

Non-substantive Change Request
OMB Control Number 0920-1428 (Exp. 01/31/2027)
mChoice: Improving PrEP Uptake and Adherence among Minority MSM through
Tailored Provider Training and Adherence Assistance in Two High Priority Settings
Date Submitted: 09/29/2025

Summary of request: CDC/NCHHSTP is requesting a change request to revise questions and content to align with EO 14168 *Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government*.

Description of Changes Requested: This request updates sex questions and removes language related to gender diversity included in the “mChoice: Improving PrEP Uptake and Adherence among Minority MSM through Tailored Provider Training and Adherence Assistance in Two High Priority Settings” Study data collection instruments and documents to be in accordance with EO 14168.

Please check the boxes below if your request includes:

- ☒ **Revision of an existing question(s)**
- ☒ **Deletion of an existing question(s)**

There is no change in Burden Hours associated with the modifications made to comply with EO 14168.

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

- SSA (Tracked and Clean)
- SSB (Tracked and Clean)
- Att 3a_Patient Recruitment Materials (Tracked and Clean)
- Att 4a_Patient Screener (English and Spanish; Tracked and Clean)
- Att 4b_Patient Locator Form (English and Spanish; Tracked and Clean)
- Att 4c_Patient Baseline Assessment (English and Spanish; Tracked and Clean)
- Att 4d_Patient Quarterly Assessment (English and Spanish; Tracked and Clean)
- Att 4e_CleverCap App Setup (Tracked and Clean)
- Att 4i_Provider Pre-Training Assessment (Tracked and Clean)
- Att 4j_Provider Post-Training Assessment (Tracked and Clean)
- Att 5a_Patient Consent to Screen (English and Spanish; Tracked and Clean)
- Att 5b_Patient Consent Form (English and Spanish; Tracked and Clean)

Table A: Description of Changes by Document	Type of Change	Question/Item	Requested Change
SSA	Removing references to gender identities in the document	See tracked changes document for changes in text (i.e., removal of other gender identities referenced on Pg. 12).	Removing reference to gender identity in the document in referenced study.
SSB	Removing references to gender identities in the document	See tracked changes document for changes in text (i.e., removal of other gender identities on Pg. 4).	Removing references to gender identities in the document.
Att 3a_Patient Recruitment Materials	Removing references to gender identity beyond male in materials	Updated Recruitment Materials to remove mention of other gender identities.	Update Recruitment Materials to remove mention of other gender identities.
Att 4a_Patient Screener (English and Spanish)	<p>Question Change and Deletion What is your sex?</p> <ul style="list-style-type: none"> • Male • Female <p>Remove Intersex and Decline to answer</p> <p>Remove questions that ask about gender identity on Pg. 6.</p> <p>Remove duplicative question on Pg.</p>	<p>Changing the wording on sex question on Pg. 4 "What sex were you assigned at birth, on your original birth certificate?" to "What is your sex?"</p> <p>Removing question on Pg. 6: "How do you currently describe yourself?"</p> <p>Removing duplicative Question 19 on Pg. 8- Are you currently participating in any other PrEP related research study?</p>	<p>Change the wording on sex question to "What is your sex?"</p> <p>Response option: Male or Female.</p> <p>Remove question: "How do you currently describe yourself?"</p> <p>Remove references to other gender identities.</p> <p>Remove duplicated question.</p>

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Att 4b_Patient Locator Form (English and Spanish)	Removed use of pronouns on Pg. 2.	Deleted use of pronouns on Pg. 2	The Locator Form does not include the use of pronouns.
Att 4c_Patient Baseline Assessment (English and Spanish) AND Att 4d_Patient Quarterly Assessment (English and Spanish_	Replacing "Gender Identity" with "Sex" as a response option on Question R2 on Pg. 69 in the Baseline, and on Question O2 on Pg. 57 in the Quarterly Assessment.	What do you think are the main reasons for why you experienced this discrimination? (Choose all that apply) Replace: <ul style="list-style-type: none"> o Your gender identity With: <ul style="list-style-type: none"> o Your sex 	What do you think are the main reasons for why you experienced this discrimination? (Choose all that apply) Replace: <ul style="list-style-type: none"> o Your gender identity With: <ul style="list-style-type: none"> o Your sex
Att 4e_CleverCap App Setup	Updating screenshots with updated content removing gender identities.	Updating screenshots from the app. to be consistent with changes (i.e., removing other gender identities).	Updating screenshots from the app. to be consistent with changes (i.e., removing other gender identities).
Att 4i_Provider Pre-Training Assessment	Question Change and Deletion	On Pg. 3-4, changed the wording on sex question on Pg. 3-4 from "What sex were you assigned at birth, on your original birth certificate?" to "What is your sex?" Removed question on Pg. 3: "How do you currently describe yourself?" On Pg. 6, removed part of Question 17 asking providers	Change the wording on sex question to "What is your sex?" Response option: Male or Female. Remove question: "How do you currently describe yourself?" Remove part of Question 17 asking providers about their comfort level prescribing PrEP to transgender persons.

		about their comfort level prescribing PrEP to transgender persons.	
Att 4j_Provider Post-Training Assessment	Removed portion of question 5 and references to gender identity	On Pg. 4, removed part of Question 5 asking providers about their comfort level prescribing PrEP to transgender persons. Removed reference to gender identities on Pg. 6.	On Pg. 4, remove part of Question 5 asking providers about their comfort level prescribing PrEP to transgender persons. Remove reference to gender identities on Pg. 6.
Att 5a_Patient Consent to Screen (English and Spanish)	Specifying sex versus gender identity.	Specifying sex versus gender identity.	Specifying sex versus gender identity.
Att 5b_Patient Consent Form (English and Spanish)	Removing reference to <gender> identity on Pg. 9.	Removing reference to <gender> identity on Pg. 9.	Removing reference to <gender> identity on Pg. 9.