

**Research and Evaluation Survey for the Public Education Campaign on Tobacco among LGBT
Young Adults (RESPECT)
(OMB Control Number 0910-0808)**

Change Request (83-C)

January 22, 2021

The Food and Drug Administration is submitting this nonmaterial/non-substantive change request (83-C) to incorporate minor edits and additions to the documents for the Research and Evaluation Survey for the Public Education Campaign on Tobacco among LGBT Young Adults (RESPECT).

Overview of the Change Request for OMB Control No. 0910-0808

This change request is to revise the data collection documents for the follow-up waves of data collection (follow-up surveys 1-3) for RESPECT, the first of which will begin in September 2016. The follow up data collection will re-contact baseline respondents and recruit new respondents to offset loss-to-follow-up. As such, this change request includes the following new and revised attachments:

We request the following changes to the data collection documents:

- **Informed Consent to complete eligibility screener**
 - Add new consent form for follow-up (returning) respondents that reminds them of their previous participation and asks if they consent to completing the eligibility screener
- **Eligibility Screener**
 - Revise previously OMB-approved eligibility screener for new respondents to create a slightly different version for follow-up (returning) respondents to confirm continued eligibility (i.e., ages 18-24) and to collect updated respondent contact information and contact preferences.
 - Expand screener logic to include respondents who write-in a response to the gender and/or sexual identity question(s).
- **Informed Consent to complete survey**
 - Add new consent form for follow-up respondents that reminds them of their previous participation and asks if they still consent to participate in the survey
- **Survey reminders for non-responsive participants (email and text messages)**
 - Revise previously OMB-approved survey reminder email and text messages to include both the previously OMB-approved formal email messages and newly developed informal email messages. In order to test their relative effectiveness, new respondents will be randomly assigned to receive either a formal or informal email both announcing the availability of the survey and reminding non responders to take the survey. We will monitor overall response rates, average speed of response, refusal rates, and contact rates. If one of the approaches performs significantly better, we will use it for future recruitment.
- **Follow-Up Survey**
 - Revise the previously OMB-approved follow-up survey instrument to:
 - Delete low priority questions to match study priorities and reduce length of survey;
 - Update placeholders with final campaign name, logo, videos, promotional materials, etc.;
 - Add clarifying instructions to respondents throughout survey to reduce respondent burden;
 - Modify e-cigarette wording to be compatible with updated national survey (i.e., PATH) definition and update images of e-cigarettes;

- Update, modify, or shorten item response lists;
- Add questions on awareness of Fresh Empire campaign;
- Add skip logic to reduce respondents' burden; and
- Update questions for clarity or consistency.

Att #	Type	Attachment Title	Revisions /Purpose
2	REVISED	FOLLOW-UP INSTRUMENT	Provides changes (in track changes) to the previously OMB-approved follow-up instrument.  Attachment2_FollowUp_Instrument_TC.
2a	NEW	RATIONALE FOR ITEM CHANGES TO FOLLOW-UP INSTRUMENT	Lists and provides rationale for changes made to the previously OMB-approved Follow-Up Instrument.  Attachment2a_Rationale for Item Change
3	REVISED	SCREENER	Includes text newly recruited respondents will see on the first screen upon launching the survey.  Attachment3_Screener_TC.docx
3a	NEW	RATIONALE FOR SCREENER CHANGES	Lists and provides rationale for changes made to the previously OMB-approved screener.  Attachment3a_Rationale for Screener Change
6	REVISED	WEB-SURVEY INFORMED CONSENT	Includes new content for returning (longitudinal) respondents will see before completing the follow up survey.  Attachment6_WebSurveyInformedConsent
11	REVISED	EMAIL AND TEXT MESSAGES TO RESPONDENTS	Revised to include both the previously OMB-approved formal email messages and newly developed informal email messages in order to compare the effectiveness of the new informal email messages with the previously OMB-approved formal email messages. In order to test their relative effectiveness, new respondents will be randomly assigned to receive either a formal or informal email both announcing the availability of the survey and reminding non responders to take the survey. We will monitor overall response rates, average speed of response, refusal rates, and contact rates. If one of the approaches performs significantly better, we will use it for future recruitment.

			 Attachment11_Email sandTextMessagesTo
13	NEW	SCREENER FOR RETURNING PARTICIPANTS (LONGITUDINAL)	Provides text returning (longitudinal) respondents will see on the first screen upon launching the survey.  Attachment13_Screen newwithInformedConsent