Pediatric Specialty and Bliss Healthcare) were removed from the study because they were no longer able to participate. Remaining clinics' satellite locations are specified for clarity. The number of study participants and burden remains unchanged.
Page 7: The addition of a $50 ToA for attending the app setup (study onboarding) visit was added to SSB.	We are proposing this new ToA in response to recommendations from key stakeholders to strengthen data collection efforts, including study onboarding, which is critical to study enrollment.
Page 8: ToA for the completion of baseline and 6-month blood specimen kits were increased to $50. A $50 bonus token was added for participants who complete all 3 initial specimen kits. The ToA for the 18-mos. blood specimen kit was increased to $75.	The EPICC study is experiencing challenges in getting participants to return DBS specimen kits. Key stakeholders have recommended that the study increase ToAs to compensate participants more appropriately for their time and effort to collect and return DBS specimen kits, we propose increasing the ToA. DBS data is critical to interpreting study outcomes.