

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

New Information Collection Request

Supporting Statement B

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1. Respondent Universe and Sampling Methods/Plan

Potential community locations for this study will be selected based on Population Reference Bureau reports estimating the geographic concentrations of women born in a country where FGM/C is common. Final selection of the implementation locations for the pilot and main study will also be based on the recommendations of the Advisory Panel of subject matter experts (**Attachment B**). The pilot and main studies will be implemented in up to six community sites (one site for the pilot, and up to five for the main study), which may include communities within Atlanta; New York City; Seattle; Washington, DC/Baltimore; San Diego; Minneapolis/St. Paul; and/or Phoenix.

For individual women within the selected communities to be eligible for the study, they must: 1) be between the ages of 18-49 years; 2) speak one of the languages for which a translated questionnaire is available (Somali, Swahili, Arabic, Amharic, or English), with the translation languages having been selected on the basis of the languages predominately spoken within targeted communities); 3) have been born in a country where FGM/C is common, or have a mother who was born in a country where FGM/C is common; and 4) be capable of providing informed consent.

This request is to allow for the fielding of a survey that relies upon venue-based and respondent-driven (VBS/RDS) sampling methodology to build the sample and to produce interviews for an overall target sample size of 1,200 respondents as follows:

- Pilot Study – A maximum of 100 respondents or 2 months in the field, whichever comes first.
- Main Study– A maximum of 1,100 respondents or 12-24 months in the field, whichever comes first.

The primary purpose of the pilot study is to evaluate the feasibility of the proposed sampling methodology for the hard-to-reach FGM/C population of interest. The anticipated sample size of 100 in the pilot study is not large enough to statistically generalize all survey findings to the specific community from which the sample will be built. However, the pilot study is expected to validate study assumptions and/or expose issues with the sampling methodology, procedures and survey questions, which will lead to revisions as appropriate for fielding the main study.

In the main study, the sample size of 1,100 is sufficient to support projections of survey outcomes for the FGM/C population from which the sample was generated, i.e., women 18-49 in the main study communities who speak one of the included languages, and are from or whose mother is from a country where FGM/C is common. With a completed sample size of 1,100 eligible respondents in the main study and an assumed design effect of 1.5, we estimate the confidence interval half-width at the 95 percent confidence level for an estimated survey proportion $p=50\%$ to be approximately 3.6 percentage points. We also expect to be able to detect a minimum difference of approximately 7.3 percentage points between two estimated proportions of women in various demographic groups (e.g. women experiencing FGM/C with higher versus lower education levels; first versus second generation) with the proportion in each group approximately one-half the size of the total sample (i.e., a base of 550 respondents in each

comparative subgroup). The sampling will not be generalizable to the US national universe of the target group of women 18-49 who are from or whose mother is from a country where FGM/C is common, but will provide insights across diverse groups into the practice of FGM/C, attitudes, and health outcomes included in the survey.

To sample women within specific communities, we will use a Venue-based and Respondent-driven sampling (VBS/RDS) approach. VBS/RDS is a non-traditional sampling approach that is often used to overcome the limitations of traditional sampling strategies for rare and hidden populations by incorporating features that are designed to limit and adjust for biases in traditional snowball sampling. [The VBS/RDS sampling approach that will be utilized for this study](#) assumes that a diverse sample of the target population in the targeted community is reached by combining the completed interviews from the VBS seed sample and the RDS referral sample. For estimation of survey outcomes from the sample, we intend to use post-stratification weights that will be constructed by ratio adjusting the combined VBS/RDS sample to match socio-geographic benchmarks of the study population. Benchmarks for age, country of origin and first generation status will be constructed using [American Community Survey data](#). With the VBS/RDS approach, respondents are recruited at times and in places where they are reasonably expected to gather and then the social networks of respondents are used to increase samples sizes within a target population.^{1,2}

For the VBS component of this approach, up to six venues will be selected within each community. Potential venues will include community centers, social service providers, health clinics, and/or businesses, and will be selected by members from within the community; venue attribute information will be used to select a diverse group of women and capture as many important population subgroups within the community as possible. For the RDS portion of this approach, initial **“seed respondents”** will be recruited from these venues. Seed respondents completing the interview will be asked to help recruit up to three eligible respondents they know. Women recruited by seed respondents are referred to as **“second-stage respondents”**. Second stage and subsequent respondents completing an interview will be asked to recruit up to three eligible respondents.

Among seed respondents, we anticipate that 50% of women who are screened will be eligible to participate; for second-stage respondents we anticipate that 70% will be eligible given that they were pre-identified by a seed respondent. Since we anticipate half of women screened will be seed respondents and half will be second-stage respondents, we anticipate overall that 60% of women who are screened will be eligible to participate. Therefore, to obtain the target sample of 100 women for the pilot study we estimate 167 will need to be screened; to obtain the target

¹ Muhib FB, Lin LS, Stueve A, et al. A venue-based method for sampling hard-to-reach populations. *Public Health Rep.* 2001; 116 (supp 1):216–22.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1913675/pdf/pubhealthrep00206-0218.pdf>

² Burt R.D., Thiede H. (2014). Assessing differences in groups randomized by recruitment chain in a respondent-driven sample of Seattle-area injection drug users .861-867. *Annals of Epidemiology*, 24 (11).

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4252737/pdf/nihms627198.pdf>

sample of 1,100 women for the main study, we estimate we will need to screen 1,833 women for a total of 2,000 women.

2. Procedures for the Collection of Information

For purposes of efficient fielding of protocols we will obtain specific attribute information for each venue, including: type of venue; languages served; approximate number of visits per day; and operating hours and days. We will use the venue attribute information to develop the sampling protocols for fielding the survey, ensuring efficient use of interviewer time while optimizing the number of completed interviews for each venue/day/day-part selected for recruiting survey respondents.

The pilot will be used to evaluate the feasibility of recruiting approximately 100 respondents, employing the following steps:

- a. NORC statisticians will determine an appropriate time-interval to approach potential respondents based on the number of visits per day at the selected venue.
- b. Field staff will approach individuals visiting a selected venue at the pre-determined time intervals and go through the informed consent process with the potential respondent, answer any questions for the potential respondent, and ask the potential respondent to verbally consent to participate in the study (**Attachments F1-F5**).
- c. Field staff will then ask respondents screening questions using the WHNS eligibility screener (**Attachment G1-G5**).
- d. For eligible respondents, the field staff administers the WHNS questionnaire (**Attachment H1-H5**) with the respondent in a private space at the selected venue.
- e. Seed respondents completing the interview will be asked to recruit second-stage respondents in their social network by giving them a study invitation card (**Attachment I**). Each seed respondent will be able to hand out up to three invitation cards. Each color-coded study invitation card will contain a unique codename that links the seed respondent to the recruited second-stage respondents. Second-stage respondents will bring the study invitation card they received to the study center, complete the eligibility screener, discuss informed consent, complete the interview, and be given their own set of study invitation cards to distribute to eligible respondents they know within their own social networks. This process will continue until the target number of interviews has been reached.

3. Methods to Maximize Response Rates and Deal with Nonresponse

Main challenges to the success of the project include willingness to engage with the study interviewers, willingness to share personal health information, and the cultural context of immigrant populations and their needs for health care services. The proposed solutions are to: a) implement the VBS/RDS approach for recruiting hard-to-reach respondents, including compensation for costs incurred; b) ensure confidentiality for all respondents, as described on the consent forms and protected through a Certificate of Confidentiality; c) carefully avoiding the collection of any personally identifying information; d) provide access to a toll free hotline for respondents to obtain answers to any questions; and e) utilize accurate, unbiased language throughout the questionnaire to avoid insinuating a value judgment for any behaviors.

For each of these solutions for maximizing cooperation and achieving desired outcomes, the following procedures will be used:

A) Implement the VBS/RDS approach for recruiting hard-to-reach respondents,^{3,4} including compensation for costs incurred. In an effort to ensure that both WHNS seed and second-stage respondents are in no way financially burdened, we plan to offer a \$20 reimbursement for all participants who completed their interview. This will be used to cover costs for travel to the location of the interview and for child care expenses during this time. Additionally, to cover the costs of cell phone calls and/or transportation incurred while contacting potential second-stage recruits, seed respondents will be offered an additional \$5 reimbursement per eligible second-stage respondent identified, for a potential total of \$15. Hence, a respondent may be able to receive up to \$35 in reimbursed out-of-pocket expenses: \$20 to cover the costs of her own participation and \$5 for each of the three additional second-stage respondent she is able to recruit. This approach of using VBS/RDS in combination with compensation for study related costs has been used successfully for NORC's Chicago African American Network Health Study (CAANHS) UConnect Study to obtain sufficient samples of men who have sex with men on sensitive topics related to HIV and the effect of social network dynamics.^{5,6,7}

If recruitment is slow and or low, we will submit to OMB a non-substantive change request to conduct an experiment to increase the offer of reimbursement to \$55. Data will be collected pre and post implementation to document impacts on participation rates and inform future studies with hard to reach populations. A subject matter expert (Crista Johnson-Agbakwu, MD) who is advising this project has ongoing research with a similar population and content area in Phoenix,

³ Muhib FB, Lin LS, Stueve A, et al. A venue-based method for sampling hard-to-reach populations. *Public Health Rep.* 2001; 116 (supp 1):216–22. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1913675/pdf/pubhealthrep00206-0218.pdf>

⁴ Burt R.D., Thiede H. (2014). Assessing differences in groups randomized by recruitment chain in a respondent-driven sample of Seattle-area injection drug users .861-867. *Annals of Epidemiology*, 24 (11). <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4252737/pdf/nihms627198.pdf>.

⁵ Young, LE, Jonas, AB, Michaels, S, Jackson, JD, Pierce, ML, Schneider, JA. Social-structural properties and HIV prevention among young men who have sex with men in the ballroom house and independent gay family communities. *Social Science and Medicine*. 2017 Feb; 174: 26-34. <http://www.sciencedirect.com/science/article/pii/S0277953616306797>

⁶ Khanna, AS, Michaels, S, Skaathun, B, Morgan, E, Green, K, Young, L, Schneider, JA, UConnect Study Team. Preexposure Prophylaxis Awareness and Use in a Population-Based Sample of Young Black Men Who Have Sex With Men. *JAMA Internal Medicine*. 2016 Jan; 176(1): 136-8. <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2470591>

⁷ Young, LE, Michaels, S, Jonas, A, Khanna, AS, Skaathun, B, Morgan, E, Schneider, JA. Sex behaviors as social cues motivating social venue patronage among young black men who have sex with men. *AIDS and Behavior*. 2017 Jan 17. doi:10.1007/s10461-017-1679-8. <https://www.ncbi.nlm.nih.gov/pubmed/28097618>

Arizona. She has found that her project had to increase reimbursement for both seed and second-stage respondents in order to obtain an adequate sample size.

B) Ensure confidentiality for all respondents, as described on the consent forms and protected through a Certificate of Confidentiality: During the process of obtaining verbal informed consent, it will be explained to each respondent that she can skip any question and can stop the interview at any time. Additionally, a Certificate of Confidentiality will be obtained to ensure the respondents' interview data and information on their participation will be kept confidential and protected at all times; the purpose of the Certificate of Confidentiality will be reviewed during the informed consent process. Reports and manuscripts will only present data that is in aggregate and anonymized, as described in the informed consent process to the participants. NORC has the experienced staff to meticulously safeguard respondents' data during data collection and will implement post-processing procedures to minimize the possibility of deductive disclosure before reports are released. Finally, to ensure confidentiality no direct identifiers will be collected for tracking reimbursement for the initial interview or for tracking second-stage respondents.

C) Ensure that no personally identifying information is collected by: using survey ID numbers to survey; using codenames for recruitment; collecting only categorical age and date information; and by obtaining verbal over written informed consent

D) Utilize a toll-free number and information line: Field Interviewers will provide a toll-free telephone number for the NORC project team. If respondents have questions about the study or need more information the toll-free number can be used to reach the central project team line directly. This information will be reviewed during the consent process.

E) Utilize accurate, unbiased language throughout the questionnaire to avoid insinuating a value judgment for any behaviors: In order to utilize accurate, unbiased language throughout the questionnaire and to avoid insinuating a value judgment for any behaviors, all study materials were developed with the help of the Advisory Panel of subject matter experts (**Attachment B**), and vetted through pre-testing in the community. During the study material development process, the NORC and CDC worked with the Advisory Panel of subject matter experts to build the questionnaire items to align with the specific research objectives. Several items were prioritized to be discussed with women who had experienced FGM/C. Participants went through the study materials to assess the acceptability and length of the questionnaire; informed consent language; and items that were priorities for additional probing to gather respondent's feedback on cultural appropriateness, comprehension, and difficulty of translated. Discussion results were shared with the study team and revisions were made in the questionnaire and informed consent documents to improve the language and ensure transitions and explanations of the modules were clearly communicated without bias or judgement.

4. Test of Procedures or Methods to be Undertaken

During 2015–2016, CDC held a subject matter expert panel meeting and conducted a feasibility assessment, including: a literature review and background document; site visits to a potential study sites in Georgia; and review of potential sampling strategies, study instruments, and study design options. Recommendations from the formative phase were to test the feasibility and effectiveness of the VBS/RDS methodology and to insure cultural competency during the pilot phase.

The pilot phase of this study is intended to:

- Evaluate potential to recruit sufficient sample of women to complete the interview;
- Assess success of seed recruitment venues and second-stage study invitation cards;
- Test study instruments (WHNS Eligibility Screener and Questionnaire) for comprehension and acceptability;
- Test field logistics related to data collection and data entry; and
- Inform development of final study protocol for the main study.

Once the pilot study is complete, we anticipate using the results to construct a final study protocol for the main study. If revisions are needed to the study instruments, we will submit an OMB change request.

Throughout the pilot project planning and implementation, a community-based, participatory research model will be employed in order to ensure successful implementation. Community stakeholders will be engaged to solicit input into the study design, recruitment plans, venue selection, and to identify and recruit female community members who could conduct the interviews. The NORC and CDC study teams, with support from the Advisory Panel, will continue be involved in the development of community networks in selected communities.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

The study design has been developed with the input of the Advisory Panel of subject matter experts (**Attachment B**). The sampling methodology and study size calculations were developed by NORC statisticians in consultation with CDC epidemiologists. Following preparation of the pilot study and main study data files, data analysis will be carried out by staff from CDC and NORC. Comprehensive data analysis plans will be developed while data collection is taking place. Analytic staff will collaborate to define a set of tabulations to be performed.

Individuals, in addition to those on the Advisory Panel of subject matter experts, who were consulted included:

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