Change Request

Women's Health Needs Study: The Health of US-Resident Women from Countries with Prevalent Female Genital Mutilation/Cutting (FGM/C)

(OMB Control No. 0920-1264 expires 05/31/2022)
August 30, 2020

Summary

CDC was previously approved to conduct the Women's Health Needs Study (WHNS), a study of women living in the United States who have experienced Female Genital Mutilation/Cutting (FGM/C). The purpose of this change request is to seek approval for minor changes to the approved OMB packet for the Women's Health Needs Study (WHNS).

Changes include: 1) modifications due to COVID-19 to avoid face-to-face contact between study staff and participants; and 2) addition of Oromo translations of the study materials (informed consent, screener, and questionnaire) to ensure that Ethiopian participants who are of the Oromo ethnic group can be included in the study.

Background and Justification

CDC is currently approved to collect information to assess the health characteristics, experiences, and needs of women living in the United States who have experienced Female Genital Mutilation/Cutting (FGM/C) or may be at risk for FGM/C because they or their mothers were born in a country where FGM/C is prevalent. Data from this study will be used to: identify public health needs of women and communities in the United States affected by FGM/C; formulate public health strategies for meeting identified needs; and inform efforts to prevent continuation of the practice of FGM/C on women who may be at risk. study population includes US resident women aged 18 to 49 years who were born, or whose mother was born, in a country where FGM/C is prevalent.

<u>1) Modifications of WHNS Study Methods for COVID-19:</u>

As currently designed, eligible respondents who consent to participate will complete a one-time, face-to-face interview using a standardized questionnaire. Due to COVID-19, face-to-face recruitment and interviews may not be possible. Study methods have been expanded to include the following options to avoid face-to-face contact between study staff and participants. No PII, including IP address, will be captured from virtual or telephone interactions or from visits to the website.

a. Venues for Venue-Based Sampling for Recruitment

The study team proposes to work with implementing organizations to include "virtual venues" in addition to the original physical venues for Venue-Based Sampling. "Virtual venues" may include virtual group events (e.g., health fairs, classes, workshops); remote outreach activities or service contacts; and other interactions with clients where potentially eligible women can be informed, recruited, and screened to participate in the WHNS study. In "virtual venues," women will be notified about the study and offered information at the end of the interaction. If the event is a virtual group setting (e.g., health fairs, classes, workshops), women will be given the study secure toll-free number to call where they could be screened for the WHNS Study. If women are notified about the study during an individual interaction, they may be screened for the study during the contact.

b. Telephone Screening and Interviewing

Study procedures have been expanded to include use of phone contact for communicating with potential and eligible respondents and for study interviews. After screening by phone, women who meet the study criteria and can be interviewed at that time will be consented and interviewed by phone. If they cannot be interviewed at that time, they will be given the secure study toll-free number and unique codename that can be used to set up a different time to complete the phone interview.

Prior to the study interview, Verbal Informed Consent will also be administered by phone. A minor wording addition was made in the Informed Consent Form (**Attachment F1 Women's Health Needs Informed Consent Form (English)**) to acknowledge that study information may be given verbally instead of handing a physical study information card to recruit second-stage respondents.

Attachment F1 Women's Health Needs Informed Consent Form (English) shows the modified English-language Informed Consent document, and the same change has been made in all other study language translations.

c. WHNS Resource Website

Due to the need for social distancing, study information and materials will be made available to potential respondents on a secure WHNS Resource Website developed and administered by NORC with a norc.org domain. The secure website will include access to the study invitation information, Informed Consent in all language translations, and study contact information. The study website will require a secure Personal Identification Number (PIN) to access (See **Attachment K WHNS Resource Website Screenshot**.) Participants will be given the web address and PIN over the phone and interviewers will explain how they can navigate to the appropriate translated materials during and after the interview.

2) Oromo Language Translations of WHNS Study Materials

Based on the population makeup of the community sites for the WHNS, the study team and WHNS implementing organizations identified an additional need to include study materials translated in the Oromo language for Ethiopian participants who are of the Oromo ethnic group.

The Oromo ethnic group is the largest ethnic group in Ethiopia and based on the most recent nationally representative data, FGM/C is practiced among the Oromo with a prevalence of 77% among Oromo women aged 15-49 living in Ethiopia.[1] Several implementation locations for the WHNS have sizeable Oromo communities, and the inclusion of Oromo translations will ensure women from these communities can be interviewed and their experience of FGM/C, attitudes, and health outcomes can be included. We provide the Oromo-language study materials, including **Informed Consent (Attachment F7), Screener (Attachment G7), and Questionnaire (Attachment H7).**

Also, we have added "Oromo" as a language option on the WHNS Screener Question 2. **Attachment G1 Women's Health Needs Study Eligibility Screener (English**) shows the modified screener in English, and the same minor change has been made in all other study language translations.

Effect of Proposed Changes on Currently Approved Instruments

The **Informed Consent Form (Attachment F1)** acknowledges that study information may be given verbally.

The **WHNS Screener (Attachment G1)** Question 2 includes Oromo as a language option.

Burden Estimate

The COVID-19 study modifications and the additional Oromo translation will have no impact on study burden.

OMB approval is requested, effective immediately.

[1] Central Statistical Agency (CSA) [Ethiopia] and ICF. 2016. Ethiopia Demographic and Health Survey 2016. Addis Ababa, Ethiopia, and Rockville, Maryland, USA: CSA and ICF.