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 A

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LIST OF ATTACHMENTS

- **Goal of the study:** 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.

- **Intended use of the resulting data:** 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.

- **Methods:** The Women's Health Needs Study (WHNS) will use a combined venue-based and respondent-driven sampling method that has proven effective among hard-to-reach populations. Using this method, participant recruitment will begin with initial seed respondents who will be asked to help recruit additional eligible participants. Eligible respondents who consent to participate will complete a one-time, face-to-face interview using a standardized questionnaire.

- **The subpopulation to be studied**: The 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.

- **How data will be analyzed:** Descriptive and multivariate analyses will be performed using SAS or STATA statistical software.

1. Circumstances Making the Collection of Information Necessary

This is a request for OMB approval of the new information collection, "Women's Health Needs Study (WHNS): The Health of US-Resident Women from Countries with Prevalent Female Genital Mutilation/Cutting (FGM/C)." Approval is requested for three years. This study supports CDC's mission as authorized in Section 301 of the Public Health Service Act [42 U.S.C. 241] (**Attachment A**).This work supports CDC strategic priority to strengthen public health and healthcare collaboration, and DRH's mission to improve maternal health through research, public health monitoring, and partnerships.

The United Nations (UN) estimates that more than 200 million girls and women alive today have undergone FGM/C in the countries where the practice is concentrated, and that 3 million girls are at risk of undergoing FGM/C every year.[1] The majority of girls are cut before they turn 15 years old.[2] While the practice of FGM/C is most generally concentrated in Asia, Africa and the Middle East, the greatest prevalence has been reported in Djibouti, Egypt, Eritrea, Guinea, Indonesia, Mali, Sierra Leone, Somalia, and Sudan.

In the past several decades, the number of immigrants and refugees to the United States from high-prevalence FGM/C countries has grown markedly, increasing the number of women and girls in the United States who have experienced or are at risk of experiencing FGM/C. A 2016 study estimates that as many as 513,000 women and girls in the United States could be at risk of experiencing FGM/C.[3] However, this estimate was derived using indirect techniques that do not account for the differing characteristics of women in the country of origin versus those who have migrated to the United States, or any other factors that are likely to affect the prevalence of FGM/C. The report highlighted the need to obtain direct information from potentially affected women by implementing a study of FGM/C in the United States. Moreover, related issues – such as how attitudes about FGM/C change with assimilation and the potential barriers to receiving adequate and appropriate health services in the United States for affected women – are poorly understood.

The US Department of Health and Human Services, Office on Women's Health and CDC Division of Reproductive Health (DRH) are working together to implement a study on the characteristics, health experiences and needs related to FGM/C among US-resident women. Previously, CDC has: participated in a sub-Interagency Policy Coordination Committee on FGM/C (ongoing since 2014); hosted a subject matter expert panel meeting in Atlanta in June 2015; and conducted a feasibility assessment, including conduct of a literature review and creation of background documents, site visits to a potential study community, and review of potential sampling strategies, study instruments, and study design options.

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1 United Nations Children's Fund, Female Genital Mutilation/Cutting: A global concern, UNICEF, New York, 2016. https://www.unicef.org/media/files/FGMC_2016_brochure_final_UNICEF_SPREAD.pdf.

2 United Nations Children's Fund, Female Genital Mutilation/Cutting: A statistical overview and exploration of the dynamics of change, UNICEF, New York, 2013. https://www.unicef.org/media/files/UNICEF_FGM_report_July_2013_Hi_res.pdf.

3 Goldberg, H., Stupp, P., Okoroh, E., Besera, G., Goodman, D., & Danel, I. (2016). Female genital mutilation/cutting in the United States: Updated estimates of women and girls at risk, 2012. Public Health Reports, 131(2), 340-347. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4765983/pdf/phr131000340.pdf.

Female Genital Mutilation/Cutting (FGM/C) can have severe, deleterious health consequences for women and girls who experience it. Furthermore, the health characteristics and needs of women living in the United States who have experienced FGM/C or are at risk for FGM/C remain understudied.

2. Purpose and Use of Information Collection

The objectives of this study are to collect scientifically valid, current information on women who have undergone FGM/C in selected communities in the United States with high concentrations of residents from countries where FGM/C is prevalent; the extent to which FGM/C affects women in these communities; women's attitudes about continuance of the practice; and their health experiences. Findings on women's reproductive health needs, experiences and attitudes related to FGM/C can be used to inform and plan programs, services, and prevention efforts. This information may be used to inform public health strategies for meeting these needs and to inform efforts to prevent continuation of FGM/C on women who may be at risk. Reports will be shared with stakeholders as well as communities from which the data is collected. 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. Descriptive and multivariate analyses will be performed using SAS or STATA statistical software to produce reports.

Previous estimates of FGM/C in the United States have relied on indirect techniques, depending on assumptions that do not take into account differing characteristics among those in the country of origin versus those who have migrated to the United States, or other factors that are likely to affect FGM/C prevalence. The lack of direct information from potentially affected women in the United States has been cited as a research gap.[4] Moreover, related issues such as how attitudes about FGM/C change with assimilation and potential barriers to receiving adequate and appropriate health services for affected women in the United States are poorly understood.

The practical utility of the data collected is that it will provide some of the first systematic information on the reproductive health experiences and needs related to FGM/C among women who live in selected communities in the United States with high concentrations of residents from countries where FGM/C is prevalent. The benefits of collecting this data include the ability to understand the public health needs of women and communities in the United States affected by FGM/C. Without this data, stakeholders will be limited by the lack of current systematic data on the reproductive health needs of these women and communities impacted by FGM/C.

The sampling is designed to provide community-level estimates (census tract, metropolitan area, and/or county level) of multiple communities in the United States where potentially affected populations are concentrated, allowing for data to inform decisions at the local level and identify traits of women at risk for FGM/C across the six communities included. The specific purposes and uses of the information collected through the questionnaire are outlined in Exhibit A2.1.

[4] Mather M, Feldman-Jacobs C. Women and girls at risk of female genital mutilation/cutting in the United States. Population Reference Bureau. 2016. Accessed 6/29/2016. Available at: http://www.prb.org/Publications/Articles/2015/us-fgmc.aspx.

These instruments have been designed to collect the minimum amount of information necessary to meet the study's objectives on FGM/C and related topics, while avoiding collection of personal identifiers from any respondent. Categorical response options have been used as necessarily so that it is not possible to indirectly identifying participants.

To meet the study objectives, The National Opinion Research Center at the University of Chicago (NORC) and CDC will work with selected participating communities to design, pilot, and conduct a study on the health and healthcare needs of US-resident women aged 18 to 49 who were born, or whose mother was born, in a country where FGM/C is prevalent. Initially, a pilot study will be conducted in one community to assess the feasibility of using both venue-based and respondent-driven sampling (VBS/RDS) approaches to recruit eligible respondents. WHNS will use a combined venue-based and respondent-driven sampling method that has proven effective among hard-to-reach populations. Potential participants will be consented **(Attachment F1-F5)** and eligibility for participation will be determined by screening **(Attachment G1-G5)**. Eligible participants will complete a one-time, face-to-face interview using a standardized questionnaire **(AttachmentH1-H5)**. Seed respondents completing the interview will be asked to recruit second-stage respondents in the 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 code name that links the recruited second-stage respondent to the seed respondent, Second-stage respondents will be recruited until the target number of interviews has been reached.

Based on findings from the pilot study, we will refine the study protocol and survey instrument. Once the pilot study is complete, we anticipate amending and updating the human subject's protocol and data collection instruments to include the additional translations and other study modifications. Altogether, the pilot and main study will survey approximately 1,200 eligible women who reside in up to six community sites across the United States, and includes translations of study materials into languages appropriate for each community.

We plan to use the pilot study to inform us on several matters for the main study. There are several possible areas of expansion or modification we expect may be submitted to the OMB in order to determine if a revision or a non-substantive change request is required based on results of the pilot study, funding opportunities and other ongoing activities in this research field. These include: additional questionnaire topics and questions related to the health characteristics, experiences, and needs of women living in the US who have experienced or may be at risk for FGM/C; an increase in sample size and possible addition of study sites; additional languages that will require translation; and potential increase in the burden hours and total cost to the government.

Exhibit A2.1: Items of Information to be Collected

Module	Description
Background Characteristics Module	Demographic data, using categorical responses, will be used to describe the diversity of the WHNS participant population and to compare women based on factors such as age, time in the United States, country of birth, and other demographic factors.

Module	Description
Marital and Household Module	Marital and household questions will be used to learn more about participant's marital status and family structure, and the family composition for those who have experienced or might be at risk for FGM/C.
Effects on Migration Module	Questions about migration will be used to further understand the location of participant's networks she relies on for social support and current employment status.
Health-Seeking Behavior and Provider Experience Modules	Questions about participants' overall health, health care utilization, health insurance, and barriers to accessing health care are central to the study goal of describing the reproductive health of the study population, and identifying the healthcare needs and barriers to obtaining that care.
Health and Family Planning Modules	Questions in this module focus on sexual history and contraceptive use, access to obstetric and gynecologic care, and cervical cancer screening. Questions also focus on influences on medical decision making, pregnancy outcomes and prenatal care. This module will help to evaluate the family planning and obstetric and gynecologic needs of the study population, and identify barriers to obtaining that care.
FGC Module	FGM/C is one of the key outcomes of the study. The FGM/C questions will determine whether participants have experienced FGM/C and, if so, the type of FGM/C. Questions will also ask about health problems known to be associated with FGM/C. The FGM/C module questions will be used to determine the prevalence of FGM/C and investigate the relationship between FGM/C and health issues.
FGC Beliefs Module	Questions on beliefs about FGM/C are included in WHNS to assess possible strategies for prevention efforts. The questions capture information on the participant's and her husband's attitudes concerning whether to continue the practice.
Education Module	Education questions will be used to gain a deeper understanding of participant's level of education, whether the education was received in the United States, and how this is associated with the practice of FGM/C.

3. Use of Improved Information Technology and Burden Reduction

The pilot questionnaire will be administered using a paper and pencil instrument interview (PAPI) format to determine if this is the preferred mode for the interviewers and respondents. The PAPI format in the pilot will allow for interviewers to highlight and quickly identify problematic or confusing questionnaire items. Respondents will be debriefed at the end of the interview to ask about the PAPI format and whether completing the questionnaire electronically would be preferred. The results of the pilot will inform the mode for the larger implementation phase in each community. In consultation with the project's Advisory Panel of subject matter

experts (**Attachment B**) and CDC, the project staff will work with each community and interviewers to determine if use of PAPI questionnaire format would be preferable to an electronic questionnaire format.

4. Efforts to Identify Duplication and Use of Similar Information

CDC is not aware of any other systematic collection in the United States of the information described herein. The information to be collected through this ICR will provide some of the first systematically collected information on the health experiences and needs of women who live in selected communities in the United States with high concentrations of residents from countries where FGM/C is prevalent.

Various federal and local agencies are working to strengthen efforts to prevent FGM/C through community-based education and health care provider outreach. CDC is developing this study with support and collaboration from the Department of Health and Human Services Office of Women's Health (OWH). In a separate but related programmatic effort, the OWH has funded an FOA titled "Female Genital Cutting (FGC) Community-Centered Health Care and Prevention Projects". Eight community awardees were selected with a performance period of three years (2016–2019) with the stated goals of: 1) addressing the gaps or problems in the FGC-related health care services for women living in the United States who have experienced FGC; and 2) addressing prevention of FGC of girls living in the United States who are at risk of undergoing the procedure in the United States or, for being sent to undergo the procedure abroad. Awardees are carrying out a range of community-based activities that include health promotion, health education for women and health care providers, and increasing cultural competence in the care of women who have experienced FGM/C. Although several awardees have collected community-level data on FGM/C, these have been tailored to inform specific, local programmatic interventions. The information collected through this ICR will fill a critical gap, not presently addressed by federal partners. Therefore, this ICR is non-duplicative and compliments ongoing federal efforts to understand FGM/C and its consequences in the United States.

5. Impact on Small Businesses or Other Small Entities

This data collection effort will not involve any small businesses.

6. Consequences of Collecting the Information Less Frequently

The proposed project involves a one-time data collection.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. Comments in Response to the FRN

A 60-day Notice was published in the Federal Register on March 20, 2018, vol. 83, No. 54, pp. 12194-12195 with the title "Women's Health Needs Study: The Health of U.S.-Resident Women from Countries with Prevalent Female Genital Mutilation/Cutting (FGM/C)" (**Attachment C1**). CDC received three comments related to this notice **(Attachment C2)**. CDC did not provide a response to one comment because it fell outside the scope of this information collection. Two other comments were sent by organizations outside of the CDC, both of which were supportive (**Attachment C2**). These two organizations commented on the importance of establishing measures to protect privacy and confidentiality, which CDC has addressed in response, along with additional comments related to utility, accuracy, quality, burden and additional areas of concern related to this information collection request (**Attachment C2**).

B. Efforts to Consult Outside the Agency

Experience working within target communities is invaluable for developing a more robust understanding of the perceptions and attitudes regarding FGM/C and other health topics relevant to specific groups of women. NORC has worked closely with CDC and CDC's subject matter experts to develop the study materials and community engagement for the pilot phase.

Additionally, the assembly of a diverse representation of researchers and clinicians familiar with FGM/C is critical to the emerging research of FGM/C in the United States. In designing this study and questionnaire, the project team consulted extensively with an Advisory Panel composed of experienced researchers familiar with the issues of FGM/C and increased risk factors for women and girls within communities of immigrants from countries where FGM/C is prevalent. See **Attachment B** for a list of Advisory Panel members of subject matter experts, and the type of input they have provided**.**

Throughout the planning and implementation of this study, a community-based, participatory approach has been employed to ensure cultural sensitivity and successful implementation. In each selected community, stakeholders have been engaged to solicit input into the 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 of Subject Matter Experts (**Attachment B**), will continue be involved in the development of community networks in selected communities.

For the pilot study: 1) meetings have been held with local community leaders to discuss the most culturally appropriate outreach strategies - these meetings will continue throughout the study to provide feedback; 2) local community members reviewed the study materials to assess and provide feedback on the comprehensibility and cultural appropriateness of the materials; and 3) the Advisory Panel of subject matter experts (**Attachment B**) reviewed the study materials to assess and provide feedback on the study design, approach, and study materials - the Advisory Panel will continue to provide feedback throughout the study.

9. Explanation of any Payment or Gift to Respondents

Women who reside in communities with large concentrations of the populations of interest for this study are particularly challenging to reach due to cultural and linguistic barriers, economic disadvantage, and acculturation. Given these challenges, we will employee a unique Venue-Based and Respondent Drive Sampling (VBS/RDS) approach, requiring compensation to respondents at various stages to cover out-of-pocket expenses for travel, childcare and cellphone charges. In general, providing such cost reimbursements has been found to be important for encouraging participation in surveys and will help to reduce the burden that may disproportionately discourage disadvantaged women from participating in this study.[5,6,7]

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. With the VSB/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.[8, 9] This sampling approach in combination with compensation for study related participation 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.[10,11, 12]

For the currently proposed information collection, VBS will be used by selecting up to six "venues" from organizations that likely serve the target study population. Venues will be selected based on knowledge of community members. Potential venues include community centers, social service providers, health clinics, businesses, and other locations frequented by potential participants. RDS will then be used to increase the number of women recruited from each venue: initial **"seed respondents"** recruited from the selected venues will be asked to help recruit up to three eligible respondents they know. Seed respondents will be given three study

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5 Singer E, Kulka RA. (2002). paying respondents for survey participation. in studies of welfare populations: data collection and research issues.105-28. Washington DC: National Academy Press. https://aspe.hhs.gov/system/files/pdf/174381/04.pdf

6 Singer E, Ye C. (2013) The use and effects of incentives in surveys. Annals of the American Association of Political and Social Science, 645:112-141. http://journals.sagepub.com/doi/pdf/10.1177/0002716212458082

7 Berry SH, Pevar J, Zander-Cotugno M. Use of incentives in surveys supported by Federal grants. Rand Corporation, March 2008. http://www.copafs.org/seminars/use_of_incentives_in_surveys.aspx

8 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

9 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.

10 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

11 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

12 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

invitation cards when their interview is complete to carry out recruitment of other eligible women. 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.

In an effort to ensure that both seed and second-stage respondents are in no way financially burdened, we plan to offer a $20 reimbursement for all participates who initiated their interview. This will be used to cover travel to the location of the interview and for childcare expenses during this time. Additionally, to cover the costs 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. Thus 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.

The offer of reimbursement for expenses for recruiting second-stage respondents has proven to be an effective tool for motivating seed respondents to identify and select potential future respondents from within their social networks and communities. This successful approach was used for the CAANHS study implemented by NORC. The additional reimbursements will be tracked with the code name of the initial seed respondent on the study invitation card that the referred women received.

If recruitment is slow and or low, we will submit a change request conduct an experiment to increase the offer of reimbursement to $55, to include up to $34 for women who initiate the survey, and $7 for each second stage respondent recruited. 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, 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.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

CDC's Information Systems Security Officer reviewed this submission, and determined that the Privacy Act does not apply (**Attachment D**). However, while the Privacy Act does not apply, given the sensitivity of the information collected, all appropriate security controls and rules of behavior will be incorporated to protect the confidentiality of information obtained. All individuals involved in any data collection activity will be trained concerning procedures and practices to ensure privacy of data and physical and technical controls will be implemented to secure the data collected.

No contact information or any form of personally identifying information (PII) will be collected for this study. Institutional Review Board (IRB) approval was granted for waiver of written

documentation of informed consent **(Attachment E).** Each participant will be assigned a survey ID number; only the survey ID number and no direct identifiers (e.g., respondent telephone numbers, addresses, and names) will appear on the study forms (screener or questionnaire). In addition, procedures have been developed so that seed respondents can easily contact study staff to determine if any of the women they referred subsequently enrolled as second-stage respondents without the need to collect any contact or other personally identifying information. For this purpose, seed respondents who agree to refer second-stage respondents will be assigned a unique codename in addition to their survey ID. Seed respondents will be given a color-coded study invitation card **(Attachment I)** with this codename to be handed to up to three eligible respondents they know. The second-stage respondents will bring the study invitation card they received to the study center, be consented for enrollment **(Attachments F1-F5)**, have eligibility determined (**Attachments G1-G5**), complete the questionnaire **(Attachments H1-H5),** and will then be given their own set of study invitation cards with unique codenames to distribute to eligible respondents they know within their own social networks. Seed respondents will also be given a matching color-coded study contact card **(Attachment J)**, along with the study schedule for when they can contact study staff and/or come in person for any study related questions or to check on and pick up their additional reimbursements. If a seed respondent forgets her own codename, then she will be matched to any second-stage respondents she referred based on the interview date and color-coding of the invitation and study contact cards.

Unique codenames for recruiting second-stage respondents will be recorded and kept in a secure reimbursement tracker, which will be completely separate from the survey management system that includes the survey ID. Unique codenames maintained by NORC will be retained in the reimbursement tracker only to track additional reimbursements a respondent may receive for second-stage respondent referrals, and will be saved only until the implementation period ends in a given community.

The WHNS interviewer will be responsible for completing all study related trackers and securing them in a locked location after each interview. Study materials will be kept locked when study staff are not present. The reimbursement trackers with the linking codename information will also be stored in a locked cabinet securely and separately from the interview data. All PAPI forms (including hard copies of the screener and questionnaires) will be transferred securely back to NORC's Central Office for data entry, editing and cleaning in preparation for data analysis and delivery.

Because the combination of specific pieces of information (e.g., study community, age of participant, age of relocation to the United States) could make it possible to extrapolate the identity of an individual, all questions on age and timing of events have been written with categorical response options. In addition, CDC will only include aggregate and summary information in reports: any information that could be used to indirectly identify an individual will be suppressed or subcategories will be further aggregated. Post-processing procedures will be implemented by NORC to minimize the possibility of deductive disclosure in preparation of delivering the dataset to CDC.

In all cases, interviews will be conducted by female WHNS interviewers who have been recruited from within the community. These interviewers will work under the direction of field managers and project staff. They will receive extensive training on human subjects protections and the survey content so that they are able to explain and clarify the intent of each question. Prior to the survey interview, the female WHNS interviews will read each respondent an informed consent document (**Attachments F1-F5)**, which will be translated and back translated to insure comprehensibility. Additionally, a checklist at the end of the informed consent document will be used to document participants' comprehension. The WHNS interviewer will document that verbal consent was given and will make a copy of the informed consent available to the respondent upon request. All participants, including those that decline a copy of the informed consent will be provided with a study contact card (**Attachments J)** with a phone number for local project personnel and the IRB will be offered (this contact card also serves as a link to reimbursement for referral of enrolled second-stage respondents). All screening, informed consent, and survey interviews will be conducted in a private location.

Certificates of Confidentiality (Certificates) protect the privacy of research subjects by limiting the disclosure of identifiable, sensitive information. Section 301(d) of the Public Health Service Act (PHS) Act, which authorizes the use of Certificates, was amended by the 21st Century Cures Act. The amended Act states that the Secretary of HHS shall issue Certificates to persons engaged in biomedical, behavioral, clinical, or other research activities in which identifiable, sensitive information is collected. In furtherance of this provision, CDC supported research commenced or ongoing after December 13, 2016, and in which identifiable, sensitive information is collected, is automatically protected by a Certificate.[13] During the informed consent process, respondents will be ensured that their questionnaire data and information on their participation will kept confidential and cannot be shared with anyone outside of the study to the fullest extent allowable by law.

Although the pilot study will be implemented in a state where interviewers are not mandatory reporters for suspected child abuse, in some states, interviewers may be considered mandatory reporters and would be compelled to report women who have had their daughters circumcised for child abuse. Given this, during the informed consent process, interviewers will explain that the study will not ask questions related to circumcision of minor daughters because of the potential legal obligation for interviewers to report this as child abuse. Participants will also be informed that if concerns about child abuse are identified during the interview, clinic standards of care, which include mandatory reporting, will be followed. In states with mandatory reporting requirements, the interviewer will ensure that the respondent understands that if they voluntarily disclose any information subject to mandatory reporting laws, the interview will stop and study staff will determine if this is a reportable event and if so, then the participant's contact information will need to be collected for reporting purposes. We anticipate that this sequence of events would be extremely rare given the extensive training of the interviewers and the careful study design to avoid disclosing information that would be subject to mandatory reporting laws.

[13] https://www.cdc.gov/od/science/integrity/confidentiality/applinst.htm.

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval

The WHNS IRB protocol was reviewed and has been approved by the IRB for the Centers for Disease Control and Prevention (**Attachment E**).

Sensitive Questions

Some topics covered in the data collection activities may be sensitive for some respondents (e.g., contraception, occurrence of pregnancy, and experience with FGM/C). However, these questions are essential to meeting the goals of the information collection. During the informed consent process, respondents will be notified of the types of the questions that will be asked and also notified that they may decline to discuss and skip any of the topics or decline to answer any question without penalty. Additionally, the questionnaire will be administered by trained female interviewers recruited and hired from within each community, and will be conducted in a private location. The project team has solicited review and feedback from the Advisory Panel of Subject Matter Experts, community stakeholders, and Implementing Organizations (study sites) on training materials and approaches for interviewers on the sensitive nature of the study topics. Training materials include techniques to handle sensitive questions and potential scenarios that may arise during the study. In-person trainings for study field staff will include discussions led by local experts on FGM/C to sensitize interviewers to the topic. .Interviewer training will include practice scenarios and preparation for possible situations that could arise during the study. The interviewer training manual explains all procedures to be used if a respondent has questions or concerns, or if a respondent chooses not to answer a study question(s). Interviewers will be trained not to give advice, diagnose, or treat any study participant. The WHNS Handling of Adverse Events and Mandatory Reporting job aid was developed to cover serious, unanticipated problems, and protocol deviations that may arise during the study. Community referral information will be made available to help interviewers answer questions about community resources and provide helpful contact information for participants, as needed.

Finally, interviewers will also be provided a toll-free telephone number for the NORC project team and a toll-free telephone number for the NORC IRB hotline that can be used if respondents have any questions about the study or their rights as study participants. At the conclusion of the survey interview, all respondents will be given information about community women's health resources where they can find additional information to answer questions or seek health care-related services.

12. Estimates of Annualized Burden Hours and Costs

Estimated Annualized Burden Hours

This study will be conducted in two phases: a pilot study and the main study. A change request will be submitted to obtain approval for any modifications and/or additional translations needed after the pilot study for the main study. During both the pilot and the main study phase, women who consent **(Attachment F1-F5)** to participate, will first be presented the WHNS Eligibility

Screener (**Attachment G1-G5**), and those who meet inclusion criteria will be administered the WHNS Questionnaire (**Attachment H1-H5**).

The target sample size for the number of women completing the WHNS Questionnaire is 100 for the pilot study and 1,100 for the main study, for a total of 1,200 women. Eligibility/screening criteria included: 1) female between 18 and 49 years of age; 2) born in a country where FGM/C is prevalent, AND/OR her mother was born in a country where FGM/C is prevalent; 3) have previously not participated in WHNS; 4) speak a language for which we have translated study materials; and 5) are able to give informed consent. Among seed respondents, we anticipate that 50% of women who are screened will be eligible to participate. This was based on approximately 35% of women age 18 years of age and older screened for the study would not fall into the 18-49 target age range for the study (source is https://www.migrationpolicy.org/data/state-profiles/state/demographics/GA). We also assumed that 10% of women screened would not qualify based on mother's birth country, and another 5% would not be eligible due to residing outside of the community under study. 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 the 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 we will need to screen 167 women, and to obtain the target 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 screened in total.

Information will be collected over a 3-year period. The pilot study will be conducted during the first 2 months of Year 1 and the main study will be collected during Year 2 and Year 3. Given the 3-year data collection period, the annualized number of women anticipated to complete the WHNS Eligibility Screener will be 667, and the annualized number of women to complete the WHNS questionnaire will be 400. Given the time needed to complete the WHNS Eligibility Screener (inclusive of informed consent process) is 5 minutes, the annualized burden for the screener will be 56 hours. Given the time needed to complete the WHNS Questionnaire is approximately 45 minutes, the annualized burden will be 300 hours. The total annualize burden for this study is thus estimated at **356 hours**.

Exhibit A12.1: Estimated Total Burden Hours

Type of Respondent	Form Name	Total No. of Respondents	Annualized number of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Annualized Burden Hours
Women age 18 to 49 who were born in, or whose mother was born in, an FGM/C	WHNS Eligibility Screener*	2,000	667	1	5/60	56

Type of Respondent	Form Name	Total No. of Respondents	Annualized number of Respondents	No. of Responses Per Respondent	Average Burden Per Response (in Hours)	Total Annualized Burden Hours
practicing country						
Women age 18-49 who were born in, or whose mother was born in, an FGM/C practicing country	WHNS Questionnaire	1,200	400	1	45/60	300
Total						**356**

*Burden hours calculated inclusion of informed consent process

Estimated Cost

The total cost to the respondents is described in Exhibit A12.2. The total estimated annualized cost to respondents is $4,665. This cost represents the total burden hours to respondents multiplied by the minimum hourly wage rate (based on highest minimum wage rates in states where we expect to implement the study, e.g., NYC and DC in 2018 at $15.00).

Exhibit A12.2: Annualized Costs to Respondents

Type of Respondent	Form Name	Annualized Burden Hours	Hourly Wage Rate	Annualized Respondent Costs
Women age 18-49	WHNS Screener	56	$15.00	$990
Women age 18-49	WHNS Questionnaire	300	$15.00	$4,500
Total				**$5,490**

13. Estimates of Other Total Cost Burden to Respondents or Record Keepers

There are no costs to respondents for participating in this survey other than their time.

14. Annualized Cost to the Government

The annualized cost to the government for carry out the data collection activities. This estimate includes the cost of recruitment, analysis and reporting, as well as the total cost of reimbursement for participant's travel, childcare, and phone costs.

Exhibit A14.1: Total Annual Cost to the Government

Expense Type	Expense Explanation	Annual Costs (dollars)
Direct Costs to the Federal Government	CDC, COR (GS-13, 0.15 FTE)	$19,530
	CDC, Contracting Officer (GS-12, 0.05 FTE)	$5,985
	CDC, Medical Epidemiologist (GS-15, 0.05 FTE)	$12,000
	CDC, Medical Epidemiologist (O-5, 0.10 FTE)	$20,000
	CDC, Epidemiologist (GS-14, 0.15 FTE)	$26,550
	Subtotal, Direct Costs	**$84,065**
Cooperative Agreement or Contract Costs	Contract Cost for specific task: NORC @ the University of Chicago	$151, 491.63
	Contract Cost for specific task: TTi	$ 25,462.57
	Subtotal, Cooperative Agreement or Contract Costs	**$176,95.20**
	TOTAL COST TO THE GOVERNMENT	**$261,019.20**

15. Explanation for Program Changes or Adjustments

This is a new data information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

No personally identifying information (PII) will be collected at any point during the study. The dataset will not be made available publically and will not be available to researchers upon request. The final report and only anonymized and aggregate tabulated data will be reported to the public.

Post-processing procedures will be implemented to minimize the possibility of deductive disclosure in preparation of delivering the dataset to CDC as well as in the preparation of the final report and aggregate tables. . NORC has a structure in place to oversee the development and dissemination of all data use standards and policies. NORC's Data Governance Board (DGB) designs, implements, and enforces all policies around all types of data exchange agreements (i.e., data use agreements (DUAs), business associate agreements (BAAs), and other data use licenses (DULs)). A subcommittee of the DGB is responsible for reviewing all agreements that govern data use, both when NORC acquires or shares restricted data with other organizations. This review safeguards data transmission and storage, ensuring that all appropriate data security and protection requirements are clearly defined.

NORC will provide CDC summary findings from the pilot study and discuss them at regularly scheduled weekly meetings. Tabulation will include descriptive characteristics of study respondents as reported in the WHNS interview (e.g., demographics, age, and country of origin) as well as productivity of the VBS/RDS methodology. Findings from the full launch of the implementation phase will be also provided via e-mail and discussed at regularly scheduled weekly meetings.

A three-year OMB clearance is requested to cover all data collection activities. Table A16.1 below outlines the project time schedule for data collection. Recruitment for the pilot data collection will be initiated 1-2 months following OMB approval. Pilot data analysis and a preliminary report will be completed 6 months after OMB approval. The recruitment and implementation for the main phase of data collection will begin 3-15 months following OMB approval. The final analysis and report will be submitted 12-36 months following OMB approval.

Schedule

Activity	Time Schedule
Recruitment and Pilot data collection (n=100)	1-2 month after OMB approval
Survey updated and translated based on pilot data collection, change request submitted to OMB	3-12 months after OMB approval
Pilot data analysis finalized and report submitted	6 months after OMB approval
Recruitment and Implementation data collection for Main study (n=1,100)	13-36 months after OMB approval
Implementation data analysis and final report submitted	37-48 months after OMB approval

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

18. Exemptions to Certifications for Paperwork Reduction Act Submissions

There are no exemptions to the certification.