

**mChoice: Improving PrEP Uptake and Adherence among Minority MSM through Provider Training and Adherence Assistance in Two High Priority Settings**

**OMB # 0920-1428**

**Feb 5, 2024**

**Summary of Changes**

We are requesting a non-substantial change to the information collection request (ICR) for the mChoice study (OMB #0920-1428).

We are making the following changes:

1. Updating the demographic questions related to sex and gender in the study instruments.
2. Adding an emtricitabine assay to the patient consent form
3. Adding a single question about when the last PrEP medication was taken to the baseline and quarterly assessments
4. Adding an explanatory statement to the app onboarding guide about logging out of the app.

In the time since the ICR was developed, the recipients were informed of the findings of a community advisory panel held to advise on the framing of questions about sex and gender in research, especially considering how to best address these questions for youth. To be responsive to these recommendations and to align with local best practices in language around sex and gender, the mChoice study team has updated the sexual orientation and gender identity questions in the survey instruments. Updating the framing of these questions also 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.<sup>1</sup> This change is responsive to input from community stakeholders and aligns with the goals and plans of this project.

Tables:

- The changes to demographic questions related to sex and gender are outlined in Table 1 below.
- The changes to the patient consent form are outlined in Table 2 below.
- The change to the baseline and quarterly assessments is outlined in Table 3 below.
- The change to the app onboarding guide is outlined in in Table 4 below.

There are no changes to the burden table, SSA, SSB, or other attachments.

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<sup>1</sup> The White House. Recommendations on the best practices for the collection of sexual orientation and gender identity data on federal statistical surveys. Jan 2023. Available: <https://www.whitehouse.gov/wp-content/uploads/2023/01/SOGI-Best-Practices.pdf>. Accessed: Nov 2 2023.

**Table 1. Summary of Changes to Demographic Questions Related to Sex and Gender in Survey Instruments**  
 (Att 4i\_Provider Pre-Training Assessment; Att 4a\_Patient Screener)

Original Question	Change Proposed	Reason for Change Proposed
<p><b>Which of the following BEST represents how you think about yourself?</b></p> <ul style="list-style-type: none"> <li>• Lesbian or gay</li> <li>• Straight, that is not lesbian or gay</li> <li>• Bisexual</li> <li>• Something else</li> <li>• Decline to answer</li> </ul>	<p><b>Which of the following BEST represents how you think about yourself?</b></p> <ul style="list-style-type: none"> <li>• Lesbian or gay</li> <li>• Straight, that is not lesbian or gay</li> <li>• Bisexual</li> <li>• Something else: _____</li> <li>• Decline to answer</li> </ul>	<p>Key stakeholder input, project goals</p>
<p><b>Do you currently describe yourself as male, female, or transgender?</b></p> <ul style="list-style-type: none"> <li>• Male</li> <li>• Female</li> <li>• Transgender male</li> <li>• Transgender female</li> <li>• None of these</li> <li>• Decline to answer</li> </ul>	<p><b>[If American Indian or Alaskan Native is not checked]</b></p> <p><b>How do you currently describe yourself? (Check all that apply)</b></p> <ul style="list-style-type: none"> <li>• Woman, including transgender woman</li> <li>• Man, including transgender man</li> <li>• Nonbinary, including gender nonconforming, and genderqueer</li> <li>• A different gender identity: _____</li> <li>• Don't know</li> <li>• Decline to answer</li> </ul> <p><b>[If American Indian or Alaskan Native is checked]</b></p> <p><b>How do you currently describe yourself? (Check all that apply)</b></p> <ul style="list-style-type: none"> <li>• Woman, including transgender woman</li> <li>• Man, including transgender man</li> <li>• Nonbinary, including gender nonconforming, and genderqueer</li> <li>• Two-Spirit</li> <li>• A different gender identity: _____</li> <li>• Don't know</li> <li>• Decline to answer</li> </ul>	<p>Key stakeholder input, project goals</p>

<p><b>Beyond the gender identities listed above, are there any other identities that you would use to describe yourself? (Select all that apply)</b></p> <ul style="list-style-type: none"> <li>• Gender non-conforming</li> <li>• Genderfluid</li> <li>• Genderqueer</li> <li>• Non-binary</li> <li>• Two-spirit</li> <li>• Another identity, please specify:</li> <li>• None of these</li> <li>• Decline to answer</li> </ul>	None	Removed as redundant with changes to the prior question (outlined in the row above).
<p><b>What sex were you assigned at birth, on your original birth certificate?</b></p> <ul style="list-style-type: none"> <li>• Male</li> <li>• Female</li> <li>• Decline to answer</li> </ul>	<p><b>What sex were you assigned at birth, on your original birth certificate?</b></p> <ul style="list-style-type: none"> <li>• Male</li> <li>• Female</li> <li>• Intersex</li> <li>• Decline to answer</li> </ul>	Key stakeholder input, project goals

**Table 2. Summary of Changes to the Patient Consent Form (Att 5b\_Patient Consent Form)**

Location	Change	Reason for Change
Page 3	Added emtricitabine PrEP to types of PrEP	Addition of emtricitabine assay to study
Page 6	Added NanoComposix Laboratory to study collaborators	Addition of the emtricitabine assay laboratory
Page 7	Added de-identified sample processing to the urine test section	Addition of information about emtricitabine assay processing

**Table 3. Summary of Changes to Baseline and Quarterly Assessments (Att 4c\_Patient Baseline Assessment; 4d\_Patient Quarterly Assessment)**

Location	Change	Reason for Change
Baseline assessment, Page 13, item F4b	Added question “When did you last take a PrEP pill?”	Provide context for laboratory studies that measure levels of tenofovir and emtricitabine.
Quarterly assessment, Page 18, item F4b	Added question “When did you last take a PrEP pill?”	Provide context for laboratory studies that measure levels of tenofovir and emtricitabine.

**Table 4. Summary of Changes to the App Onboarding Guide (4e\_CleverCap App Setup)**

Location	Change	Reason for Change
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Page 1	<b><u>Added text: “It is important to note that once you log into the app, there is no automatic time out. You must manually log out of the app through use of the side menu bar every time you want to be logged out of the app to maintain confidentiality.”</u></b>	Ensure participants are aware of how to log out/maintain confidentiality by requiring sign in screen
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**Attachments:**

- Att 4a\_Patient Screener\_TRACK CHANGES
- Att 4a\_Patient Screener\_CLEAN
- Att 4i\_Provider Pre-Training Assessment\_TRACK CHANGES
- Att 4i\_Provider Pre-Training Assessment\_CLEAN
- Att 4c\_Patient Baseline Assessment\_TRACK CHANGES
- Att 4c\_Patient Baseline Assessment\_CLEAN
- Att 4d\_Patient Quarterly Assessment\_TRACK CHANGES
- Att 4d\_Patient Quarterly Assessment\_CLEAN
- Att 4e\_CleverCap App Setup\_TRACK CHANGES
- Att 4e\_CleverCap App Setup\_CLEAN
- Att 5b\_Patient Consent Form\_TRACK CHANGES
- Att 5b\_Patient Consent Form\_CLEAN