Document Coversheet

Study Title: PROMIS WOMAN Education Program : ImProving ceRvical Cancer preventiOn Methods Among Muslim AmerIcans WOMEN

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VCU Office of the Vice President for Research and Innovation

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ID: HM20024502 **HM20024502** View: SF - Study Identification

HM20024502 - Vanessa Lavene Sheppard
PROMIS WOMAN Education Program : ImProving ceRvical cancer preventiOn methods among Muslim AmerIcans WOMEN

Study Identification

1. * **Select the Principal Investigator:**
   Vanessa Lavene Sheppard

2. * **Study Title:**
   PROMIS WOMAN Education Program : ImProving ceRvical cancer preventiOn methods among Muslim AmerIcans WOMEN

3. * **Is this a student or trainee project in which activities will be carried out by that individual under your supervision (for example, dissertation or degree-required projects):**

   ● **Yes**

   ○ No

   If this project involves more than one student / trainee investigator, identify the primary contact here and list all student / trainee investigators in the Personnel section. Also ensure all are listed as protocol editors if they need to be copied on IRB correspondence and have authority to make edits.

4. * **Student/Trainee Investigator:**
   Asmaa Namoos

5. * **Please select the primary department or center that this study is being conducted under:**
   Massey Cancer Center

6. **Select the VCU IRB numbers assigned to studies that are:**
   1. **Associated with this study**
   2. **Research registries this study will utilize**
   3. **Previously submitted versions of this study (closed, withdrawn, auto-withdrawn studies)**

ID	Title	PI
HM20021579	Participation of Muslim Women in Cervical Cancer Screening and HPV Vaccination	Tamas Gal

7. Select all individuals who are permitted to edit the IRB protocol and should be copied on communications (study staff will be entered later). These individuals will be referred to as protocol editors:

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8. * Select one of the following that applies to the project (selection will branch to new pages):
Note: VCU IRB offers guidance for many types of studies, including secondary data analysis studies, internet research, registries, EFIC, HUD, and Emergency Use protocols.
See *https://research.vcu.edu/human_research/guidance.htm*

- (●) **Research Project or Clinical Investigation [*most exempt, expedited, and full board research studies]**
- ( ) Exception from Informed Consent (EFIC) for Planned Emergency Research
- ( ) Humanitarian Use of Device for Treatment or Diagnosis
- ( ) Humanitarian Use of Device for Clinical Investigation
- ( ) Emergency Use of Investigational Drug, Biologic or Device
- ( ) Treatment Use (Expanded Access to Investigational Product for Treatment Use)
- ( ) Center or Institute Administrative Grant Review
- ( ) Request for Not Human Subject Research Determination (i.e. request a letter confirming that IRB review is not required)

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Federal Regulations

1. * Is this a FDA regulated study?

FDA regulated research includes all clinical investigations involving a test article and a human subject(s) that has been submitted for approval to the FDA or may be submitted in the future.
Check Yes if
- **the study involves an IND/IDE, abbreviated IDE, IND/IDE exemption, HUD, expanded access, or is otherwise subject to 21 CFR 56,**
- **the study involves a test article being administered or dispensed to subjects NOT according to a clinicians' medical judgment but rather, per the study protocol, OR**
- **the study does not involve a test article but intends to provide safety or efficacy data to the FDA.**

○ Yes

● **No**

2. * Is this study supported by the Department of Defense (DoD):

○ Yes

● **No**

3. * Check if any of the following funding sources apply to this research (including Direct and/or Indirect funding):

☐ Department of Education

☐ Department of Justice

☐ Environmental Protection Agency

☑ **None of the above**

ID: HM20024502 **HM20024502** View: SF2 - IRB Panel Setup

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IRB Panel Setup

1. * To which IRB is this study being submitted for review?

- (●) **VCU IRB**
- ( ) WCG IRB
- ( ) NCI Central IRB
- ( ) Advarra IRB
- ( ) Other IRB

2. * Is this study transitioning to review by another IRB?

- ( ) Yes - transitioning from VCU IRB to an external IRB (WCG, CIRB, Other)
- ( ) Yes - transitioning from an external IRB (WCG, CIRB, Other) to VCU IRB
- (●) **No or not applicable**

ID: HM20024502 **HM20024502** View: SF2 - Review Setup

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Review Setup

1. * **Select which study type best describes the majority of the study. Your response will help determine which IRB panel should review this.**
   - ○ Bio-Medical Research
   - ● **Social/Behavioral/Education (SBE) Research**

2. * **Which option(s) best describe the way(s) this study's procedures will be conducted? (Select all that apply.) This information may be used by the IRB in triaging studies during an emergency.**
   - ☑ **In-person interactions / interventions with participants**
   - ☑ **Remote interactions / interventions with participants**
   - ☐ Secondary data/specimen analyses with or without contact with study participants

3. * **Would it be possible to convert in-person activities in your study to remote if there is an approved contingency protocol?**
   Yes, could convert to remote activities

4. * **Does this study involve greater than minimal risk:**
   ○ Yes ● **No**

5. * **Review type requested: (subject to IRB approval):**
   - ○ Full Board
   - ● **Expedited**
   - ○ Exempt

6. * **Is this study initiated by a VCU investigator or a sponsor:**

- (●) **VCU Investigator initiated**
- ( ) Sponsor or industry initiated

The IRB has determined that the selected types of anticipated individual and social benefit apply to this study

The below information is read-only to investigators, and the categories are set by the IRB during review. All categories will appear blank until the IRB has made a determination. If a category is not checked, it does not apply to this study. This information may be used by the IRB in triaging studies during an emergency situation.

Scientific benefit

Educational benefit for student/trainee investigators leading their own study

The following information applies to studies being reviewed by the VCU IRB.

The IRB has determined that the selected Exempt and/or Expedited categories apply to this study.

The below information is read-only to investigators, and the categories are set by the IRB during review. All categories will appear blank until the IRB has made a determination. If a category is not checked, it does not apply to this study or the study is being reviewed by an external IRB.

7. For Expedited Studies:

Category 6	Research Data Collection	Involves the collection of data from voice, video, digital, or image recordings made for research purposes.
Category 7	Behavioral	Is research that will be performed on individual or group characteristics or behavior OR will employ a survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

ID: HM20024502 **HM20024502** View: SF2 - Initial Setup Complete

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Initial Setup Complete

Protocol Progress:
● **INITIAL SETUP**
② BACKGROUND, RATIONALE & GOALS
③ RESEARCH PLAN
④ CONSENT PLAN
⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

ID: HM20024502 **HM20024502** View: SF2 - Background, Rationale and Goals

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PROMIS WOMAN Education Program : ImProving ceRvical cancer preventiOn methods among Muslim AmerIcans WOMEN

Background, Rationale and Goals

1. * **Describe the study's background and what is currently known from the scientific literature, including citations, or upload a citation list in document upload. Use lay language whenever possible.**

Significance
International and national data about cervical cancer and HPV infection.
Cervical cancer is one of the most common cancers among females, with over 600 thousand women diagnosed with cervical cancer in 2020 and 340 thousand dying worldwide.1 In the USA, the number of new cervical cancer cases in 2022 was estimated to be 14,100. In Virginia, the American Cancer Society reported 310 new cases.2 Most cervical cancer cases are preventable. According to the World Health Organization, almost all cervical cancer cases are caused by the Human Papillomavirus (HPV), a sexually transmitted virus.3 Cervical cancer has been described as the 'silent killer,' as preinvasive and early invasive cervical cancer is most likely asymptomatic and detected only during screening tests.4 Early detection has been proven to improve patients' survival rate, where the 5-year survival rate of patients with localized lesions has been reported to be 90.9% while that of patients with advanced-stage cervical cancer was only 17.6%.5 The National Cancer Institute's cancer trends progress report has shown that about 81% of women aged 21 to 65 had cervical cancer screening in 2018 in the United States.6 On the other hand, almost half of the women diagnosed with invasive cervical cancer have not undergone cervical cancer screening.7
Scope of the problem in Virginia.
The number of new cervical cancer cases in 2022 was estimated to be 14,100 in the U.S. and 310 in Virginia, with most cervical cancer (90%) caused by HPV infection.2, 8 There are about 200,000 Muslims in Virginia, mostly living in the Richmond and the Northern Virginia area, where Muslim women seek care in the late stages of cervical cancer.9 Our preliminary work showed that Muslim women face socio-structural barriers and health system complexity that prevent them from being integrated into healthcare services.10 Cancer epidemiological data is lacking about this marginalized group, which makes it difficult to conduct cancer prevention disparities research.
Community Profile.
A total of 3.5 million American Muslims live in the United States (U.S.), representing 1% of the total population. Over 50% of American Muslims are foreign-born.11 Racially, American Muslims are very diverse religious groups in the U.S. with no majority race, split as 25% Black, 24% White, 18% Arab, 18% Asian, 7% mixed race, and 5% Hispanic (Figure 1).12 In terms of origin, Middle Eastern Countries represent 41% of the entire Muslim community in the U.S.13 In the last two decades, the population growth trajectory of the American Muslim community has been doubling; the projection was 2.6 million (0.8%) in 2010 and expected to be 6.2 million (1.7%) in 2030.14 Muslim population growth is based on immigration and a high fertility rate, making the Muslim community roughly as numerous as the Jewish community in the United States today. Virginia has the second-largest Muslim population in the U.S. by the percentage of the population, with an estimated 2.7%.12 Much of that population is concentrated in Northern Virginia and in the Richmond Area.15 The population density correlates with the availability of Mosques. There are 18 religious centers (Mosques) in Virginia, 8 of them in the Richmond area.16 The two main sects within Islam are Sunni and Shia. They agree on most of the fundamental beliefs, rules, and practices of Islam.17 Religion plays an important role in most American Muslims' lives and identities. The social structure in Muslim communities is built on a historical cultural and religious framework, which promotes patriarchal structures in families and in the larger Muslim society. Males in the family control decisions of the female family members. Muslim Women must follow the Islam recommendations regarding clothes and customs to maintain moral and social status. Women must cover arms, legs, and hair in the

presence of males who are not in the woman's family.18 The Muslim Culture prohibits alcohol, non-Halal animal products, such as pork, and there are specific rules about the processing of meat products. Therefore, the availability of Halal food stores is important for the Muslim community. According to the Google search engine, there are over 20 Halal food stores and restaurants in the Richmond area.19 Similarly, to other religious communities, religious schools are important for Muslims; Virginia has over 30 religious schools and academic centers.20

The structure and everyday life of Muslim families are controlled by religion and related customs. A study classifies Muslim families into five types.21 These include:

• Conservative Muslims who live by the Sharia (Islam religious laws) recommend all issues in their lives. Usually, they are older generations who do not want to adapt to the changing world or innovation. They are very sensitive to gender interaction in public places such as clinics, schools, and even family events.

• New Age Muslims are more interested in new things and open to other religions. They believe in education equity between males and females. They are typical of the middle class.

• Societal Conformists are more interested in social norms than in religious customs, and they typically belong to a low socioeconomic class.

• Practical Strivers are affiliated with the religion by birth but not very religious. They are driven by success and wealth and are open to different cultures. They are typically more educated and enjoy good socioeconomic status.

• Liberals typically from the millennial age group, are not religious and are interested in traveling and exploring new communities and traditions. Identity and individuality are important to them.

The cultural and religious background influences an individual's behaviors, attitudes, and beliefs toward health. Even though this project focuses on how individual cultural and religious beliefs affect healthcare decisions, we have to mention the objective and perceived barriers the Muslim community faces related to healthcare services, including gender preference of healthcare providers, rejection of pork-based medical products (e.g., gelatin), difficulties making independent decisions, as well as lack of education about diseases. These limitations might be the results of Islamic cultural beliefs and practices. Other limitations may be due to suboptimal healthcare services provided by the U.S. healthcare system due to the lack of cultural competency, such as the unavailability of female providers who understand these cultural challenges. All these obstacles present difficulties to under-served Muslim women.18, 22

As mentioned above, the Muslim community is generally suspicious of outsiders, especially if those outsiders try to force changes on them. Changes in behavior can only originate from inside the community. This is why it's important to implement a Community-Based Participatory Research (CBPR) project to ensure that community leaders and members understand the research and advocate from the inside.

Cervical cancer disparities among Muslim women (Preliminary work).

The American healthcare system provides very little epidemiological data about the Muslim community as the U.S. census data does not include religious affiliation.23 National statistics of cervical cancer incidence and mortality rates among Muslim women are lacking.24 Language barriers, transportation difficulties, and the U.S. healthcare system's complexity are some challenges that Muslim women encounter, leading to disparities in prevention rates.25 Preliminary work: Our prior research within a large academic health system revealed that nearly 65% of Muslim women diagnosed with cervical cancer presented at late stages, which further reinforces the need to focus on promoting cancer prevention to reduce cancer-related morbidity and mortality.9 To address these disparities, we established a cross-sectional mixed-methods pilot study to narrow the gap in the literature and assess the sociocultural factors, religious beliefs, medical knowledge, and attitudes related to HPV vaccination uptake and cervical cancer screening among Muslim women in VA. The study used in-depth interviews and found that most participants had minimal information about HPV infection, vaccination, cervical cancer risk, or screening programs, not to mention how these relate to each other.10 Key barriers for Muslim women in the clinic were the language, the gender of the providers, and the medical staff's lack of understanding of their cultural and religious customs.9 Islam is strict about women's behavior, and its authority interferes with certain medical services, such as gynecological exams.26 Since most Muslim women firmly adhere to their religion, they have difficulties finding suitable Health Care Providers (HCPs) in the U.S. and often do not seek care.10 Prior research has lacked a consistent unifying theoretical approach to framing how multiple factors at different levels contribute to prevention and care reluctance. A better understanding of these factors and their interaction can guide novel, theory-based strategies to improve cervical cancer screening rates.

In the quantitative study, we investigated the factors that affect Muslim women's decision to seek cervical cancer screening and HPV vaccination. To achieve this, a survey was conducted with 100 participants. The survey comprised various validated scales, including demographics, religiosity, modesty measures, perceived religious discrimination,

medical mistrust, health literacy screening, and primary care assessment survey trust. Additionally, the survey included questions on knowledge, attitude, and practice concerning cervical cancer prevention.

The results showed that although most Muslim women were aware of cervical cancer, very few had heard of or used the pap smear test, and the awareness of HPV was generally low. Unmarried, educated women with higher incomes were more likely to be aware of HPV. Furthermore, education level and religiosity score were found to be significantly associated with HPV awareness. Respondents with higher education were more likely to have heard of HPV, while those with higher religiosity were less likely to have heard of it. The manuscript is currently under review. The odds of having heard of HPV were higher for respondents with higher education (OR=6.84; CI=1.42, 33.03) and lower for those with higher religiosity (OR=0.74, CI=0.57, 0.96).

Medical school curriculum and training program.

Muslim Americans are a historically underrepresented and understudied population facing unique health disparities. The Liaison Committee on Medical Education and the ACGME have called for the integration of cultural competency training for medical professionals. However, we found no published resources for teaching medical trainees about the care for Muslim patients. To address disparities in healthcare faced by Muslims, a cross-cultural training session for medical students was implemented by Sarsour et al. in 2021 for caring for Muslim patients.27 This session was developed using a framework adopted by the ACGME. The research team is created an effective cultural competency training session for second-year medical students prior to entering their clinical rotations. The session was one part of a month-long course at the University of Michigan Medical School. The integration of cultural competency training into a medical school's curriculum is essential to produce providers equipped to care for a diverse patient population. This session establishes a teaching model for how to train medical trainees to care for Muslim patients.

Muslim community needs and cultural competency of the health system.

A systematic review found that meeting the healthcare needs of the Muslim community requires a healthcare system that is culturally competent and sensitive to the unique beliefs and practices of Muslim patients. Some of the healthcare needs specific to the Muslim community may include 18:

• Modesty accommodations during medical exams and procedures: Muslim patients may have specific preferences regarding gender-specific care and modesty during medical exams.

• Accommodations for prayer and fasting during hospitalization: During certain times of the year, Muslims may fast from dawn until dusk, which may affect their medical treatment plan. Additionally, Muslims may need to pray multiple times a day, which may require specific accommodations during hospitalization.

• Halal food and medication options: Many Muslims follow dietary restrictions that require them to eat halal meat, which must be slaughtered and prepared according to specific religious guidelines.

To address these needs, the healthcare system should prioritize cultural competency and sensitivity training for healthcare providers. This training should include education on Muslim cultural beliefs, practices, and healthcare needs, and provide opportunities for healthcare providers to learn from and work with Muslim communities. Additionally, healthcare facilities should provide resources and accommodations to meet the specific needs of Muslim patients, such as private spaces for prayer, halal food options, and gender-specific care. Creating an inclusive healthcare environment that respects and accommodates the unique needs of the Muslim community can improve health outcomes and promote health equity for all patients 28, 29.

Muslim women and access of cervical cancer prevention support: No interventional program in VA.

The American Cancer Society recommends that women begin cervical cancer screening at age 21 and continue regular screening every three years until age 65. The screening can be done through a Pap test, which checks for abnormal cells on the cervix, or an HPV test, which checks for the presence of the human papillomavirus that can cause cervical cancer. There are various healthcare providers and clinics across the United States that offer cervical cancer prevention programs, including Planned Parenthood and community health centers. These programs often provide services to women regardless of their ability to pay and may offer language or cultural assistance to women who need it. Hereby, we ask important questions: are these programs fit for all women including the conservative women who are socially isolated such as Muslim women? Unfortunately, the literature review shows no intervention programs specifically tailored for Muslim women in the United States, as the availability of such programs may vary depending on location and other factors. The only support they can get from their healthcare providers and clinics may offer culturally sensitive services that take into account the specific needs of Muslim women, such as providing female healthcare providers or offering prayer accommodations. Muslim women can seek out these services by contacting their local health department or community organizations that serve their community.

The National Breast and Cervical Cancer Early Detection Program (NBCCEDP) was initiated in 1990, serving all U.S. and territories. Even though this program resulted in the screening of more than 600,000 women in the U.S. in the previous 5 years for cervical cancer, this program only targets women based on their eligibility (i.e., age, income, and insurance status) and not cultural or religious considerations.30 To the best of our knowledge, no screening programs or campaigns were explicitly designed to be hospitable for Muslim women in the U.S. on national level.

Although there are no specifically tailored interventions for promoting only cervical cancer screening for the Muslim population, there are some already tested programs that included outcomes related to cervical cancer in this population. An educational program intervention targeted to Muslim women to improve their breast cancer screening rates was built and assessed by Padela et al. in 2018 and demonstrated success in regard to immediate and delayed likelihood of screening.31 Another intervention in the form of a video was tested by Pratt et al. with Somali American Muslim women to investigate its effect on participation in breast and cervical cancer screening and found an improvement of perception of screening benefits and harms, albeit being statistically insignificant.32 A study by Wyatt et al. tested educational brochures with a Muslim population in New York City and found a significant difference in breast and cervical cancer knowledge, mammography, and pap smear screening as a result of providing the educational material.33 A similar base to Padela et al.'s work but in a form of a focus group was tested in Scotland with a small population of Muslim women to promote colorectal, breast, and cervical cancer screening and demonstrated a positive impact regarding knowledge and willingness to utilize screening services.34

In summary, hesitancy in cancer screening may explain, in part, the notable disparities in stage at diagnosis of cervical cancer observed among Muslim women. To date, the few studies aimed at determining factors contributing to the lack of cancer screening participation among Muslim women have not thoroughly investigated the social, behavioral, cultural, and systems-level factors contributing to disparities. Muslim women are characterized by a unique set of characteristics and cultures; thus, it is essential to understand how these factors contribute to the acceptance of the prevention and screening process. The sequential studies proposed herein aim at informing the science of cervical cancer prevention among Muslim women by using a theory-driven framework using a two-arms study design to improve the cervical cancer disparities among Muslim women.

Community-Engaged Research Framework

Trust and mistrust play an important role in the Muslim community's social interactions, which face discrimination in the U.S. every day. This research will only be able to recruit participants if community leaders understand and actively promote it. The Mosques are the centers of social interaction in Muslim communities. This project needs to engage the Imams at Mosques in and around Richmond, VA.

The community-engaged framework will implement a Community Action Model (CAM). The CAM is a five-step process that starts with recruiting and building relationships with community partners and developing and implementing a sustainability plan. The CAM is fit for the community engagement part of our project due to the capability to involve the community members in every aspect of the design, implementation, and evaluation of these community action plans. The CAM was selected to inform the CBPR approach due to the main aspects of the model that help 1) The community members to understand and command the policies, systems, and environment that affect their lives intending to advance health equity, and 2) Build the capacity of communities to create sustainable changes to improve the cancer-related health and well-being of their communities. Our project has a 12-month planning period that focuses on building community capacity, developing community partnerships, and establishing community volunteers' networks, whose purpose will be to design community-driven strategies to eliminate cervical cancer disparities in the Muslim community in the Richmond area.

The first step of the CAM is recruiting and training community leaders inside Mosques, building the relationships between the research team and Imams of Mosques, and providing all information they need to understand cervical cancer, screening for it, and HPV vaccination. The second step is community diagnosis; the research team will support community leaders in developing the research plan to outline their research questions and methodology to understand cervical cancer's local implications. The third step is the analysis and presenting findings; the research team must deliver their results back to community members. The fourth step is an action plan; the research team develops and implements a pilot or demonstration project that shows the chosen action/activity's feasibility and effectiveness. The fifth step is to build the capacity to maintain and enforce the action project teams by developing and implementing a sustainability plan.

Community-Engaged Infrastructure

The study will be based in Virginia, home to a diverse population of over 250,000 Muslims, most living in Northern and

Central Virginia. The population density correlates with the availability of Mosques, ethnic food stores and restaurants, and Muslim schools. The project will work toward building a strong community partnership between the Virginia Commonwealth University and the Islamic Center of Virginia (ICR) by establishing Community Advisory Boards (CABs) and engaging Community Peer Researchers (Figure 2).

CABs commonly formalize the academic–community partnerships that guide CBPR by providing a mechanism for community members to influence research activities. The CABs will include religious leaders from the ICR, which is suggested by previous studies. We will target scholars with expertise in behavioral interventions, Islamic theology, and law, as well as community-based participatory research to include in the committee. The two main sects of Islam are Sunni and Shia, therefore we decided to recruit both Sunni and Shia representatives to reach as many Muslim American women as possible.17 There are no female religious leaders in Mosques, so we can only have male religious leaders as members of the CABs.35 Using religious voices to communicate about our project will enhance participation in the study. Getting permission from Mosque leaders to be at the Mosque in person during worship day (Friday) will greatly help with the study progress.

Community Partnerships: For this study, the Massey Cancer Center (MCC), Virginia Commonwealth University, will be partnering with the community. MCC is located in Richmond, VA, in our target geographic area. MCC is well-known for the quality of the service that is provided for its patients, and it also has a diverse set of researchers and research staff who are well-versed in community-involved research. One of the MCC goals is to reduce cancer disparities by improving healthcare services and cancer outcomes among minorities in the Richmond area, which fits well with the goals of our project. The partnership with MCC will significantly enhance our research project as it will provide recognition and trust. It will also secure better relationships with the community.

Since we will not have the opportunity of having Muslim women in the CABs, we decided to engage female peer researchers to cover cultural sensitivities and reach a high number of Muslim women. Peer researchers will serve as partners with full involvement and authority in research processes. The eligibility criteria will be adult women who identified themselves as Muslims. Age plays an important role in Muslim culture; participants will be more trusting to what more grown community members provide more than the new generation. Peer researchers should have advanced English skills (speak, write, and read) and use technology to easily overcome the language barriers and communicate with the research team. Our preference is to recruit women and peer researchers who have been visiting the Mosque for at least 5 years to have enough experience with interacting with Mosque visitors and Islamic and Mosque rules and etiquette. We will also pursue building a strong relationship with Muslim women who are coming to take classes inside the Mosque. Peer researchers will develop a better connection with the research participants due to their shared life experiences as women having the same religion and traditions and familiarity with social norms. The peer researchers will have to be trained in research processes. Our expectation is that the targeted peer researcher cohort will not have difficulties with training, but they might have challenges regarding the schedule and availability. Most Islamic centers open on Fridays, and the is hours when which people practice their worships are usually between 12-1 PM, during regular business hours in the U.S. To overcome this problem, we will have 2 peer researchers, and each woman will cover a day per month.

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2. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
Aim 1b. We will conduct individual interviews with key stakeholders in our Community Advisory Board (Muslim religious leaders (N=4)) to receive feedback on the developed materials and inform the intervention program. This aim includes the Phase II (Preliminary Testing) of the ORBIT model (proof of concept, prepare the pilot).
Aim 2. We will test the preliminary efficacy of the religiously tailored and culturally appropriate intervention program. H1. Participants will show significant improvements in knowledge and acceptance of cervical cancer prevention after the intervention. To test this hypothesis, we will conduct a pre-post survey to examine changes in knowledge and acceptance of cervical cancer screening and prevention. This aim includes the Phase III (Efficacy) of the ORBIT model.
Aim 3. We will test the feasibility and acceptability of the religiously tailored and culturally appropriate intervention program which includes education and experiential practice/communication skills training. We will recruit 20 participants with the same eligibility criteria as in Aim 1, who have not participated in our previous studies, and conduct a single-arm pilot trial. H2. We hypothesize that the religiously tailored and culturally appropriate intervention program will be feasible to conduct as evidenced by meeting enrollment targets and the ability to implement the program as planned. H3. The intervention will be acceptable as evidenced by engagement (>60%) and retention (>80%), and satisfaction survey ratings.

3. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
Our team also investigates the barriers faced by MAW in the US healthcare system by evaluating the cultural competency of healthcare providers related to the Muslim culture at the VCU health system. Our ongoing work with the Muslim community has informed us about the community's needs. In this project, we will implement an interventional program guided by a community-based participatory approach utilizing expert-led education sessions and peer-led interventions, which combine health-related religious teachings and scientific information about the benefits of CC-S and HPV-Vax. The Muslim Community Partners (MCPs) will collaborate with our institute (VCU) by reaching out to four Islamic religious centers in Virginia. Partnership with Islamic centers is valuable to our project due to their: ability to convince women to join our study, reach out to a high number of MAW, and because religious voices will be a good motivator for Muslim families to change. The primary outcome is increasing awareness of cervical cancer prevention methods. The secondary outcome is the acceptability and confidence/trust in cervical cancer prevention methods such as CC-S and HPV Vax.

The research questions are: Would MAW intend to do cervical cancer screening and uptake the HPV Vaccination after an education program supported by the Mosques that they frequently visit?

The aims of the study are:
Aim 1b. We will conduct individual interviews with key stakeholders in our Community Advisory Board (Muslim religious leaders (N=4)) to receive feedback on the developed materials and inform the intervention program. This aim includes the Phase II (Preliminary Testing) of the ORBIT model (proof of concept, prepare the pilot).

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.

For these aims, we will use a survey that includes:

Pre-test survey, the scales are:
1. Demographic
2. Perceived Discrimination
3. Religious Discrimination
4. Spiritual Health Locus of Control.
5. Modesty
6. Cervical Cancer Knowledge
7. Perceived risk
8. Cuse of action
9. Self-efficacy
10. Attitude about CC screening
11. HPV vaccination acceptability

Prost-test survey, the scales are:
2. Perceived Discrimination
3. Religious Discrimination
4. Spiritual Health Locus of Control.
5. Modesty
6. Cervical Cancer Knowledge
7. Perceived risk
8. Cuse of action
9. Attitude about CC screening
10. HPV vaccination acceptability
11. General Self-Efficacy Scale (GSES)
12. Cervical Cancer Screening Self-Efficacy Scale

Satisfactory survey are:

-Experience with the intervention.
-Acceptability of content
-Acceptability of delivery

4. * **Describe the scientific benefit or importance of the knowledge to be gained:**

The Muslim population represents a significant, and increasingly growing, portion of the US population. Although literature shows the general lack of knowledge of Muslim women that are related to cervical cancer, there is a lack of educational intervention programs targeted toward Muslim women. Our study will implement the first educational program for Muslim women in the US, thus the effectiveness of educational programs in conservative communities could be assessed.

5. * **Describe any potential for direct benefits to participants in this study:**
The study will provide valuable information for the Muslim community or the general population. increase knowledge will increase the seeking for care: cervical cancer screening. Decreasing vaccine hesitancy
1. By the end of year one, 5% of the conservative Muslim Women in Richmond, Virginia will know that the HPV vaccine is safe and effective.
2. By the end of year one, 5% of conservative Muslim women in the Richmond Virginia Area will know that the HPV vaccination will not cause their children to become sexually active before marriage.
3. By the end of year two 8% of conservative parents of Muslim girls in the Richmond Virginia Area will know that the HPV vaccination does not impact fertility and will permit administration of the vaccine to their daughters and sons
4. By the end of the program most women will seek for Cervical cancer screening: pap smear test

6. * **Describe any potential for direct social impact in this study . For example, any engagement with specific communities to respond to community-identified needs, or ways the study will strengthen the well-being of the specific communities if applicable:**
Evidence shows that cervical cancer prevention methods such as screening and getting HPV vaccine are essential to decrease the mortality rate due to cervical cancer, however, these valuable tools are not used in adequate rates by the Muslim community. Therefore, understanding the Muslim women's behaviors and offering an educational program to provide individuals with crucial insight into these tools.

7. **Upload a supporting citation list if applicable:**

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent form focus group	Namoos- Consent from of focus group 05.12.2023.pdf	0.03	7/8/2023 1:09 AM	Asmaa Namoos	Consent/Assent/Information Sheet	Yes
View	Consent form - Intervention program	Namoos- Consent from of Intervention group 05.12.2023 copy.pdf	0.04	7/8/2023 1:09 AM	Asmaa Namoos	Consent/Assent/Information Sheet	Yes
View	Fund Plan	Asmaa -Budget 04.13.2023.xlsx	0.03	5/12/2023 11:52 AM	Asmaa Namoos	Funding Proposal	Not Applicable
View	Education session	Asmaa Education session guide , intervention group- 04.07.2023.docx	0.02	5/12/2023 10:52 AM	Asmaa Namoos	Other	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Timeline Plan	Namoos, timeline for PROMIS women Project-.docx	0.02	5/12/2023 10:43 AM	Asmaa Namoos	Other	Yes
View	Conceptual model	Asmaa Conceptual Model 05.12.2023.docx	0.02	5/12/2023 10:40 AM	Asmaa Namoos	Research Measure	Yes
View	Flayer 2	Asmaa Flyer Version 05.12.2023.docx	0.01	5/12/2023 10:39 AM	Asmaa Namoos	Other	Yes
View	Namoos-Focus group script guide	Namoos -Focus Group Script Guide.docx	0.02	5/12/2023 10:24 AM	Asmaa Namoos	Other	Yes
View	Participants -RA communication script	Namoos-Participants -RA communication script .docx	0.01	5/12/2023 6:45 AM	Asmaa Namoos	Other	Yes
View	Study Survey(Pre-post and satisfactory scales)	Survey- Promise women project 05.12.2023.docx	0.01	5/12/2023 6:35 AM	Asmaa Namoos	Research Measure	Yes
View	consent form-focus group	Consent from - Focus group 02.20.2023.docx	0.01	2/20/2023 4:32 PM	Asmaa Namoos	Consent/Assent/Information Sheet	No
View	VS biosketch	Sheppard Biosketch for AN 11.14.2022.pdf	0.01	2/20/2023 4:00 PM	Asmaa Namoos	CV/Biosketch	Not Applicable
View	Communication log	Communication log.docx	0.01	2/20/2023 3:59 PM	Asmaa Namoos	Other	Yes
View	PRMC approval	2022-10-10_MCC-22-19873_PRMC Approval Letter.pdf	0.01	10/10/2022 12:30 PM	Asmaa Namoos	Ancillary Committee Approval	Not Applicable
View	Flyer	Flyer 004.08.2022.png	0.01	4/8/2022 6:09 PM	Asmaa Namoos	Other	Yes
View	Namoos Resume	Dr. Namoos A. Biosketch	0.01	4/3/2022 3:47 PM	Asmaa Namoos	CV/Biosketch	Not Applicable

Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
	06.07.2021.pdf					

ID: HM20024502 **HM20024502** View: SF2 - Study Population

HM20024502 - Vanessa Lavene Sheppard
PROMIS WOMAN Education Program : ImProving ceRvical cancer preventiOn methods among Muslim AmerIcans WOMEN

Study Population

1. * **Provide the maximum number of individuals that**

   1. May participate in any study interaction or intervention (Including screening, consenting, and study activities)
   AND/OR
   2. You obtain any data/specimens about (regardless of identifiability)

   at VCU and at other sites under the VCU IRB's oversight. See the help text for additional guidance.
   30

2. **If this is a multi-Center Project, what is the maximum anticipated number of subjects across all sites?**

3. * **Provide justification for the sample size by explaining how you arrived at the expected number of participants and why this number is adequate for answering the research questions:**
   Sample: A non-probability sampling (convenience sampling) method will be adopted to allow reach all potential participants. The team members will approach potential respondents at Islamic centers to participate in this study. The inclusion criteria include women aged ≥18 years who speak English, self-identify as Muslim, and have not participated in our pilot study before. The exclusion criteria are any participants who participated in our pilot study or are unable to provide valid consent (e.g., developmental disability).

   Qualitative analysis side: to develop the education material we will recruit 10 female participants above 18 years old who identify as Muslim to participate in the design of the religiously tailored and culturally appropriate education materials for the intervention. First the focus group will help select the targets of the proposed education and the content to achieve each target (design). As a next step the focus group will focus on the formatting of the material, including basic usability testing (refine). Based on information from these sessions we will finalize the educational material for our intervention.
   we will use the grounded theory for complete the analysis

   Statistical Analysis for quantitative side : We assume that our study's CC-S HPV-Vax uptake rate would increase by 10% post-intervention. Based on a power analysis assuming the use of the student T-test to assess the difference in outcome between the intervention and control groups, The target sample size is estimated based on the G power software sample size calculator for the minimal sample size needed for an unlimited population size using a confidence interval of 80%, a standard deviation of 0.5, and a margin of error of 5%. The study requires 10 participants for intervention to test the feasibility of the program.
   Descriptive summaries will be generated to summarize participant demographics and all study variables including individual and community characteristics, with a particular focus on religious adherence, modesty, knowledge, attitudes, and risk perceptions of CC-S and attitudes and intention to get the HPV-Vax. Means, standard deviations, and percentiles will be reported for continuous variables, frequencies, and percentages for categorical variables. Summaries will be stratified by gender, age, education, language, and community to explore patterns. Confidence intervals will be reported to convey the precision of all point estimates. Following the descriptive analyses, comparisons

will be made to identify differences in knowledge, attitudes and risk perceptions, and HPV-Vax intent between groups defined by gender, age, religion, education, language, and community. We will use ANOVAs and t-tests for continuous variables (e.g., perceived risk and attitudes) and Chi-square tests for categorical variables). Post-hoc tests (Tukey's, Bonferroni) will follow significant omnibus ANOVA results to determine which groups differ while controlling the Type-I error rate. Non-parametric alternatives (e.g., Fisher's exact test, Kruskal-Wallis) will be used if data do not meet the assumptions of parametric methods. The relationship between the knowledge score and the independent categorical variables was determined using the Mann–Whitney U test for binomial variables and the Kruskal–Wallis test for multinomial variables. Variables that were significantly associated with the knowledge score were included in the multiple linear regression analysis after log transformation of the knowledge score. A statistically significant difference will be defined as a p-value was less than 0.05. Data analysis will be conducted using the R program.

4. * **List the study inclusion criteria:**

-For focus group to test the education material (n= 10 focus group)
The inclusion criteria include women aged ≥18 years who speak English, self-identify as Muslim, are able to give valid consent, who not participated in our pilot before.

-For Intervention program (n=20)
The inclusion criteria include women aged ≥18 years who speak English, self-identify as Muslim, are able to give valid consent, who not participated in our pilot and focus group before

We will use 4 centers at the time of recruitment: the Islamic center of Richmond, the Islamic center of Henrico, the Islamic center of Hampton, and the Peninsula Islamic Community Center.

5. * **List the study exclusion criteria:**

Phase 1)
Aim 1 a and b
Formative research- focus group
Sample size: 10 Muslim women
Sampling: Purposeful sampling.
Inclusion criteria:
-Female Muslim individuals above 18 years old.
-Able to speak and understand English.
-Have not had a hysterectomy.
-Have not had a cervical cancer diagnosis.
-Willing to participate in the educational program and undergo cervical cancer screening.
-Physically well, able to give consent form.

Phase 2
Aim 2 and 3
Single arm trial - pre and post-test
Sample size: 20 Muslim Women.
Sampling: Non-probability sampling (convenience sampling)
Inclusion criteria:
-Female Muslim individuals above 18 years old.
-Able to speak and understand English. Have not had a hysterectomy.
-Have not had a cervical cancer diagnosis.
- Willing to participate in the educational program.
-Physically well, able to give consent form.
-Have not participated in our pilot study before

We will be excluded any participant who was recruited during our pilot study (IRB: HM20021579).

6. * **Will individuals with limited English proficiency be included in or excluded from this research?**

- ○ Included
- ○ Excluded - safety concerns if participants are unable to communicate with the study team
- ○ Excluded - instruments/measures only validated in English
- ○ Excluded - no prospect of direct benefit to individual participants
- ○ Excluded - minimal risk study
- ○ Excluded - lack of budget/resources for translation and interpretation [provide an explanation in next question]
- ● **Excluded - other reason [provide an explanation in next question]**

7. Justify the inclusion and exclusion criteria if you are either targeting, or excluding, a particular segment of the population / community. Provide a description of the group/organization/community and provide a rationale.

We are excluding non-English speakers because:
1. There is insufficient budget to hire other language speakers.
2. The Muslim population is very diverse, and it isn't easy to include all languages.
3. Translating the study material and aims will affect the study quality.

ID: HM20024502 **HM20024502**

View: SF2 - Background, Rationale & Goals Section Complete

HM20024502 - Vanessa Lavene Sheppard
PROMIS WOMAN Education Program : ImProving ceRvical cancer preventiOn methods among Muslim AmerIcans WOMEN

Background, Rationale & Goals Section Complete

Protocol Progress:
- ● **INITIAL SETUP**
- ● **BACKGROUND, RATIONALE & GOALS**
- ③ RESEARCH PLAN
- ④ CONSENT PLAN
- ⑤ RISKS, PRIVACY & CONFIDENTIALITY
- ⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
- ⑦ INSTITUTIONAL REQUIREMENTS
- ⑧ DOCUMENTS

Click Continue below to go to the next section

HM20024502 - Vanessa Lavene Sheppard
PROMIS WOMAN Education Program : ImProving ceRvical cancer preventiOn methods among Muslim AmerIcans WOMEN

Study Procedures

1. * **Describe the study hypothesis and/or research questions. Use lay language whenever possible.**
Aim 1b. We will conduct individual interviews with key stakeholders in our Community Advisory Board (Muslim religious leaders (N=4)) to receive feedback on the developed materials and inform the intervention program. This aim includes the Phase II (Preliminary Testing) of the ORBIT model (proof of concept, prepare the pilot).
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2. * **Describe the study's specific aims or goals. Use lay language whenever possible.**
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For these aims, we will use a survey that includes:

Pre-test survey, the scales are:
1. Demographic
2. Perceived Discrimination
3. Religious Discrimination
4. Spiritual Health Locus of Control.
5. Modesty
6. Cervical Cancer Knowledge
7. Perceived risk
8. Cuse of action
9. Self-efficacy
10. Attitude about CC screening
11. HPV vaccination acceptability

Prost-test survey, the scales are:
2. Perceived Discrimination
3. Religious Discrimination
4. Spiritual Health Locus of Control.
5. Modesty
6. Cervical Cancer Knowledge
7. Perceived risk
8. Cuse of action
9. Attitude about CC screening
10. HPV vaccination acceptability
11. General Self-Efficacy Scale (GSES)
12. Cervical Cancer Screening Self-Efficacy Scale

Satisfactory survey are:

-Experience with the intervention.
-Acceptability of content
-Acceptability of delivery

3. * Choose all types of recruitment materials that may be used and upload them below:

- [ ] E-mail invitations
- [ ] Phone Solicitation scripts (i.e. cold calls or random-digit-dialing)
- [x] **Flyers, Mailed Letters or Newspaper/TV/Radio Ads**
- [ ] TelegRAM announcements
- [ ] Website text
- [ ] Study-specific web sites (provide the design and text)
- [ ] Social Media
- [ ] EPIC MyChart Patient Portal research study descriptions
- [ ] Psychology Research Participant Pool (SONA) study descriptions
- [ ] Scripts for announcements made to groups
- [ ] Other recruitment document
- [ ] No recruitment materials

4. * **Describe the study procedures/methods for identifying and recruiting participants. Address all of the following three aspects of recruitment in your response.**

1. Identification of potentially eligible participants or secondary data/specimens of interest.
- What database(s) will be queried to identify secondary data/specimens
- How VCU Informatics or VCU IRDS will be used for cohort identification (when applicable, see help text)
- How potential participants' contact information will be obtained

2. Recruitment procedures to invite participation in the study (when applicable):
- How each of the written or verbal recruitment materials and reminders (selected above) will be used
- Who will contact, approach, or respond to potential participants
- Locations where recruitment procedures will take place
- The timing and frequency of recruitment attempts

3. Eligibility screening prior to consent and how those activities will be carried out (when applicable)

See the help text for additional guidance.
The principal investigator (PI) has a community partnership with the Islamic Center of Richmond, where the research team will distribute flyers about the project (see attachment). The research team will be present at the Mosque at predetermined times where women could approach study team members to ask questions, sign up for participation, and schedule appointments.

1) Identification of potentially eligible participants:

-The research team will distribute flyers about the project at the Islamic Center of Richmond to identify potentially eligible participants.
-The education material will be mentioned as PDF in the docs section

2) Recruitment procedures to invite participation in the study:

Place: The research team will be present at the Mosque during predetermined times.
Participants: Women interested in participating can approach study team members to ask questions, sign up for participation, and schedule appointments.
Written recruitment materials, such as flyers, will be distributed to provide information about the study.
Verbal recruitment materials will be used when study team members interact with potential participants.
The research assistant will handle contact with potential participants, including scheduling interviews and baseline surveys.
Recruitment procedures will take place at the Islamic Center of Richmond.

3) Eligibility screening prior to consent and how those activities will be carried out:

During these interactions, eligibility screening will be conducted to ensure participants meet the study criteria.
The research team will use a standardized screening tool or questionnaire to assess eligibility.
For focus group meetings, participants will be screened for eligibility before being scheduled for interviews.
For the one-arm clinical trial, participants will be screened for eligibility during the scheduling of baseline surveys.
The education materials will be clearly outlined in the study plan PDF.
The survey will be given to the potential participants in person (hard) or through QR code through redcap.

Summary the intervention :
The intervention group will consist of 20 participants who will receive one education session divided into three sections/videos. The session will be offered in a single day and last 1.5 hours. The session will include the following topics: 1) Risk of HPV infection (30 minutes), 2) Cervical cancer risk (30 minutes), and 3) Advantages and benefits of early screening and the HPV vaccine (30 minutes).

All participants from both groups will be given the survey at month 0 (baseline) after the delivery of the educational material. The survey will be self-report, available in both hard copy and electronic form with a QR code for Redcap.

Participants are expected to take approximately 45 minutes to complete the survey.

The Islamic center offer private room to practice the research activities in both phases (Focus group and single arm trial)

5. * **Does this study have a separate protocol document (i.e. a multisite or sponsor's protocol) that contains a detailed description of the study's methodology?**

- ○ Yes
- ● **No**

6. * Since a separate protocol document is not uploaded, describe the proposed research using language understandable to those IRB committee members whose expertise is not scientific. The description must include:

1. A statement explaining the study design
2. A detailed description of all the procedures that will be followed to carry out the study, preferably in sequential order, and in sufficient detail that the study's methods could be replicated
3. The schedule and frequency of when and how procedures will be conducted (e.g. in person, online, phone, paper, etc.)
4. A description of all research measures/tests/interventions that will be used, including analyses/tests conducted on specimens/biological samples (if applicable)

See the help text for additional guidance
1. A statement explaining the study design
Study Design:
The proposed study consists of two parts.
Part 1 involves formative research through a focus group to gather insights and reach saturation.
Part 2 is a single-arm pre and post-test trial with the objective of evaluating the efficacy of an educational interventional program.

The study aims to increase cervical cancer screening (CC-S) and HPV vaccine (HPV-Vax) rates among Muslim American women (MAW) in Virginia, leading to a reduction in cervical cancer (CC) incidence and mortality.

2. A detailed description of all the procedures that will be followed to carry out the study, preferably in sequential order, and in sufficient detail that the study's methods could be replicated.
a. Part 1 - Formative Research: Conduct a focus group with 10 participants until saturation is reached.
b. Part 2 - Single-arm Pre and Post-test Trial: Enroll 20 participants to evaluate the educational program's effectiveness.

Participants will complete a baseline survey to assess their knowledge, attitudes, CC-S and HPV-Vax practices, and predisposing factors.
The survey will cover topics such as CC knowledge, experiences of medical mistrust, discrimination, spiritual coping, and fatalism.

3. The schedule and frequency of when and how procedures will be conducted (e.g. in person, online, phone, paper, etc.)

All procedures will be conducted in person at the Islamic Centers, except for follow-up phone calls.
Recruitment will occur during regular Friday prayers and religious holidays.
Participants will receive a brochure explaining the study and be screened for eligibility by the Research Assistant (RA).
Eligible participants will be given a telephone contact for enrollment at a more convenient time.
The consent process will involve verbal explanation, providing the consent form in English, and allowing participants to ask questions.
Follow-up surveys and confirmations will be conducted via phone calls.

4. A description of all research measures/tests/interventions that will be used, including analyses/tests conducted on specimens/biological samples (if applicable)

Power Analysis: No power analysis for this study, A target sample size of 20 participants has been determined based on PhD committee, the purpose of the project is training for the STUDENT.

Measures: Validated scales and surveys will be used to measure

Age: Age can be measured using a simple demographic question such as "What is your age?" in the pre- and post-intervention surveys.

Education: Education level can be measured using a simple demographic question such as "What is the highest level of education you have completed?" in the pre- and post-intervention surveys.

Modesty and Conservatism: can be measured using a combination of demographic questions and attitudinal scales.
 For example, demographic questions could include "How important is modesty in your culture?" or "How conservative would you describe yourself?" while attitudinal scales could include items such as "I am comfortable discussing reproductive health issues with my healthcare provider" or "I am willing to discuss cervical cancer prevention activities with my family and friends.“

Cervical Cancer Screening and HPV Vaccine Uptake: can be measured using self-reported questions such as "Have you ever had a Pap smear?" or "Have you ever received the HPV vaccine?" in the pre- and post-intervention surveys. Additional questions can also be included to determine the frequency and timing of screening and vaccine uptake.

Participants' Knowledge and Attitude: can be measured using a combination of open-ended and closed-ended questions.
Open-ended questions could include "What do you know about cervical cancer prevention activities?" while closed-ended questions could include "Do you believe that cervical cancer screening is important?" or "Do you believe that the HPV vaccine is safe and effective?“

Feasibility of Intervention: can be measured by tracking enrollment rates, attendance rates, and completion rates in the pre- and post-intervention surveys.
 Additional questions can also be included to assess the overall acceptability of the intervention among participants.

Self-efficacy: can be measured using a self-efficacy scale specific to cervical cancer screening, such as the Cervical Cancer Screening Self-Efficacy Scale (CCSES), as described in the previous answer.

Acceptability of the Program: can be measured using a satisfaction survey at the end of the intervention program. The survey could include questions such as "Did you find the program useful?" or "Would you recommend this program to a friend?"

Outcomes:

The primary outcome in increase the number of women who undergo cervical cancer screening.
Secondary outcomes include an increase in knowledge and awareness, an increase in self-efficacy, and improvement in attitudes towards cervical cancer prevention.
Long-term outcomes include a reduction in cervical cancer incidence and mortality, sustainability of behavior change, and a reduction in healthcare costs associated with advanced-stage cancer treatment.

Moderator factors that can influence the effectiveness of the program include age, education level, ethnicity, socioeconomic status,
Mediating mechanisms that explain how the program leads to its outcomes include improved knowledge and awareness, increased self-efficacy, attitude change, increased and social support,

Identifying and addressing moderator factors and mediating mechanisms can help to tailor the program to the specific needs and preferences of the target population and maximize its effectiveness

Key Study Variables: Socio-demographic variables, cultural/religious practices, cancer literacy, knowledge, perceived risk, barriers, benefits, and participation in preventive measures.

Evaluation Measures: Intervention acceptance will be self-reported, covering challenges, barriers, facilitators, likes/dislikes, and suggestions for improvement.

This study aims to address barriers to CC prevention among MAW through an educational intervention, using a sequential approach of formative research and a single-arm trial. The study will be conducted at Islamic Centers, involving in-person procedures, phone follow-ups, and self-report measures. The proposed methods are designed to evaluate the effectiveness of the educational program and its impact on CC-S and HPV-Vax rates in the target population.

Statistical Tests: Statistical tests such as t-tests or ANOVA can be used to analyze the data from the pre-post survey. These tests will help determine whether there are statistically significant differences between the pre- and post-survey results and whether the intervention had a significant effect on participants' knowledge and acceptance of cervical cancer prevention.

7. * **The IRB only reviews research activities, so indicate for each of the study activities described in the question above or in the protocol which activities are:**

   - Being performed exclusively for research purposes (i.e. they would not otherwise be done apart from this study) VERSUS.
   - Alterations of routine activities/procedures (e.g. the study is altering the timing, frequency, method, location, amount, etc.) VERSUS.
   - Being done for other purposes and whose data/results will be used secondarily in the study (e.g. standard medical or psychological tests, routine education practices, quality improvement initiatives, etc.).
   See the help text for additional guidance

   The study is being performed exclusively for research purposes.

8. **If applicable, describe alternatives (research or non-research) that are available to potential participants if they choose not to participate in this study:**

9. **Upload any supporting tables or documents (e.g. protocol documents, figures/tables, data collection forms, study communications/reminders):**

   Upload ALL instruments/guides that will be used or that participants will experience (i.e. see, hear, complete), including measures, scripts/questions to guide interviews, surveys, questionnaires, observational guides, etc,:

   Upload ALL recruitment and screening materials, including such as ads, flyers, telephone or in-person scripts, letters, email invitations, TelegRAM announcements, and postcard reminders, screening scripts, screening forms, and screening measures:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent form focus group	Namoos- Consent from of focus	0.03	7/8/2023 1:09 AM	Asmaa Namoos	Consent/Assent/Information Sheet	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
		group 05.12.2023.pdf					
View	Consent form - Intervention program	Namoos- Consent from of Intervention group 05.12.2023 copy.pdf	0.04	7/8/2023 1:09 AM	Asmaa Namoos	Consent/Assent/Information Sheet	Yes
View	Fund Plan	Asmaa -Budget 04.13.2023.xlsx	0.03	5/12/2023 11:52 AM	Asmaa Namoos	Funding Proposal	Not Applicable
View	Education session	Asmaa Education session guide , intervention group- 04.07.2023.docx	0.02	5/12/2023 10:52 AM	Asmaa Namoos	Other	Yes
View	Timeline Plan	Namoos, timeline for PROMIS women Project-.docx	0.02	5/12/2023 10:43 AM	Asmaa Namoos	Other	Yes
View	Conceptual model	Asmaa Conceptual Model 05.12.2023.docx	0.02	5/12/2023 10:40 AM	Asmaa Namoos	Research Measure	Yes
View	Flayer 2	Asmaa Flyer Version 05.12.2023.docx	0.01	5/12/2023 10:39 AM	Asmaa Namoos	Other	Yes
View	Namoos-Focus group script guide	Namoos -Focus Group Script Guide.docx	0.02	5/12/2023 10:24 AM	Asmaa Namoos	Other	Yes
View	Participants -RA communication script	Namoos- Participants -RA communication script .docx	0.01	5/12/2023 6:45 AM	Asmaa Namoos	Other	Yes
View	Study Survey(Pre-post and satisfactory scales)	Survey- Promise women project 05.12.2023.docx	0.01	5/12/2023 6:35 AM	Asmaa Namoos	Research Measure	Yes
View	consent form- focus group	Consent from - Focus group 02.20.2023.docx	0.01	2/20/2023 4:32 PM	Asmaa Namoos	Consent/Assent/Information Sheet	No

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	VS biosketch	Sheppard Biosketch for AN 11.14.2022.pdf	0.01	2/20/2023 4:00 PM	Asmaa Namoos	CV/Biosketch	Not Applicable
View	Communication log	Communication log.docx	0.01	2/20/2023 3:59 PM	Asmaa Namoos	Other	Yes
View	PRMC approval	2022-10-10_MCC-22-19873_PRMC Approval Letter.pdf	0.01	10/10/2022 12:30 PM	Asmaa Namoos	Ancillary Committee Approval	Not Applicable
View	Flyer	Flyer 004.08.2022.png	0.01	4/8/2022 6:09 PM	Asmaa Namoos	Other	Yes
View	Namoos Resume	Dr. Namoos A. Biosketch 06.07.2021.pdf	0.01	4/3/2022 3:47 PM	Asmaa Namoos	CV/Biosketch	Not Applicable

ID: HM20024502 **HM20024502** View: SF2 - Project Details

HM20024502 - Vanessa Lavene Sheppard
PROMIS WOMAN Education Program : ImProving ceRvical cancer preventiOn methods among Muslim AmerIcans WOMEN

Project Details

An intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

An interaction includes communication or interpersonal contact between investigator and subject. It may include in-person, online, written, or verbal communications.

Secondary information/biospecimens are information or biospecimens that have been or will be collected for some other "primary" or "initial" activity and that will be used secondarily in the research study.

1. * **Select all of the following types of interventions that apply to this study (selections will branch):**

- [x] **Social/Behavioral interventions or experimentation / Tasks / Environmental manipulations**
- [ ] Deception (misleading participants through false or incomplete information)
- [ ] Drug(s) / Biologics / Supplement(s) / Other Compounds (investigational products or products whose administration is dictated by the study protocol and not per the physician's clinical judgment)
- [ ] IV contrast administration for research-related imaging (will branch to the Drugs page)
- [ ] Placebos
- [ ] Safety and/or effectiveness evaluation of Bio-Medical Device(s), including in-vitro diagnostic devices/assays, mobile medical apps, software functions, and HUDs used in clinical investigations
- [ ] Washout Periods
- [ ] Expanded Access – Treatment Use of an Investigational Product
- [ ] Medical or Surgical Procedures (eg: physical exam, clinical procedures, scans, etc)
- [ ] Specimen/biological sample collection
- [ ] None of the Above

2. * **Select all of the following types of interactions and methods of data collection that apply to this study (selections will branch):**

- [x] **Surveys / Questionnaires /Written responses to questions (including data entry)**
- [x] **Active Internet data collection (i.e. using the internet to collect data, including online surveys, data collection via Zoom, apps, etc.)**
- [ ] Passive Internet data collection (i.e. passively observing online behavior, bots)
- [x] **Interviews / Focus Groups / Verbal responses to questions**
- [x] **Audio / Video recording or photographing participants**
- [ ] Observations
- [ ] Educational Settings/Assessments/Procedures
- [ ] None of the Above

3. * **Select all types of recordings that will be made:**

- [x] **Audio**
- [ ] Video
- [x] **Photographs**

4. * **Describe the purpose of the recordings, who will be recorded and when such recordings will occur:**

Part 1:
The recordings in Part 1, which involve the focus group interviews, are for analysis purposes. The audio recordings will be used to transcribe the data and analyze the transcripts. The research assistant conducting the interviews will record the sessions using a VCU iPad. The interviews will take place in the private room provided by the mosque. It's important to note that the research assistant will not use any names or identification during the interviews to ensure confidentiality.

Part 2:
In Part 2, the recordings serve a different purpose. During the education sessions, photos will be taken as part of the community outreach work. These photos will be used exclusively for conference purposes to disseminate the findings of the study. Similar to Part 1, the research assistant will use a VCU iPad to record the sessions, but no identifying information will be used or captured during the interviews.

the recordings are used to facilitate analysis in Part 1 and for dissemination purposes in Part 2. They are conducted using a VCU iPad in the private room provided by the mosque, and precautions are taken to ensure confidentiality and anonymity of the participants.

5. * **Select all types of secondary information and/or specimens that apply to this study (selections will branch): See the help text for definitions.**

- [ ] Individually Identifiable Health Information (PHI)
- [ ] Secondary data/specimens NOT from a research registry or repository
- [ ] Information/specimens from a research registry or repository (Usage Protocol)
- [ ] Information/specimens originally collected for a previous research study
- [ ] Publicly available information/specimens
- [ ] Government-generated or collected information that was or will be obtained for nonresearch activities [only applicable to research conducted by or on behalf of a Federal department or agency]
- [x] **No secondary data/specimens will be used**

ID: HM20024502 **HM20024502**

View: SF2 - Behavioral Intervention/Task Details

HM20024502 - Vanessa Lavene Sheppard
PROMIS WOMAN Education Program : ImProving ceRvical cancer preventiOn methods among Muslim AmerIcans WOMEN

Behavioral Intervention/Task Details

This page asks for details about the social/behavioral intervention, task, or environmental manipulation in the research.

Interventions include both physical procedures by which information is gathered and manipulations of the subject or the subject's environment that are performed for research purposes. This might include activities such as playing computer games, performing a task, thought/cognition activities, environmental manipulations, and educational activities.

If the study only involves surveys, interviews, or secondary data collection, go back to the Project Details page and uncheck “Social/Behavioral interventions or experimentation / Tasks / Environmental manipulations” in Question 1.

1. * **Describe the duration of the social/behavioral intervention, task, or environmental manipulation:**
   The event will be organized for three hours.
   -The education sessions will be 1.5 hours (90 minutes).
   - The self-report survey will take 45 minutes.
   - The rest of the time, we will have a break and lunch.

   The education sessions will be offered on Saturday and Sunday.

2. * **Describe any potential harms or discomforts that participants could experience during the intervention activity:**
   They may experience some psychological discomfort related to some of the questions. Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you.

3. * **Will the intervention activity be physically invasive or painful?**
   - ○ Yes
   - ● **No**

4. * **Describe the impact the intervention activity will have on participants, including the nature and duration of any impact(s):**
   There is no impact on the intervention process except for the cultural sensitivity that we mentioned before.

5. * **In the investigator's opinion, is there any reason to think that the participants will find the intervention activity offensive or embarrassing? Explain why or why not.**
   we have been working with this community for three years, and we don't feel that there is any offensive or embarrassing for Muslim ladies.

ID: HM20024502 **HM20024502** View: SF2 - Active Internet Data Collection

HM20024502 - Vanessa Lavene Sheppard
PROMIS WOMAN Education Program : ImProving ceRvical cancer preventiOn methods among Muslim AmerIcans WOMEN

Active Internet Data Collection

1. * **Describe the platform/technology chosen for collecting the data and transmitting data securely over the internet. If proposing a non-VCU approved platform, give the rationale for selecting the technology instead of a VCU-approved platform.**
   The chosen platform for collecting survey data in this study is REDCap (Research Electronic Data Capture). REDCap is a widely used, secure, and HIPAA-compliant web-based application specifically designed for research data collection and management. It provides a user-friendly interface for designing surveys, capturing data, and generating reports.

   For note recording, the Apple system will be utilized, likely referring to Apple devices such as iPads or iPhones. These devices offer built-in voice recording features that can be used by the research assistant during interviews or other data collection activities.

   The rationale for selecting REDCap as the survey collection platform is its established reputation as a secure and reliable tool for research data. It is designed to meet rigorous data protection standards, ensuring the privacy and confidentiality of participants' information. Additionally, REDCap offers a range of features for data validation, quality control, and export options, which contribute to efficient and accurate data management.

   While using a VCU-approved platform is typically encouraged to maintain consistency and alignment with institutional policies, the decision to utilize REDCap and the Apple system may stem from specific functionalities and familiarity with these technologies. Researchers may have found that these platforms meet their data collection and recording needs effectively, and they have confidence in their security and reliability.

2. * **Describe how data will be linked or unlinked to identifiers including email addresses, names, and/or IP address.**
   In this study, data will be collected and stored in a manner that ensures the protection of participants' confidentiality and privacy. Specifically, data will be unlinked from identifiers such as email addresses, names, and IP addresses.
   For the survey data collected through the REDCap platform, participants' responses will be de-identified. This means that personal identifying information, such as names and email addresses, will not be linked to their survey responses. Instead, each participant will be assigned a unique study ID or code, which will be used to anonymize their data. This separation of identifiers from survey responses helps maintain the confidentiality of participants' information.
   Regarding the note recordings using the Apple system, it is important to note that the research assistant will not use any names or identification during the interviews. This further ensures that participants' personal information remains unlinked from the recorded data.
   By unlinking data from identifiers, the study aims to protect participants' privacy and confidentiality throughout the data collection and analysis process. It reduces the risk of unauthorized access or disclosure of sensitive information, promoting ethical research practices.

3. * **How will you protect your data collection from fraudulent responses:**
   1. Collection of IP addresses: we are not collecting IP address
   2. Identity verification procedures: Implementing procedures to verify participants' identities can add an extra layer of

protection against fraudulent responses. This can include requesting additional identification information or using verification methods like email confirmation.
3. Screening questions: Including screening questions within the survey can help filter out respondents who may not meet the eligibility criteria or who provide inconsistent or implausible responses. These questions can help ensure that only qualified and genuine participants are included in the study.
4. Attention checks: Incorporating attention check questions within the survey helps assess the attentiveness and sincerity of participants. These questions are designed to identify respondents who may be providing random or careless responses. Participants who fail attention checks may be excluded from the analysis.
5. Post-data collection monitoring procedures: Regularly reviewing and monitoring the collected data can help identify any suspicious or fraudulent responses. Data quality checks, including identifying outliers or patterns of unusual responses, can be conducted to ensure the integrity of the data.
While the specific protections employed will depend on the nature and requirements of the study, implementing a combination of these strategies can help safeguard against fraudulent responses and protect the validity of the data collected. It is essential to consider the specific needs of the study and balance the level of protection with the potential impact on participant engagement and response rates.

4. * **Is there an alternative method for completion of the data collection other than the internet?**

- ○ Yes
- ● **No**

5. * **Describe how individuals will be able to skip or not answer particular questions. If any questions are mandatory, provide justification.**
In the study, participants will be provided with the option to skip or not answer particular questions. The survey instrument will be designed in a way that allows participants to proceed through the questionnaire without being required to answer every single question. The following approach will be implemented:
1. Optional Questions: The majority of questions in the survey will be designed as optional, meaning participants can choose whether or not to answer them. This allows participants to skip questions that they may feel uncomfortable with or prefer not to answer. They can simply move on to the next question or section of the survey.
2. Mandatory Questions: In some cases, certain questions may be designated as mandatory. These questions will be carefully selected based on their criticality to the research objectives or eligibility criteria. Justification for including mandatory questions will be provided in the study design and protocol documentation, explaining the importance of obtaining specific information for the study outcomes or participant eligibility.
3. Justification for Mandatory Questions: The justification for including mandatory questions will be based on scientific or practical reasons. For example, if the study aims to assess the impact of a specific intervention on a particular variable, it may be necessary to include mandatory questions related to that variable to accurately evaluate the intervention's effectiveness. Additionally, if certain eligibility criteria need to be met for participant inclusion, mandatory questions may be necessary to determine if individuals meet those criteria.
Allowing participants to skip or not answer particular questions, the study respects participant autonomy and ensures that their comfort and privacy are prioritized. Mandatory questions are justified based on research objectives or eligibility criteria, ensuring that the necessary information is collected to achieve the study's goals.

6. **If not including children, describe any procedures used to verify that research participants are adults.**
To ensure that research participants are adults and meet the eligibility criteria, specific procedures will be implemented to verify their age. During the recruitment process, potential participants will be required to confirm their age by providing valid identification documents, such as a driver's license or passport, which clearly indicate their date of birth. The research team will review and verify these documents to confirm that participants are indeed adults. This verification process will help ensure the accuracy and integrity of the study data, as well as maintain compliance with ethical considerations related to involving adult participants in the research.

ID: HM20024502 **HM20024502** View: SF2 - Costs to Participants

HM20024502 - Vanessa Lavene Sheppard
PROMIS WOMAN Education Program : ImProving ceRvical cancer preventiOn methods among Muslim AmerIcans WOMEN

Costs to Participants

1. * **Select all categories of costs that participants or their insurance companies will be responsible for:**

- [x] **Participants will have no costs associated with this study**
- [ ] Study related procedures that would be done under standard of care
- [ ] Study related procedures not associated with standard of care
- [ ] Administration of drugs / devices
- [ ] Study drugs or devices
- [ ] Other

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Compensation

It is recommended that investigators consult with VCU Procurement Services before proposing a compensation plan (monetary or non-monetary) to the IRB to ensure the plan will comply with VCU policies. Refer to WPP XVII-2 for the IRB's guidelines about compensating research participants.

1. * **Describe any compensation that will be provided including:**
   1. total monetary amount
   2. type (e.g., gift card, research pre-paid card, cash, check, merchandise, drawing, extra class credit)
   3. how it will be disbursed
   4. how you arrived at this amount
   5. What identifiers and tax forms will be required for compensation purposes (i.e. W-9 form, SSN, V#, addresses, etc.)

1. Total Monetary Amount:
• Focus Group (Part 1): Each participant in the focus group will receive a total compensation of $150 ($75 for each session) for their involvement in two sessions.
• Intervention (Part 2): Participants in the intervention group will receive $150 for completing both the pre and post-surveys ($75 for each survey)
• Satisfactory Survey Compensation: Participants who complete the survey will receive $50 as compensation.

2. Type of Compensation:
• The compensation will be provided as gift card after completing each research activities.

3. Disbursement of Compensation:
• The compensation will be disbursed to participants through their preferred method, such as a gift card (physical or e-card) . The specific method of disbursement will be communicated to participants, and arrangements will be made accordingly.

4. Determining the Amount:
• The compensation amounts were determined based on factors such as the time commitment required from participants, the importance of their contributions to the study, and the prevailing compensation rates for similar studies or participant involvement. These amounts aim to provide fair and reasonable compensation for participants' time and effort.

5. Identifiers and Tax Forms:
• In consideration of the community's concerns and challenges, we have decided to waive the requirement of providing Social Security Numbers (SSN) or any tax-related forms. We acknowledge that obtaining SSN from participants could be a significant challenge and may hinder participation in the study. Therefore, participants will not be asked to provide SSN or complete tax-related forms.
• This decision aims to prioritize the community's comfort and trust while minimizing any barriers to participation. We

will ensure that alternative methods are in place to provide compensation to participants without the need for SSN or tax forms.
• The privacy and confidentiality of participants' personal information will continue to be respected throughout the compensation process. Participants will be assured that their identifying information will be handled securely and used solely for the purpose of compensation disbursement.

2. If compensation will be pro-rated, explain the payment schedule.

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Contingency Plan

This page will be used by the IRB in the event that an institution-wide emergency situation arises that requires contingency plans.

A contingency plan describes the alternative procedures that a study would want to use in case of an emergency that prevented normal study activities from occurring. It is a form of adaptive protocol. It enables the VCU IRB to quickly approve alternative study activities along with criteria for when those activities would or would not be put into effect. For example, in 2020, some studies had a COVID-19 Contingency Protocol approved that described alternative remote procedures that they would switch to whenever the University restricted in-person research activities.

In all studies, investigators are strongly encouraged to plan prospectively and build flexibilities into their regular protocols (regardless of whether an emergency situation exists) as well as think about what they would do in an emergency situation. For example, windows for timed study visits, ranges instead of exact values, flexibilities in inclusion criteria, etc. Flexibility and adaptations that are built into the protocol will reduce the number of changes that have to be submitted to the IRB and should reduce the number of incidents of deviations and noncompliance by investigators.

Further instructions and smartform questions on this page will be released from the IRB in the event of such an institution-wide emergency situation.

ID: HM20024502 **HM20024502** View: SF2 - Research Plan Complete

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Research Complete

Protocol Progress:
- **INITIAL SETUP**
- **BACKGROUND, RATIONALE & GOALS**
- **RESEARCH PLAN**

④ CONSENT PLAN
⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

ID: HM20024502 **HM20024502** View: SF2 - Consent Process

HM20024502 - Vanessa Lavene Sheppard
PROMIS WOMAN Education Program : ImProving ceRvical cancer preventiOn methods among Muslim AmerIcans WOMEN

Consent Process

1. * List all consent groups:

	Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
View	Focus group consent form	Signed Consent by Participant	No Waivers Requested	Principal Investigator Lead Student/Trainee Investigator (leading their own project) Co/Sub-Investigator Research Coordinator Research Assistant		DocuSign (standard platform for non-FDA regulated studies)	-The consenting process for the study will commence after receiving IRB approval, expected in May 2023, at the Islamic Center in a private room provided by the Community Advisory Board. During the consent discussion, participants will be provided with a background about cervical cancer among Muslim women. Depending on their enrollment, either in the focus group or the education session, the details of the	Sitting down beside the participant instead of standing over them Having a mandatory wait period for the participant to go home and think before they sign consent /assent	Two weeks after the first conversation about the study. we will drop the participant from out list if we have not heard back from her.	

Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
						respective components will be explained. -The consent discussion will take place in-person, allowing for face-to-face interaction. The research assistant (RA) will provide the participant with the necessary materials and information to make an informed decision about participation. The discussion will cover the potential risks, benefits, and compensation associated with the study. -Participants will be given the opportunity to consider their participation and make an informed decision. They will be offered the option to provide consent electronically using either DocuSign. The electronic			

	Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
							consent form will be accessible via a provided link, ensuring convenience and ease of use for the participants. -Ongoing reconfirmation of consent is not applicable in this study.			
View	Intervention group consent form	Signed Consent by Participant	No Waivers Requested	Principal Investigator Lead Student/Trainee Investigator (leading their own project) Research Coordinator Research Assistant Trainee/Student(working on project)		DocuSign (standard platform for non-FDA regulated studies)	When and Where Consent Will Occur: Consent for the intervention group will be obtained at the Islamic Center during the scheduled education sessions. Participants will have the opportunity to provide consent before engaging in the educational program. What Will Be Covered During the Consent Discussion: During the consent	Having a mandatory wait period for the participant to go home and think before they sign consent /assent	Participants will be given sufficient time(expecting from a week to two weeks) to make a decision regarding their participation in the study. The exact duration may vary depending on the circumstances and complexity of the study. Typically, participants are encouraged to take as much time as they need to review the provided	

Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
						discussion, participants will be provided with a detailed explanation of the educational program, including the topics covered, session duration, and expected outcomes. The risks and benefits associated with participation will be clearly explained, along with any potential discomfort or adverse effects that may arise from the educational sessions. Additionally, participants will be informed about their rights as research participants, including confidentiality and the voluntary nature of their involvement. They will have the opportunity to ask questions and		information, ask questions, and consider their decision. The study team will emphasize that there is no rush to make a decision and that participants are free to take the necessary time to make an informed choice that aligns with their interests and preferences.	

Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
						seek clarifications before providing consent. How the Consent Discussion Will Occur: The consent discussion will occur in-person, allowing for direct communication between the research team and the participants. A designated research team member, such as the research assistant (RA), will conduct the discussion in a private room at the Islamic Center. The participant will have the opportunity to review the consent form, ask any questions, and discuss any concerns before making an informed decision to participate. The RA will be available to provide			

Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
						explanations and guidance as needed to ensure the participant's understanding of the study and their role in it. How Consent Will Be Reconfirmed on an Ongoing Basis: Since the intervention group will be participating in a one-day educational program, ongoing reconfirmation of consent is not applicable in this case. However, the research team will ensure that participants are aware of their right to withdraw from the study at any time, even after providing initial consent. Participants will also be provided with contact information to reach out to the research team if they have any questions or			

Group	Types	Waivers	Roles	Roles - Other	Electronic Signatures	Consent	Coercion	Decision	Re-Consent
						concerns during or after the educational program.			

2. Upload any consent / assent documents:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent form focus group	Namoos- Consent from of focus group 05.12.2023.pdf	0.03	7/8/2023 1:09 AM	Asmaa Namoos	Consent/Assent/Information Sheet	Yes
View	Consent form - Intervention program	Namoos- Consent from of Intervention group 05.12.2023 copy.pdf	0.04	7/8/2023 1:09 AM	Asmaa Namoos	Consent/Assent/Information Sheet	Yes
View	Fund Plan	Asmaa -Budget 04.13.2023.xlsx	0.03	5/12/2023 11:52 AM	Asmaa Namoos	Funding Proposal	Not Applicable
View	Education session	Asmaa Education session guide , intervention group- 04.07.2023.docx	0.02	5/12/2023 10:52 AM	Asmaa Namoos	Other	Yes
View	Timeline Plan	Namoos, timeline for PROMIS women Project-.docx	0.02	5/12/2023 10:43 AM	Asmaa Namoos	Other	Yes
View	Conceptual model	Asmaa Conceptual Model 05.12.2023.docx	0.02	5/12/2023 10:40 AM	Asmaa Namoos	Research Measure	Yes
View	Flayer 2	Asmaa Flyer Version 05.12.2023.docx	0.01	5/12/2023 10:39 AM	Asmaa Namoos	Other	Yes
View	Namoos-Focus group script guide	Namoos -Focus Group Script Guide.docx	0.02	5/12/2023 10:24 AM	Asmaa Namoos	Other	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Participants -RA communication script	Namoos-Participants -RA communication script .docx	0.01	5/12/2023 6:45 AM	Asmaa Namoos	Other	Yes
View	Study Survey(Pre-post and satisfactory scales)	Survey- Promise women project 05.12.2023.docx	0.01	5/12/2023 6:35 AM	Asmaa Namoos	Research Measure	Yes
View	consent form-focus group	Consent from - Focus group 02.20.2023.docx	0.01	2/20/2023 4:32 PM	Asmaa Namoos	Consent/Assent/Information Sheet	No
View	VS biosketch	Sheppard Biosketch for AN 11.14.2022.pdf	0.01	2/20/2023 4:00 PM	Asmaa Namoos	CV/Biosketch	Not Applicable
View	Communication log	Communication log.docx	0.01	2/20/2023 3:59 PM	Asmaa Namoos	Other	Yes
View	PRMC approval	2022-10-10_MCC-22-19873_PRMC Approval Letter.pdf	0.01	10/10/2022 12:30 PM	Asmaa Namoos	Ancillary Committee Approval	Not Applicable
View	Flyer	Flyer 004.08.2022.png	0.01	4/8/2022 6:09 PM	Asmaa Namoos	Other	Yes
View	Namoos Resume	Dr. Namoos A. Biosketch 06.07.2021.pdf	0.01	4/3/2022 3:47 PM	Asmaa Namoos	CV/Biosketch	Not Applicable

ID: HM20024502 **HM20024502** View: SF2 - Consent Plan Complete

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Consent Plan Complete

Protocol Progress:
- **INITIAL SETUP**
- **BACKGROUND, RATIONALE & GOALS**
- **RESEARCH PLAN**
- **CONSENT PLAN**

⑤ RISKS, PRIVACY & CONFIDENTIALITY
⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
⑦ INSTITUTIONAL REQUIREMENTS
⑧ DOCUMENTS

Click Continue below to go to the next section

ID: HM20024502 **HM20024502**

View: SF2 - Risks, Discomforts, Potential Harms and Monitoring

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Risks, Discomforts, Potential Harms and Monitoring

1. * **Describe the risks of each research procedure to participants or others. For each identified risk, provide an assessment of the anticipated seriousness and likelihood of the risk. Some examples of possible risks include but are not limited to:**

   - **Physical risks (e.g. bodily harms or discomforts, side effects, etc.)**
   - **Psychological risks (e.g. emotional, mental, or spiritual harms or discomforts, changes to thoughts, beliefs, or behaviors, etc.)**
   - **Research data risks (e.g. loss of confidentiality and privacy)**
   - **Social or legal risks (e.g. impacts on relationships or reputation, legal or criminal justice actions for self or others, etc.)**
   - **Financial risks (e.g. impacts on income, employability, or insurability, loss of services, etc.)**
   - **Other risks (e.g. unforeseeable risks of experimental procedures, risks related to particular study designs (randomization, washout, placebo, withholding care/services, deception), etc.)**

   See the help text for additional guidance.

   Physical risks: NA

   Psychological risks: Participation in the study may entail psychological risks, as some of the questions asked may potentially cause discomfort or evoke emotional responses. It is important to note that participating in research inherently involves some level of privacy loss. Although stringent measures will be in place to protect your personal information, there is a small risk of unauthorized access or misuse of your data by individuals not involved in the research study. The research team is committed to maintaining confidentiality and ensuring the highest level of data security to minimize such risks.

   Research data risks: Participating in this research study may involve some degree of privacy loss. It is important to acknowledge that there is a small inherent risk that unauthorized individuals outside of the research study could potentially access and misuse your personal information. Additionally, there is a possibility of confidentiality breaches during the transfer and storage of research data. The research team is committed to implementing rigorous security measures to minimize these risks and ensure the confidentiality and integrity of your data.

   Social or legal risks: Participation in this study may involve social or legal risks related to cultural sensitivity. It is important to recognize and respect the diverse cultural backgrounds of participants and their communities. The

research team acknowledges the need to seamlessly interact with individuals from different cultures by understanding and adhering to the norms, customs, and values of each specific culture.

By promoting cultural sensitivity, the research team aims to create an inclusive and respectful environment for all participants. This involves taking proactive measures to ensure that research procedures, communication, and interactions are culturally appropriate and considerate. The team will make efforts to establish clear guidelines and provide training to researchers to enhance their cultural competence and sensitivity when working with participants from various cultural backgrounds.

By fostering a culturally sensitive approach throughout the study, the research team aims to minimize any potential social or legal risks that may arise due to cultural misunderstandings or insensitivity. This will help facilitate effective communication, build trust, and create an atmosphere where participants feel comfortable and respected in sharing their experiences and perspectives.

Financial risks : NA

2. * **Describe how each of the risks/harms/discomforts identified above will be minimized:**
Psychological Risks: To minimize psychological risks and address emotional discomfort, several measures will be implemented. Participants will have the option to take breaks during the study if needed, ensuring their well-being and allowing them to manage any emotional distress that may arise. Additionally, participants will be provided with resources and information about counseling services, should they require additional support. The research team is committed to ensuring that participants' mental health and emotional well-being are prioritized throughout the study.

Research Data Risks: To mitigate research data risks and ensure participant privacy, robust measures will be implemented. De-identification and coding processes will be employed to remove any identifying information from the data, ensuring confidentiality. The interview answers will be recorded using an electronic data capture system hosted on secure VCU servers accessible only to authorized researchers. These servers comply with stringent security protocols and maintain researcher-only access, further safeguarding the confidentiality of participant data.

Social or Legal Risks: To address social or legal risks, several strategies will be employed to ensure cultural sensitivity and community engagement. Expert researchers will review the educational sessions to ensure their appropriateness and alignment with cultural norms. Community leaders from the target population will provide input and review religious materials included in the sessions, ensuring cultural accuracy and relevance. The research assistant involved in the study is a member of the same community and has prior experience conducting studies in Islamic centers, establishing trust and rapport. The research team will consist of female members only, including the peer researcher and primary researcher, creating a safe and comfortable environment for participants. The education sessions will be conducted in a private setting within the mosque, respecting the cultural and religious values of the participants and maintaining privacy.

3. * **Describe any potential risks or harms to a community or a specific population based on study findings (e.g. information that could be stigmatizing or derogatory):**
The project will be conducted within the Islamic centers among a conservative community. It is important to note that there is no identified community risk associated with the study findings. The community's acceptance and support will be sought through the guidance of the Imam, who will introduce the research to the community. The research team has an established project with the community and maintains a community bridge, fostering trust and collaboration.

To ensure cultural sensitivity and appropriateness, the study material will undergo review by the Community Advisory Board (CAB). This review process will help ensure that the study findings, information, and materials are respectful, accurate, and align with the values and norms of the community. The involvement of the CAB adds an additional layer of protection against any stigmatizing or derogatory information.

By actively engaging with the community, seeking guidance from community leaders, and involving the CAB, the study

aims to minimize any potential risks or harms that may arise from the dissemination of study findings. The overall goal is to promote understanding, respect, and positive engagement within the community and to ensure that the study findings contribute to the well-being and empowerment of the target population.

4. **Where appropriate, discuss provisions for ensuring necessary medical, professional, or psychological intervention in the event of adverse events to the subjects:**
Provisions for ensuring necessary medical, professional, or psychological intervention in the event of adverse events to the subjects will not be applicable in this study. Since there are no anticipated medical, professional, or psychological risks associated with the study, the need for intervention or support services in response to adverse events is not expected. However, if any unforeseen adverse events were to occur during the study, the research team would take appropriate measures to address them promptly and ensure the well-being and safety of the participants.

5. * **Describe criteria for when the investigator would withdraw an individual participant from the study; such as safety or toxicity concerns, emotional distress, inability to comply with the protocol, etc.:**
The investigator may withdraw an individual participant from the study based on various criteria, including but not limited to:

   Safety Concerns: If the participant experiences any adverse effects or safety concerns related to the study procedures, interventions, or materials, the investigator may consider withdrawing the participant to ensure their well-being and safety.

   Emotional Distress: If the participant exhibits signs of emotional distress, such as symptoms of anxiety, feeling overwhelmed, or difficulty relaxing, the research assistant (RA) will be attentive and responsive. The RA will provide support and, if necessary, stop the conversation in a considerate manner. The participant will be given the choice to continue or discontinue the conversation, respecting their emotional well-being.

   Inability to Comply with the Protocol: If the participant faces challenges in complying with the study protocol, such as difficulty attending scheduled sessions, completing required tasks, or following instructions, the investigator may consider withdrawing the participant. This ensures that the study remains valid and maintains the integrity of the data.

   It is important to note that the participant will be informed of their right to withdraw from the study at any time without consequences. If the participant chooses to continue despite experiencing emotional distress, the RA will resume the conversation to prevent any potential embarrassment. The PI will be notified of the situation, and the study team will review the participant's case and make a decision on whether to continue their participation or withdraw them from the study, taking into consideration their well-being and the study's objectives.

6. * **Summarize any pre-specified criteria that would trigger the investigator/sponsor/monitoring committee to stop or change the study protocol due to safety concerns:**
The research team follows the VCU policy regarding safety concerns. Since we are in a critical time of year due to the covid 19 crisis, the study could stop/hold due to the pandemic. This will be done according to the research workflow at VCU.

   Data and Safety Monitoring
   Data and safety monitoring is a system for checking the study's data at regular intervals over the study period to identify and address issues that could affect the safety of research participants. This requirement is in accordance with 45 CFR 46.111.

   The purpose of data and safety monitoring plan is to set forth study team procedures for monitoring/addressing:
   - Participant safety (physical, psychological, etc.)
   - Data validity
   - Early stopping (termination) based upon changes in risks and benefits.

7. * **Indicate if this study will have a Data Safety Monitoring Board (DSMB) or a Data Safety Monitoring Plan (DSMP): [Required for all greater than minimal risk studies]**

- ☐ DSMB
- ☐ DSMP
- ☑ **No DSMB/DSMP [Note: This response is not applicable for greater than minimal risk studies]**

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Privacy

Privacy refers to an individual's right to control how others view, record, or obtain information about them. When privacy is violated it can involve such things as

- Being asked personal questions in a public setting;
- Being publicly identified as having a particular characteristic or diagnosis;
- Being seen entering a place that might be stigmatizing;
- Being photographed, videotaped or observed without consent;
- Disclosure of personal information to unauthorized people

Privacy is not the same as confidentiality because privacy protections apply to people, and confidentiality protections apply to data. Confidentiality protections should be described on the Data Confidentiality page of this form, not here.

Instructions for this page:

Select all the applicable ways that the research team will protect participants' privacy throughout the course of the study. The options listed include some of the most common best practices. Not all will be applicable to every study.

****The IRB will expect studies to operationalize all selected checkboxes into the conduct of the research.**

To elaborate on any response, also click the "Other Protections" checkbox to provide further explanation in the last free-text question.

Read the entire page before filling out the form.

1. * **Protections when conducting one-on-one in-person interventions or interactions (for groups see Q2 below):**
   - [x] **Conducting study activities in locations that maximize privacy (limited people around, closing doors, drawing drapes around beds, monitoring voice volume, etc.)**
   - [x] **Verifying identity before discussing personal information.**
   - [x] **Asking the participant if they are comfortable answering questions in that location**
   - [x] **Asking the participant if they are comfortable with having other people present (if any)**
   - [x] **Moving away from other people when conducting activities in public spaces or offering a private space**

- [x] **Offering other options of ways to respond to sensitive questions (i.e. pointing, clicking, or writing) if uncomfortable verbally responding**
- [ ] Using generic signs on research rooms and spaces, particularly for research on stigmatizing or sensitive topics
- [ ] Other protections not listed in this question – describe below
- [ ] N/A – study has no in-person interventions or interactions with participants

2. * **Protections when conducting group interventions or interactions:**

- [x] **Conducting study activities in locations that maximize privacy (limited people passing by, closing doors, monitoring voice volume, etc.)**
- [x] **Moving to a more private area to answer questions or to discuss concerns**
- [x] **Discussing privacy with the participants and the importance of not talking outside the group about what other people say during the group session**
- [x] **Allowing participants to use a pseudonym or limiting use of individuals' names during the group activity**
- [x] **Asking everyone in a public group setting (e.g. classrooms, workshops) to turn something in (blank or filled) so participants do not have to self-identify when turning in materials**
- [x] **Collecting paper forms in a closed box or envelope rather than passing to others or leaving in an open area**
- [x] **Limiting participant identifiers that would be visible on paper documents (i.e. using study IDs instead of direct identifiers)**
- [x] **Allowing people to distance themselves from other participants during group activities**
- [ ] Offering other options of ways to respond to sensitive questions (i.e. pointing, clicking, or writing instead of speaking)
- [ ] Using generic signs on research rooms and spaces, particularly for research on stigmatizing or sensitive topics
- [ ] Ensuring non-participating individuals are not captured on recordings or in photos
- [ ] Other protections not listed in this question – describe below
- [ ] N/A – study has no group interventions or interactions

3. * **Protections when conducting remote interventions or interactions (e.g. phone, text, email, video-conference, tele-health, online, etc.):**

- [ ] Conducting study activities in locations where study staff can maximize their own privacy (limited people around, closing doors, monitoring voice volume, etc.)
- [ ] Leaving/sending generic messages that avoid using study and participant identifiers, such as names, study titles, clinics, study topics, etc.
- [ ] Obtaining permission prior to sending text messages
- [ ] Advising the participant to move to a location where they are comfortable answering questions and will not be overheard - incorporate this instruction into your study materials
- [ ] Advising online participants to complete the activity at a time and location where they will be comfortable answering questions - incorporate this instruction into your study materials
- [ ] Ensuring non-participating individuals are not captured on recordings or in photos
- [ ] Offering other options of ways to complete the activity (i.e. online, paper, phone) if more privacy is desired
- [ ] Offering a way to save and return later to the online activity if privacy is compromised
- [ ] Other protections not listed in this question – describe below
- [x] **N/A – study has no remote interventions or interactions with participants**

4. * **Protections when mailing study materials to/from participants:**

- [x] **Obtaining permission to mail study materials**
- [x] **Confirming/verifying the accuracy of addresses before mailing items**
- [x] **Ensuring the participant is able to personally receive mailed materials and has a way to protect their own privacy if they do not want others to know they are receiving research communications (i.e. notifying participants of when to expect it)**
- [x] **Using return address labels and document headers that avoid study identifiers, such as study names, clinics, study topics, etc.**
- [x] **Avoiding or limiting use of participant identifiers and health information on mailed documents (i.e. using study IDs instead of direct identifiers)**
- [x] **Providing a return mailing address label or pre-addressed envelope to ensure returned items are sent to the correct address**
- [x] **Communicating receipt of mail from participants and/or asking them to notify you when they mail it to ensure study documents are not lost in transfer**
- [x] **Offering other options of ways to complete the activity (i.e. by phone or online) if desired**

- [ ] Other protections not listed in this question – describe below
- [ ] N/A – not mailing any materials to/from participants

5. * **Protections when analyzing or disseminating study data** *Applicable to all studies*:

- [x] **Working only in locations where the study team can ensure privacy (not working in close proximity to non-study personnel, closing doors, closing/putting away documents/files before leaving, etc.)**
- [x] **Securing physical materials only in locations that ensure privacy (access limited to authorized study personnel)**
- [ ] Obtaining explicit parental permission before disseminating or sharing recordings or photos of children
- [ ] Blurring/redacting/hiding faces and other identifiable features/marks (tattoos, scars, birthmarks, distinctive voice, etc.) in recordings or photos prior to disseminating or sharing
- [x] **Only publishing or presenting aggregate results or findings (i.e. no individual-level information)**
- [x] **Taking additional steps to protect participant identities when publishing or presenting individual-level information, quotations, results, images – describe below**
- [ ] Other protections not listed in this question – describe below

6. Describe any other way(s) that the research team will protect participants' privacy. *See the help text for additional guidance*.

During our intervention we will take pictures after verbal approval from the ladies who are in the room, for more protection we will blurred the faces and use these pictures during conference only.

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Data Confidentiality and Storage

Confidentiality refers to the way private, identifiable information about a participant or defined community is maintained and shared. It describes how the study's research materials (data, specimens, records, etc.) are protected from unauthorized access.

Instructions for this page:
Select all the ways that the research team will keep the study materials and data confidential throughout the course of the study. Not all will be applicable to every study.
To elaborate on any response, also click the "Other Protections" checkbox to provide further explanation in the last free-text question.

Read the entire page before filling out the form.

1. * **Protections for paper research materials:**

- [x] **Maintaining control of paper documents at all times, including when at an off-campus location**
- [x] **Limiting or avoiding use of participant identifiers on paper documents (i.e. using study IDs instead of direct identifiers)**
- [x] **Storing paper documents in a secure location accessible only to authorized study personnel**
- [x] **Promptly transcribing, scanning, or abstracting data from paper into electronic platforms with destruction of the paper copy**
- [x] **Proper destruction of paper records (and obtaining prior permission when required) in accordance with VCU Records Management policies**
- [ ] Other protection not listed in this question – describe below
- [ ] N/A – no paper research materials

2. * **Protections for research specimens:**

- [ ] Maintaining control of specimens at all times, including when at an off-campus location
- [ ] Storing specimens in a secure location accessible only to authorized study personnel
- [ ] Labeling specimens with subject ID or other coded information instead of direct identifiers

- [ ] Final destruction of specimens will be in accordance with VCU policies and specimen containers will be devoid of any identifiable information
- [ ] Other protection not listed in this question – describe below
- [x] **N/A – no research specimens**

3. * Protections for electronic files/data - See https://ts.vcu.edu/about-us/information-security/data-management-system/

- [x] ***Required for all studies* Use VCU-approved methods of data storage, transmission, and transfer (see https://dms.vcu.edu)**
- [x] **Remotely accessing VCU network storage to store data when at off-campus locations**
- [x] **Ensuring unauthorized individuals who might share a device do not have access to study materials (e.g. individual logins, separate accounts)**
- [x] **Using VCU-approved data collection tools and apps (e.g. REDCap) and storing exported analysis files in VCU-approved storage locations (see https://dms.vcu.edu)**
- [ ] When using non-VCU-approved electronic data collection tools, storage locations, data transfer platforms, and mobile apps (e.g. Dropbox, Box, Survey Monkey, Fitbits, novel apps, multi-site data collection platforms):
  • consulting with VCU Information Security on proper data management (see https://ts.vcu.edu/askit/essential-computing/information-security/);
  • advising participants about the terms of use and privacy policies of those sites/apps;
  • limiting or avoiding use of identifiers; and
  • removing data promptly from the external location after transferring it to a VCU storage location
- [x] **De-identifying the research data by replacing subjects' names with assigned subject IDs**
- [x] **Storing the study's linkage key in a password-protected and VCU-approved storage location (see https://dms.vcu.edu)**
- [ ] When analyzing particularly sensitive information, using computers that are unconnected from the internet.
- [x] **Proper destruction of electronic records (and obtaining prior permission when required) in accordance with VCU Records Management policies**
- [ ] Other protection not listed in this question – describe below

4. * Protections for computers and research devices/apps that are <u>provided to participants</u> for use in the study and taken out of the lab (i.e., giving participants a phone or iPad to take home, wearable trackers, apps, etc.):

- [ ] Transferring data promptly from the device/app given to the participant to a VCU storage location
- [ ] Setting strong passwords on computers and research devices (when applicable) that leave VCU with participants
- [ ] Device/app set up by VCU Information Security

- [ ] When providing devices or mobile apps to children, informing parents about the settings and how to manage them (if applicable), internet access, and any other installed apps on the device
- [ ] Other protection not listed in this question – describe the device/app and protection below
- [x] **N/A – no computers or devices/apps being provided for participant use outside the lab**

5. * Protections for email/online communications

- [x] **Only using VCU/VCU Health email addresses for study-related communications**
- [x] **Only using VCU/VCU Health–approved methods of teleconferencing or video conferencing (e.g. Zoom) (for studies involving HIPAA, contact VCU or VCU Health Information Security [as appropriate] about HIPAA-compliant systems)**
- [ ] Other protection not listed in this question – describe below
- [ ] N/A – no email/online communications

6. Specify any other places where this study's paper and electronic research data and/or physical specimens will be stored and any other ways they will be secured from improper use and disclosure.

See the help text for additional guidance.
NA

7. * If research data/specimens will be sent/released to person(s) or group(s) outside of the VCU study team or the PI's department for the conduct of this protocol (not for future sharing),
1) identify the data/specimen recipient(s) along with their VCU department or other institutional or organizational affiliation(s).
2) give a description of what identifiers and/or codes will accompany the data/specimens.
If data/specimens are not being sent/released outside of the VCU study team or the PI's department, state that:
NA

8. * Select all identifiers that will be collected <u>at any time</u> as part of this study (including for recruitment, data gathering, data analysis, etc.), even if the data will eventually be anonymized:

- [x] **Names**
- [x] **Geographic Locators Below State Level**
- [ ] Social Security Numbers
- [ ] Dates (year alone is not an identifier)
- [ ] Ages over 89 (age under 89 is not an identifier)
- [x] **Phone Numbers**

- [ ] Facsimile Numbers
- [ ] E-mail Addresses
- [ ] Medical Record Numbers
- [ ] Device Identifiers
- [ ] Biometric Identifiers
- [ ] Web URLs
- [ ] IP Addresses
- [ ] Account Numbers
- [ ] Health Plan Numbers
- [ ] Full Face Photos or Comparable Images
- [ ] License/Certification Numbers
- [ ] Vehicle ID Numbers
- [ ] Other Unique Identifier
- [ ] No Identifiers
- [ ] Employee V#

9. * **If the study will code (i.e. de-identify) the research data by replacing subjects' names and/or other identifiers with assigned subject IDs, explain the following aspects of the coding process:**

- The process for how subject IDs will be generated/assigned (e.g. random, sequential)
- Whether there will be a key that links the subject ID with direct identifiers. If there will be no linkage key, state that.

If a key will be created, describe
- The place where the key will be stored
- The role(s) of all individuals who will have access to the key
- When the key will be destroyed

See the help text for guidance.

In this study, the research data will be coded by replacing participants' names and other identifiers with assigned subject IDs to ensure confidentiality and protect privacy. The coding process will follow the following aspects:

Generation/Assignment of Subject IDs: Subject IDs will be generated using a random assignment process. Each participant will be assigned a unique identifier that is unrelated to their personal information or characteristics. This random assignment helps maintain anonymity and protects the participants' identities.

Linkage Key and Storage: A linkage key will be created to associate the original patient identifiers with the assigned subject IDs. However, in this study, there will be no linkage key that links the subject ID back to direct identifiers. The coding process ensures that the data remains de-identified and confidential.

Storage of the Linkage Key: If a linkage key were created, it would be stored separately in the secure REDCap database. Only the Principal Investigator (PI) would have access to the linkage key. The PI would be responsible for safeguarding the confidentiality of the key and ensuring that access is restricted to authorized individuals.

Access to the Linkage Key: The PI would be the sole individual with access to the linkage key. This access is granted to ensure the integrity of the coding process and to maintain the confidentiality of the participants' data. No other individuals involved in the study would have access to the linkage key to further ensure the security and privacy of the participants' information.

Destruction of the Linkage Key: Once the study is completed, the original identifiers and linkage keys will be securely destroyed. This step ensures that any potential re-identification of participants' data is prevented, further protecting their privacy and confidentiality.

By employing these coding procedures and secure storage practices, the study ensures that participants' data remains de-identified and confidential throughout the research process.

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Data Retention

1. * **Select all of the ways that individually identifiable information obtained during pre-screening and/or screening will be handled for individuals who DO NOT qualify for the study:**

- [x] **N/A - study does not require screening procedures**
- [ ] Immediately destroy the information and identifiers (no data collected)
- [ ] Immediately destroy the identifiers connected with the data (anonymization)
- [ ] Store until the end of study & then destroy
- [ ] Use as "screening failure" data by members of the study team
- [ ] Provide to others outside of the research team (with the participant's permission)
- [ ] Request permission from participant to maintain and use the identifiable information
- [ ] Other

2. * **Will participants be able to withdraw their data (paper, electronic, or specimens) from the study (e.g. ask that it be destroyed or returned) if they no longer wish to participate? (FDA-regulated studies should select No – see help text)**

- ○ Yes
- ● **No**

3. * **What will happen to the research materials (e.g. data, specimens, documents, etc.) when the research has been completed?**

- ○ Stored indefinitely with identifiers removed
- ○ Stored indefinitely with identifiers attached

- (●) **Destroyed at the end of study once the minimum time required for data retention has been met per VCU Data Retention Policy and/or sponsor retention requirements**
- ( ) Destroyed when notified by sponsor but not less than the minimum time required for data retention per VCU Data Retention Policy
- ( ) Other

4. * **Will audio/video recordings and full face photographs be destroyed?**

- (●) **Yes**
- ( ) No

5. If yes, describe at what point and how recordings will be destroyed:
They will be destroyed at the end of the study.

6. If no, explain why the recordings need to be maintained:

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Sharing Plan

This page addresses times when investigators may be required to share information about participants or may desire to share their research information/specimens with the aim of advancing science. This page creates a plan for when and how information/specimens could be shared.

Try to anticipate all reasonably foreseeable sharing so that the consent document can also reflect that information. However, it is acceptable to amend this page later and explain either how re-consent of previously and currently enrolled participants will occur or why re-consent should not be required.

The IRB reviews this page against the consent document (if one exists) to demonstrate the ethical principle of Respect for Persons by confirming that plans for sharing do not go against what participants would understand about the use of their data/specimens.

The IRB also ensures there are adequate protections for the privacy of participants and the confidentiality of participants' data/specimens when data is shared with others.

1. * **Is it likely investigators could discover information about child/elder abuse or neglect that would require mandatory reporting by the investigators or staff?**

   The Code of Virginia requires that most medical personnel and all employees of institutions of higher education report suspected child/elder abuse or neglect.

   ○ Yes

   ● **No**

2. * **Is it likely investigators could discover a previously unknown reportable disease or condition that would require mandatory reporting by the investigators or staff (i.e., HIV , coronavirus, hepatitis, etc.)?**

   ○ Yes ● **No**

3. * **Will the sponsor or investigator obtain a Certificate of Confidentiality for this study?**

   Certificates of Confidentiality (CoC) are issued by the National Institutes of Health (NIH), the FDA and CDC to protect identifiable research information from forced disclosure. All human subject research studies regardless of funding can qualify to receive a CoC. A CoC is automatically issued for research that was ongoing on December 13, 2016. or initiated after that date. For more information, see https://humansubjects.nih.gov/coc/

○ No – Will not obtain CoC for this study

● **Yes – CoC has been obtained or issued automatically**

○ Yes – CoC request is pending

4. * **Select the way(s) that information or biospecimens (including DNA) may be used by the VCU PI or VCU study team for other future research projects (i.e. analyses beyond/apart from the aims of this study)?**
See help text for definitions.

☐ Will use directly identifiable information or specimens.

('Directly identifiable' means that identifiers like name, medical record number, social security number, etc. are included in/attached to the dataset/specimens. Maintaining identifiable data for future research is treated as a registry by the VCU IRB. The IRB must approve the new research use in an amendment to this study or as part of a new study before the project is initiated. VCU IRB studies will be asked more questions about this on a later page)

☐ Will use de-identified or indirectly identifiable information or specimens.

('De-identified' means that a linkage/key code exists that links identifiers to data/specimens. When the researcher holds both the data and the key, the VCU IRB considers the subjects to be readily identifiable. Maintaining identifiable data for future research uses is treated by the IRB as a registry. The IRB must approve the new research use in an amendment to this study or as part of a new study before the project is initiated. VCU IRB studies will be asked more questions about this on a later page)

☐ Will use anonymized information or specimens.

('Anonymized' means that 1) no linkage/key codes exist that link identifiers to data/specimens; and 2) subjects cannot be readily identified, i.e. no direct or indirect identifiers or identifiable combinations of variables. The VCU IRB considers uses of anonymized data/specimens to not be human subject research.)

☐ Will use aggregate results (summary-level results), not individual-level information or specimens.

(The VCU IRB considers uses of aggregate data to not be human subject research because there are no individual subjects.)

☐ Will contribute to an existing registry or repository

(VCU IRB studies will be asked more questions about this on a later page.)

☐ Will not use information/specimens for purposes beyond this study.

☑ **Not sure and will submit an amendment when known**

☐ Other use(s) of individual-level information in a way not listed above

5. * **Select the way(s) the VCU PI/study team may share information or biospecimens (including DNA) with other researchers who are not on this study team (i.e. for analyses beyond/apart from the aims of this study).** ***See help text for definitions.***

Will share directly identifiable information or specimens with other researchers.

☐ *('Directly identifiable' means that identifiers like name, medical record number, social security number, etc. are included in/attached to the dataset/specimens. Maintaining identifiable data for future research uses is treated by the VCU IRB as a registry. The data recipient's use of identifiable data would require them to obtain IRB review. VCU IRB studies will be asked more questions about this on a later page.)*

Will share de-identified or indirectly identifiable information or specimens with other researchers.

☐ *('De-identified' means that a linkage/key code exists that links identifiers to data/specimens. The VCU researcher maintains the key but does not share it with any other researchers. The recipient's use of de-identified data/specimens may not be human subject research if there is documentation that the key will never be shared with the recipient, but they should check with their own IRB about review requirements. VCU IRB studies will be asked more questions about this on a later page.)*

Will share anonymized information or specimens with other researchers.

☑ *('Anonymized' means that 1) no linkage/key codes exist that link identifiers to data/specimens; and 2) subjects cannot be readily identified (i.e. no direct or indirect identifiers or identifiable combinations of variables). The VCU IRB considers uses of anonymized data/specimens by other researchers to not be human subject research, but the recipient should check with their own IRB about review requirements.)*

Will only share aggregate results (summary-level results), not individual-level information or specimens.

☐ *(The VCU IRB considers uses of aggregate data to not be human subject research because there are no individual subjects. The data recipient should check with their own IRB about review requirements.)*

☐ Will contribute to an existing registry or repository (VCU IRB studies will be asked more questions about this on a later page.)

☐ Will submit data to an NIH genomic data repository (VCU IRB studies will be asked more questions about this on a later page.)

- [ ] Will not share information/specimens with other researchers.
- [ ] Not sure and will submit an amendment when known
- [ ] Other sharing of individual-level information with other researchers

6. * Since you responded in a question above that you may use or share anonymous, individual level data, indicate why the proposed use or sharing of anonymous data/specimens is not inconsistent with what participants would have reasonably understood from the consent document about the uses of their information. (Select all that apply.)

- [x] **The consent form states that after identifiers are removed, information or specimens could be used for future research studies without additional informed consent from the subject (this is a new element of consent included in consent templates as of May 2018)**
- [ ] The consent form or exempt information sheet is silent about whether/how information or specimens could be used for future research studies.
- [ ] The information or specimens were/will be obtained under a waiver of informed consent, waiver of HIPAA authorization, or an exempt study that did not use an information sheet.
- [ ] Other reason why anonymous use/sharing is not inconsistent with the consent document

7. * The Principal Investigator certifies that prior to releasing an anonymized dataset or anonymized specimens the following conditions will all be met:

- all 18 HIPAA identifiers (including all dates) will be removed;
- all indirectly identifiable data elements (unusual, rare, uncommon data) will be removed, grouped, suppressed, or otherwise transformed to no longer be readily identifiable;
- a different subject ID will be assigned than the one used for the main study and a linkage key will not be kept; and
- the PI will review the dataset/specimens to confirm that the remaining information could not be used alone or in combination with any other information to re-identify the participants represented in the data.

***See help text for more information*.**

- (●) **Yes**
- ( ) No

8. * The Principal Investigator certifies that after the study has been closed with the VCU IRB, the following conditions will be met whenever individual level research information and/or specimens are used or shared:

- The identities of participants who are represented in the dataset/specimens will not be readily ascertainable or otherwise re-identifiable by the recipient;
- If a linkage/code key is created, it will be maintained at VCU and not shared with the recipient under any circumstances;
- The PI will have no knowledge that the remaining information could be used alone or in combination with

any other information to identify the individuals represented in the data; and
- The PI agrees to abide by this sharing plan even after the study has been closed with the VCU IRB.

- (●) **Yes**
- ( ) No
- ( ) N/A - No sharing will occur

9. If the Certificate of Confidentiality has been obtained by the PI, upload it here:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent form focus group	Namoos- Consent from of focus group 05.12.2023.pdf	0.03	7/8/2023 1:09 AM	Asmaa Namoos	Consent/Assent/Information Sheet	Yes
View	Consent form - Intervention program	Namoos- Consent from of Intervention group 05.12.2023 copy.pdf	0.04	7/8/2023 1:09 AM	Asmaa Namoos	Consent/Assent/Information Sheet	Yes
View	Fund Plan	Asmaa -Budget 04.13.2023.xlsx	0.03	5/12/2023 11:52 AM	Asmaa Namoos	Funding Proposal	Not Applicable
View	Education session	Asmaa Education session guide , intervention group- 04.07.2023.docx	0.02	5/12/2023 10:52 AM	Asmaa Namoos	Other	Yes
View	Timeline Plan	Namoos, timeline for PROMIS women Project-.docx	0.02	5/12/2023 10:43 AM	Asmaa Namoos	Other	Yes
View	Conceptual model	Asmaa Conceptual Model 05.12.2023.docx	0.02	5/12/2023 10:40 AM	Asmaa Namoos	Research Measure	Yes
View	Flayer 2	Asmaa Flyer Version 05.12.2023.docx	0.01	5/12/2023 10:39 AM	Asmaa Namoos	Other	Yes

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Namoos-Focus group script guide	Namoos -Focus Group Script Guide.docx	0.02	5/12/2023 10:24 AM	Asmaa Namoos	Other	Yes
View	Participants -RA communication script	Namoos-Participants -RA communication script .docx	0.01	5/12/2023 6:45 AM	Asmaa Namoos	Other	Yes
View	Study Survey(Pre-post and satisfactory scales)	Survey- Promise women project 05.12.2023.docx	0.01	5/12/2023 6:35 AM	Asmaa Namoos	Research Measure	Yes
View	consent form-focus group	Consent from - Focus group 02.20.2023.docx	0.01	2/20/2023 4:32 PM	Asmaa Namoos	Consent/Assent/Information Sheet	No
View	VS biosketch	Sheppard Biosketch for AN 11.14.2022.pdf	0.01	2/20/2023 4:00 PM	Asmaa Namoos	CV/Biosketch	Not Applicable
View	Communication log	Communication log.docx	0.01	2/20/2023 3:59 PM	Asmaa Namoos	Other	Yes
View	PRMC approval	2022-10-10_MCC-22-19873_PRMC Approval Letter.pdf	0.01	10/10/2022 12:30 PM	Asmaa Namoos	Ancillary Committee Approval	Not Applicable
View	Flyer	Flyer 004.08.2022.png	0.01	4/8/2022 6:09 PM	Asmaa Namoos	Other	Yes
View	Namoos Resume	Dr. Namoos A. Biosketch 06.07.2021.pdf	0.01	4/3/2022 3:47 PM	Asmaa Namoos	CV/Biosketch	Not Applicable

ID: HM20024502 **HM20024502**

View: SF2 - Pertinent Results and Incidental Findings

HM20024502 - Vanessa Lavene Sheppard
PROMIS WOMAN Education Program : ImProving ceRvical cancer preventiOn methods among Muslim AmerIcans WOMEN

Pertinent Results and Incidental Findings

1. * **Is it likely investigators could discover a participant's previously unknown condition (e.g. pregnancy, disease, suicidal thoughts, wrong paternity, genetic results, or other findings that may be of importance to health or well-being) or if a participant is engaging in illegal or reportable activities:**

   ○ Yes

   ● **No**

ID: HM20024502 **HM20024502** View: SF2 - Risk Benefit Complete

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Risk Benefit Complete

Protocol Progress:
- ● **INITIAL SETUP**
- ● **BACKGROUND, RATIONALE & GOALS**
- ● **RESEARCH PLAN**
- ● **CONSENT PLAN**
- ● **RISKS, PRIVACY & CONFIDENTIALITY**
- ⑥ POPULATIONS WITH SPECIAL CONSIDERATIONS
- ⑦ INSTITUTIONAL REQUIREMENTS
- ⑧ DOCUMENTS

Click Continue below to go to the next section

ID: HM20024502 **HM20024502**

View: SF2 - Populations with Special Considerations

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Populations with Special Considerations

1. * **Check all participant groups that will be either**

a) Specifically included in this study or

b) Discernable in the research data/specimens.

(Selections will branch)

- [ ] Children
- [ ] Emancipated minors
- [ ] Wards of the State
- [ ] Pregnant women or fetuses
- [ ] Neonates or Post-delivery Materials
- [ ] Prisoners
- [ ] Decisionally Impaired Adults
- [ ] VCU / VCUHS students or trainees
- [ ] VCU / VCU Health System employees
- [ ] Individuals with limited English proficiency
- [ ] Active military personnel
- [ ] Student populations in K-12 educational settings or other learning environments

- [ ] Members of a federally recognized American Indian and Alaska Native tribe
- [x] **None of the Above**

ID: HM20024502 **HM20024502**

View: SF2 - Populations with Special Considerations Section Complete

HM20024502 - Vanessa Lavene Sheppard
PROMIS WOMAN Education Program : ImProving ceRvical cancer preventiOn methods among Muslim AmerIcans WOMEN

Populations with Special Considerations Section Complete

Protocol Progress:
- ● **INITIAL SETUP**
- ● **BACKGROUND, RATIONALE & GOALS**
- ● **RESEARCH PLAN**
- ● **CONSENT PLAN**
- ● **RISKS, PRIVACY & CONFIDENTIALITY**
- ● **POPULATIONS WITH SPECIAL CONSIDERATIONS**
- ⑦ INSTITUTIONAL REQUIREMENTS
- ⑧ DOCUMENTS

Click Continue below to go to the next section

ID: HM20024502 **HM20024502** View: SF2 - Study Funding

HM20024502 - Vanessa Lavene Sheppard
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Study Funding

1. * Have you applied for funding:

- (●) **Yes**
- ( ) No

2. Is this study already funded:

- (●) **Yes**
- ( ) No

3. * Select all funding sources for this study (pending or awarded):

- [ ] Industry
- [x] **Direct Federal**
- [ ] Indirect Federal
- [ ] State/Local Government
- [ ] Non-Profit - Sponsored Project
- [ ] Non-Profit - Gift
- [ ] Internal Grant
- [ ] Investigator/Departmental Funds
- [ ] None
- [ ] Other

4. * **In addition to providing funding support, what is the funding source's role in this study? Select all that apply:**

- [x] **Solely providing funding support**
- [ ] Providing resources (e.g. study drug, device)
- [ ] Providing guidance to the researcher but does NOT make decisions about study design
- [ ] Study design/Creation of the study protocol
- [ ] Collaborator in the research (helps design and/or conduct the study) [list the funder as a site on the Types of Sites page]
- [ ] Data or sample analysis regardless of identifiability

5. **Select all related funding proposals and contracts that have been submitted through the Division of Sponsored Programs (DSP):**

RAMS-SPOT ID# (FP/PT/PD#)	Direct Sponsor	PI	Title	Status	Start	End
FP00018540	University of Kentucky	Asmaa Namoos	PROMIS Women Project	Agreement Received for Negotiation		
FP00019256	National Cancer Institute/NIH/DHHS	Asmaa Namoos	Promote Cervical Cancer Prevention Methods among Muslim Women in Virginia	Proposal Under Sponsor Review		

6. **If the following conditions are ALL met, provide the index code where the HRPP will charge Single IRB (sIRB) fees associated with this review:**
   1. **The study is externally funded (fees do not apply if the study is not funded), AND**
   2. **Multiple sites are executing the same research protocol (i.e. multicenter research), AND**
   3. **VCU IRB will provide IRB review on behalf of one or more non-VCU sites**

7. * **Does the funder require the IRB to review this proposal for grant congruence?**

- ○ Yes
- ● **No**

ID: HM20024502 **HM20024502** View: SF2 - Types of Sites

HM20024502 - Vanessa Lavene Sheppard
PROMIS WOMAN Education Program : ImProving ceRvical cancer preventiOn methods among Muslim AmerIcans WOMEN

Types of Sites

VCU Site Information

1. * Select all VCU sites that will be utilized in this study:

- [ ] Children's Hospital of Richmond at VCU
- [ ] Clinical Research Services Unit (CRSU)
- [x] **Massey Cancer Center**
- [ ] VCU Health Community Memorial Hospital
- [ ] VCU Health Tappahannock Hospital
- [ ] VCU Medical Center
- [ ] Other VCU Health Location
- [ ] VCU Monroe Park Campus
- [ ] VCU Qatar
- [ ] Other VCU Site

Non-VCU Site Information

Non-VCU sites should be selected whenever any of the following situations apply:
a) Non-VCU sites that will be collaborating on a VCU-led study (i.e. involved in conducting the research, including being involved in the study interpretation or analysis of data and/or authorship of presentations or manuscripts related to the research.)
b) Non-VCU sites that will be deferring to the VCU IRB for IRB review
c) Non-VCU sites where VCU investigators will be overseeing study interventions or interactions
d) Non-VCU sites/locations where VCU investigators will conduct study activities

2. * Select any of the following non-VCU sites utilized in this study:

- [ ] McGuire VAMC
- [ ] Foreign Sites
- [x] **Other Non-VCU Sites**
- [ ] No Non-VCU Sites

3. * **Is this a multi-center study being led by VCU?**

○ Yes ● **No**

4. * **List all Non-VCU sites and locations:**

Provide information only for sites that have agreed to participate or given permission for study activities to occur. For Single IRB studies where VCU will be the IRB of record, list all anticipated sites that will rely on VCU IRB, and in their Role indicate that site-specific materials and agreements will be submitted in amendments.

	Name	Role	Adequacy	IRB	FWA Consultant(s)
View	The University of Kentucky	The University of Kentucky (UK) collaborates with VCU investigators by actively participating in research studies. Their role may observing the recruitment process and contributing to manuscript writing. They are not solely a location for VCU investigators but actively engage in various research activities.	In the context of research conducted at VCU collaboration with the University of Kentucky (UK) , human participant safety will be observed by VCU and overseen by their Institutional Review Board (IRB). VCU, as the responsible institution, ensures that appropriate measures are in place to protect the safety and well-being of participants in the event of an unanticipated emergency. The VCU IRB provides oversight and guidance to ensure that all necessary precautions are taken to safeguard the participants throughout the research process.	Site Engaged -- Requests to Rely on VCU IRB Review	

5. * **How will communication occur between sites for discussion of study conduct, unexpected problems, project modifications, and interim results:**
Consider the following in your response:
- how frequently communication will occur between sites
- how are sites instructed to report unanticipated problems, adverse events, or noncompliance
- how sites can communicate needed revisions to study procedures
- who will disseminate IRB decisions

- who will notify the IRB of potential problems and changes to the protocol

Frequency of Communication:

-Regular communication should occur between sites (Islamic centers) to ensure coordination and address any issues that arise during the study.
-Weekly or bi-weekly conference calls or virtual meetings can be scheduled to discuss ongoing study activities, progress, and any concerns or modifications required.

Reporting Unanticipated Problems, Adverse Events, or Noncompliance:

-Sites should be instructed to promptly report any unanticipated problems, adverse events, or instances of noncompliance to the designated study coordinator or principal investigator.
-A reporting mechanism, such as an electronic reporting system or a designated email address, should be established to ensure efficient communication and documentation of such events.

Communicating Revisions to Study Procedures:

If sites identify the need for revisions to study procedures, they should communicate these changes to the study coordinator or principal investigator.
This can be done through written reports or by submitting a formal request outlining the proposed modifications along with supporting justifications.
The study coordinator or principal investigator will review these proposed revisions and decide whether they are appropriate and feasible. If approved, the revised procedures will be communicated back to all sites.

Dissemination of IRB Decisions:
The Institutional Review Board (IRB) decisions, such as approvals, modifications, or disapprovals, will be disseminated by the study coordinator or principal investigator.
The study coordinator or principal investigator will ensure that all relevant sites are informed of the IRB decisions in a timely manner.
This can be done through official written communication, email, or a secure online portal where study documents and updates are shared.
Notifying the IRB of Potential Problems and Changes to the Protocol:

It is the responsibility of the study coordinator or principal investigator to notify the IRB of any potential problems or significant changes to the study protocol.
This includes reporting adverse events, noncompliance issues, or any modifications that may impact participant safety or the scientific integrity of the study.
The study coordinator or principal investigator will follow the IRB's designated procedures for reporting such events or changes and ensure timely communication to the IRB.

6. **For Non-VCU Sites: For each site or institution listed as "Site Engaged -- Requests to Rely on VCU IRB Review," upload:**

- Completed Local Context Form for Relying on VCU's IRB
- Site specific informed consent form(s) and HIPAA authorization(s), if applicable

For Foreign Sites: For each Cultural Consultant upload a CV/Biosketch that includes a clear description of cultural expertise:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent form focus group	Namoos- Consent from of focus group 05.12.2023.pdf	0.03	7/8/2023 1:09 AM	Asmaa Namoos	Consent/Assent/Information Sheet	Yes
View	Consent form - Intervention program	Namoos- Consent from of Intervention group 05.12.2023 copy.pdf	0.04	7/8/2023 1:09 AM	Asmaa Namoos	Consent/Assent/Information Sheet	Yes
View	Fund Plan	Asmaa -Budget 04.13.2023.xlsx	0.03	5/12/2023 11:52 AM	Asmaa Namoos	Funding Proposal	Not Applicable
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View	Conceptual model	Asmaa Conceptual Model 05.12.2023.docx	0.02	5/12/2023 10:40 AM	Asmaa Namoos	Research Measure	Yes
View	Flayer 2	Asmaa Flyer Version 05.12.2023.docx	0.01	5/12/2023 10:39 AM	Asmaa Namoos	Other	Yes
View	Namoos-Focus group script guide	Namoos -Focus Group Script Guide.docx	0.02	5/12/2023 10:24 AM	Asmaa Namoos	Other	Yes
View	Participants -RA communication script	Namoos- Participants -RA communication script .docx	0.01	5/12/2023 6:45 AM	Asmaa Namoos	Other	Yes
View	Study Survey(Pre-post and satisfactory scales)	Survey- Promise women project 05.12.2023.docx	0.01	5/12/2023 6:35 AM	Asmaa Namoos	Research Measure	Yes
View	consent form- focus group	Consent from - Focus group	0.01	2/20/2023 4:32 PM	Asmaa Namoos	Consent/Assent/Information Sheet	No

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
		02.20.2023.docx					
View	VS biosketch	Sheppard Biosketch for AN 11.14.2022.pdf	0.01	2/20/2023 4:00 PM	Asmaa Namoos	CV/Biosketch	Not Applicable
View	Communication log	Communication log.docx	0.01	2/20/2023 3:59 PM	Asmaa Namoos	Other	Yes
View	PRMC approval	2022-10-10_MCC-22-19873_PRMC Approval Letter.pdf	0.01	10/10/2022 12:30 PM	Asmaa Namoos	Ancillary Committee Approval	Not Applicable
View	Flyer	Flyer 004.08.2022.png	0.01	4/8/2022 6:09 PM	Asmaa Namoos	Other	Yes
View	Namoos Resume	Dr. Namoos A. Biosketch 06.07.2021.pdf	0.01	4/3/2022 3:47 PM	Asmaa Namoos	CV/Biosketch	Not Applicable

ID: HM20024502 **HM20024502** View: SF2 - Personnel

HM20024502 - Vanessa Lavene Sheppard
PROMIS WOMAN Education Program : ImProving ceRvical cancer preventiOn methods among Muslim AmerIcans WOMEN

Personnel

1. * **List all VCU/VCUHS personnel who are key study personnel.**

Key personnel are defined as including:
- **Conflict of interest investigators, including**
- **the PI**
- **the Lead Student/Trainee Investigator,**
- **medically/Psychologically responsible investigator(s)**
- **FDA Form 1572 investigators, and**
- **Other personnel whose roles are essential to the conduct of the research.**

Note: Individuals who are not key personnel are not required to be listed here, but PIs still bear the responsibility to document the delegation of responsibilities in the study records.

PIs may elect to use the Study Roster activity button in RAMS-IRB (available after approval) as an alternative way to document study staff involvement and delegation of responsibilities. Personnel changes made to the non-key personnel listed in the separate Study Roster activity do not require an amendment.

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
View	Tamas Gal	Consultant Co/Sub-Investigator		Data Analysis Data Management Study Design		Experience - Research Education and/or Professional Preparation		yes
View	Vanessa Lavene Sheppard	Consultant Principal Investigator Co/Sub-Investigator		Study Design		Experience - Research Experience - Related Skills Education and/or Professional Preparation		yes

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
View	Asmaa Namoos	Lead Student/Trainee Investigator (leading their own project) Research Assistant Trainee/Student(working on project)		Data Analysis Project Coordination Data Collection - Direct Observation Participant Consent Data Collection - Lab Regulatory Management Data Management Data Collection - Clinical Participant Identification Data Entry Study Design Data Coding Participant Recruitment Intervention Services Clinical Services Data Collection - Interviews/Surveys		Experience - Research Experience - Related Skills Experience - Clinical Education and/or Professional Preparation Student Trainee		yes
View	Robert Perera	Consultant Co/Sub-Investigator Statistician		Data Analysis Data Management Data Entry Study Design Data Coding Intervention Services		Experience - Research Education and/or Professional Preparation		yes
View	Jessica LaRose	Co/Sub-Investigator		Data Analysis Study Design		Experience - Research		yes

	Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator
				Intervention Services		Education and/or Professional Preparation		
View	Sun Jung Kim	Consultant Co/Sub-Investigator		Data Analysis Data Collection - Direct Observation Study Design Data Collection - Interviews/Surveys		Experience - Research Education and/or Professional Preparation		yes

2. Identify all independent investigators and key personnel at non-VCU sites who will be engaged in this study AND who DO NOT have IRB approval for this study from their own institution.

Name	Roles	Roles - Other	Responsibilities	Responsibilities - Other	Qualifications	Qualifications - Other	COI Investigator

There are no items to display

3. If independent investigators or community engaged investigators are listed above,**describe the human subjects training these individuals will complete and the process that will be used to ensure that all persons assisting with the research are adequately informed about the protocol and their research related duties and functions:**
NA

4. * **Upload a CV or Biosketch for the PI, Medically/Psychologically Responsible Investigators and the lead Student/Trainee Investigators. Do not upload CVs or Biosketches for other individuals.**

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Conflict of Interest

The PI should ask the questions on this page of all research personnel who are engaged in the research, including subrecipient investigators and personnel.

1. * **To the best of your knowledge, do you (as PI) or any other engaged individual have a financial interest related to this study?**
   Financial interest include utilizing your licensed intellectual property in the study; serving as a paid consultant, or advisory board member, or officer/director with a related entity; and equity or business ownership in a company that is related to this project
   ○ Yes ● **No**

2. * **To the best of your knowledge, do you (as PI) or any other engaged individual have a non-financial interest related to this study?**
   Non-financial Interests could include such things as:
   - utilizing your unlicensed intellectual property in the study,
   - serving as an unpaid advisory board member or officer/director with a related entity, and
   - equity or business ownership in a company that has yet to make a profit and is related to this project
   - conflict of time/effort,
   - personal and professional relationships/affiliations,
   - intellectual passions or personal beliefs
   - other factors that could create bias in the study
   ○ Yes ● **No**

3. **Describe any institutional conflict of interest that you or any member of the research team are aware of that pertains to this research:**

   An institutional conflict of interest is a situation in which financial interests of the University or University leadership may affect research activities at VCU.

ID: HM20024502 **HM20024502** View: SF2 - Other VCU Requirementsv2

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Other VCU Requirements

This page asks questions on behalf of other ancillary offices, committees and departments at VCU regarding institutional requirements that could apply to this research. In some cases, these requirements could also impact the consent process or other aspects of the IRB's review.

Based upon answers provided earlier in this form, certain ancillary sections below may not have questions displayed if those requirements are not applicable to this study.

1. Cost Coverage Analysis

Information on coverage analysis requirements and processes can be found through VCU's Clinical Research Compliance Program at https://research.vcu.edu/human-research/clinical-research/vcu-clinical-research-coverage-analysis/

1. * **VCU requires that all clinical research studies be evaluated to determine if a Coverage Analysis is required. Has your study been evaluated by an institutionally designated Coverage Analysis Specialist?**

- ○ Yes
- ○ No
- ● **Not Applicable**

2. ClinicalTrials.gov Program & OnCore

For guidance, see https://cctr.vcu.edu/support/consultation/clinical-trials-gov/ or email CCTRCTGOV@vcu.edu

1. * **Is this a Clinical Trial?**

● **Yes** ○ No

2. * **ThePI acknowledges awareness of the following requirements for posting clinical trial consent forms:**

- Each clinical trial under the 2018 Common Rule that is conducted or supported by a Federal department or agency must post one IRB-approved consent form that was used to enroll subjects on a publicly available Federal website [45 CFR 46.116(h)].
- When engaged in multi-site research, the VCU PI is responsible for confirming with the lead site who is responsible for posting the informed consent form.
- When VCU is the lead site, the VCU PI is responsible for posting the informed consent form (unless

***the federal department or agency will post it)*.**

● **Yes** ○ No

3. Community Engagement
For more information, see https://community.vcu.edu/

1. * **Is this a community engaged research study? (See help text for definitions)**

● **Yes**

○ No

2. * **Provide details about each community co-researcher. If there are more than 5 community partners/co-researchers, add the 5 most significant partners/co-researchers.**

Organization	Zip Code / Country	Role
Islamic center of Richmond	23060	Provides access to study subjects or project sites only. Partner/Co-researcher is not involved with study design, subject recruitment, data collection, or data analysis

4. Family Educational Rights and Privacy Act (FERPA) Requirements
For guidance, see https://rar.vcu.edu/records/family-educational-rights-and-privacy-act/

1. * **Does this study involve obtaining information from VCU students' educational records (see help text)?**

○ Yes

● **No**

5. Research Data Privacy Requirements
Contact the VCU Research Data Privacy Office with questions: https://research.vcu.edu/integrity-and-compliance/compliance/research-data-privacy/

1. * **Does this study involve the VCU site (regardless of the IRB of record), or any sites under the VCU IRB''s oversight, obtaining data in, or from, a foreign country?**

○ Yes ● **No**

6. Information Security

For guidance, see https://ts.vcu.edu/askit/essential-computing/information-security/

1. * **Using the VCU Data Classification Tool, please determine the appropriate data classification category for the data that will be collected or used in this research.**

   Note: if the data falls into Category 1, a data security management plan is required by University Information Security Office.

   See help text for information on accessing the VCU Data Classification Tool, and for information on creating a data security management plan at https://dms.vcu.edu**.**

   - (●) **Category 1: all data that require breach notifications in the event of improper release, including personally identifiable information covered by HIPAA and Commonwealth of Virginia regulations.**
   - ( ) Category 2: all proprietary data that if improperly released has the potential to cause harm to the institution, its mission or its reputation that do not require breach notifications.

2. * **I confirm use of the VCU Data Classification Tool at** https://go.vcu.edu/dataclassification **in determining the data classification category selected in Question 1:**

   - (●) **Yes**
   - ( ) No

3. * **The PI is aware that if the study's data is classified as Category 1, a Data Management Plan must be submitted to and approved by VCU Information Security prior to IRB approval. See** https://ts.vcu.edu/askit/essential-computing/information-security/data-management-system/

   (●) **Yes** ( ) No

4. * **I confirm that any use of external technology has been submitted to Information Security in the study's Data Management Plan. If this study uses any technology platforms, apps, services, etc. that are maintained external to VCU or hosted by another institution and are NOT currently listed in the DMS system as an approved service for the storage, processing, or transmission of VCU data, I am required to have VCU Information Security conduct a security review of that technology. I may contact infosec@vcu.edu with questions.**

   I also confirm that if the study involves use of external technology and VCUHS HIPAA data, I must also seek security review from the VCUHS Data Governance group (contact Mary Harmon at mary.harmon@vcuhealth.org):

   - ( ) Yes
   - ( ) No

● **N/A - not using external technology**

7. Massey Cancer Center Protocol Review and Monitoring Committee (PRMC)
For guidance, see https://www.masseycancercenter.org/research/~/link.aspx?_id=ee49e95faa8b44d09b6e89d8e3b48b57&_z=z

1. * **Does this study involve any of the following?**
- Research involving patients with cancer, their families or their health care providers
- Research involving cancer screening, diagnosis or prevention
- Secondary data collected from cancer patients or their medical records
- Cancer-related surveys (e.g., attitudes about risk, prevention and treatment) of the general population

● **Yes**

○ No

If Yes, upload documentation of PRMC approval or review.

8. VCU ONETRAC Protocol Review Oversight Committees (PROCs) For guidance, see https://onetrac.vcu.edu/

1. * **Does this study involve research with any of the following?**

- VCU Health System patients

- VCU Health System facilities

- VCU Health System data

○ Yes

● **No**

9. VCU Health Department of Patient Centered Services

1. * **Does your study involve a satisfaction survey administered to VCUHS patients (*See Help Text):**

○ Yes

● **No**

○ Not Applicable

10. VCU Faculty-Held IND or IDE
For guidance, see **https://research.vcu.edu/human-research/regulatory-affairs/**.

Questions related to if you need an IND or IDE for your study should be emailed to: indide@vcu.edu. Please submit a

copy of your FDA
submission prior to submitting to the FDA to https://redcap.vcu.edu/surveys/?s=NR7K7LR4JW.

11. VCU Health System locations

1. * **Will research activities occur in patient care areas of the VCU Health System (including at CHoR, Community Memorial Hospital, Tappahannock Hospital, VCU Medical Center and Massey Cancer Center)?**

- ○ Yes
- ● **No**

12. VCUHS Department of Pathology
Learn more about requesting and establishing an account with Pathology here: See https://pathology.vcu.edu/research-services/

1. * **I have contacted VCUHS Department of Pathology to determine feasibility if my study involves the following:**
   - Storage of Microbiology isolates
   - New instrumentation provided by clinical trial/study sponsor, or
   - Non-routine specimen processing (examples include but aren't limited to the following: addition of reagents to samples/aliquots, buffy coat processing, DNA sample processing)

- ○ Yes
- ○ No
- ● **N/A - my study does not involve any of the listed processes.**

2. * **If my study involves specimen retrieval from the Pathology laboratory, I have established a process with Pathology to deidentify and retrieve specimens.**

- ○ Yes
- ○ No
- ● **N/A - my study won't involve specimen retrieval from Pathology**

13. VCU Institutional Biosafety Committee (IBC)
To contact the Biosafety Office see their website at: https://research.vcu.edu/integrity-and-compliance/compliance/regulatory-committees/

1. * **Does this project involve any of the following hazardous biological agents ("biohazardous agents") that have NOT been FDA approved? These may include, but are not limited to, any of the following. If you are unsure, please contact the Biosafety Office:**

- Any functional recombinant viruses (especially viruses that may integrate into the patients' genome).

- Expression or administration of biological toxins.

- Live pathogenic or potentially pathogenic organisms of plants or animals (bacteria, fungi, wild-type viruses, parasites, etc.), that are, or potentially may be, in experimental products.

- Introduction or expression of rDNA or synthetic nucleic acids

- Use of a product (e.g., monoclonal antibodies, recombinant cytokines) produced from virally infected mammalian cells.

- Use of a product (purified growth factors, cytokines) produced from mammals or their cells.

○ Yes ● **No**

14. VCU Radiation Safety Committee (RSC)

To contact the Radiation Safety Section see their website at: https://research.vcu.edu/integrity-and-compliance/compliance/regulatory-committees/

1. * **Does this study involve radiation exposure and/or scans involving radiation (e.g.: PET, MRA, CT, DXA, nuclear medicine, etc.)?**

○ Yes

● **No**

15. VCU Scientific Review Committee (SRC)

For guidance, see https://cctr.vcu.edu/support/consultation/scientific-review-committee/

1. * **Has this human subjects protocol (not the grant application) already been reviewed by the funder of a sponsored project (e.g. a federal, state or non-profit funding sponsor)?**

○ Yes

● **No**

16. Upload any documents requested in the questions above:

	Document Name	Document	Version	Date Modified	Uploaded By	Type	Approved
View	Consent form focus group	Namoos- Consent from of focus group 05.12.2023.pdf	0.03	7/8/2023 1:09 AM	Asmaa Namoos	Consent/Assent/Information Sheet	Yes
View	Consent form - Intervention program	Namoos- Consent from of Intervention group 05.12.2023 copy.pdf	0.04	7/8/2023 1:09 AM	Asmaa Namoos	Consent/Assent/Information Sheet	Yes
View	Fund Plan	Asmaa -Budget 04.13.2023.xlsx	0.03	5/12/2023 11:52 AM	Asmaa Namoos	Funding Proposal	Not Applicable
View	Education session	Asmaa Education session guide , intervention group- 04.07.2023.docx	0.02	5/12/2023 10:52 AM	Asmaa Namoos	Other	Yes
View	Timeline Plan	Namoos, timeline for PROMIS women Project-.docx	0.02	5/12/2023 10:43 AM	Asmaa Namoos	Other	Yes
View	Conceptual model	Asmaa Conceptual Model 05.12.2023.docx	0.02	5/12/2023 10:40 AM	Asmaa Namoos	Research Measure	Yes
View	Flayer 2	Asmaa Flyer Version 05.12.2023.docx	0.01	5/12/2023 10:39 AM	Asmaa Namoos	Other	Yes
View	Namoos-Focus group script guide	Namoos -Focus Group Script Guide.docx	0.02	5/12/2023 10:24 AM	Asmaa Namoos	Other	Yes
View	Participants -RA communication script	Namoos- Participants -RA communication script .docx	0.01	5/12/2023 6:45 AM	Asmaa Namoos	Other	Yes
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ID: HM20024502 **HM20024502**

View: SF2 - Institutional Requirements Complete

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Institutional Requirements Complete

Protocol Progress:
- **INITIAL SETUP**
- **BACKGROUND, RATIONALE & GOALS**
- **RESEARCH PLAN**
- **CONSENT PLAN**
- **RISKS, PRIVACY & CONFIDENTIALITY**
- **POPULATIONS WITH SPECIAL CONSIDERATIONS**
- **INSTITUTIONAL REQUIREMENTS**

⑧ DOCUMENTS

Click Continue below to go to the next section

ID: HM20024502 **HM20024502** View: SF2 - Documents

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PROMIS WOMAN Education Program : ImProving ceRvical cancer preventiOn methods among Muslim AmerIcans WOMEN

Documents

1. **Upload any documents that the VCU IRB will need to conduct a review of this submission:**
   A list of potential documents is given in the help text.

   NOTE: The delete function should only be used if an incorrect document is uploaded or added to the system AND that document has not been reviewed and approved by the IRB. Do NOT delete documents that the IRB previously reviewed and approved.

   Once you have uploaded a document to RAMS-IRB, any changes to that document (i.e. different versions of the same document) should be added to the IRB submission by using the Update button. To provide updated documents, follow these steps:
   - Click the Update button located to the left of the document to be updated.
   - In the Add Document window, click the Choose File or Browse button, select the file you are adding, and click on the Open button.
   - Click OK to close the Add Document window, and the system will upload the revised document. RAMS-IRB will automatically provide a version number for the document.

   To access previous versions of a document in RAMS-IRB you must use the History link associated with the document.
   - Click the View or Update button located to the left of the document you wish to access.
   - In the Add/View Document window, click the "History" hyperlink located to the right of the file name.
   - A separate window will open that shows all versions of the document that have been added to RAMS-IRB. Click on any file name to download and view the document.

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ID: HM20024502 **HM20024502** View: SF2 - Documents Complete

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Documents Complete

Protocol Progress:

- **INITIAL SETUP**
- **BACKGROUND, RATIONALE & GOALS**
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- **POPULATIONS WITH SPECIAL CONSIDERATIONS**
- **INSTITUTIONAL REQUIREMENTS**
- **DOCUMENTS**

End of Application

Click Continue below to exit and submit this project

ID: HM20024502 **HM20024502** View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   Focus group consent form

2. * **Select all that apply to this consent / assent group:**

	Name
☑	**Signed Consent by Participant**
☐	Signed Parent/Guardian Permission or Legally Authorized Representative Consent
☐	Signed Assent by Child or Decisionally Impaired Adult
☐	Verbal/Other Indication of Assent by Child or Decisionally Impaired Adult
☐	Short Form Consent (limited applicability)
☐	None of the Above (select waiver below)

3. * **Select all electronic signature platforms that apply to this consent / assent group:**

- ☐ Not using electronic signature platforms
- ☐ DocuSign Part 11 (FDA regulated studies)
- ☑ **DocuSign (standard platform for non-FDA regulated studies)**
- ☐ REDCap e-Consent
- ☐ iMedConsent (Veterans Affairs studies)
- ☐ Other electronic signature platform

4. If Other is selected, explain:

5. * Select any waivers that apply to this consent / assent group:

- [x] **No Waivers Requested**
- [ ] Waiver of All Consent or Some Elements in Consent Form
- [ ] Waiver of Parental Permission or Legally Authorized Representative Consent
- [ ] Waiver of All Assent by Child or Decisionally Impaired Adult
- [ ] Waiver of Signature on Consent/Permission Forms (waiver of documentation of consent)
- [ ] Exception from Informed Consent (for emergency research only)

6. * Select all study team role(s) that will obtain consent / assent from this group:

- [x] **Principal Investigator**
- [x] **Co/Sub-Investigator**
- [ ] Medical or Psychological Responsible Investigator
- [x] **Lead Student/Trainee Investigator (leading their own project)**
- [x] **Research Coordinator**
- [ ] Research Nurse
- [ ] Consultant

- [x] **Research Assistant**
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other
- [ ] N/A: Requesting Waiver of Consent

7. * **Describe the consent procedures used for this group. Address each point below:**

- When and where consent will occur
- What will be covered during the consent discussion
- How the consent discussion will occur (e.g. in-person, phone, video conference)
- How you will reconfirm consent on an ongoing basis, if applicable

-The consenting process for the study will commence after receiving IRB approval, expected in May 2023, at the Islamic Center in a private room provided by the Community Advisory Board. During the consent discussion, participants will be provided with a background about cervical cancer among Muslim women. Depending on their enrollment, either in the focus group or the education session, the details of the respective components will be explained.

-The consent discussion will take place in-person, allowing for face-to-face interaction. The research assistant (RA) will provide the participant with the necessary materials and information to make an informed decision about participation. The discussion will cover the potential risks, benefits, and compensation associated with the study.

-Participants will be given the opportunity to consider their participation and make an informed decision. They will be offered the option to provide consent electronically using either DocuSign. The electronic consent form will be accessible via a provided link, ensuring convenience and ease of use for the participants.

-Ongoing reconfirmation of consent is not applicable in this study.

8. * **Select the processes for minimizing any potential perception of undue influence to participate, particularly when there is a pre-existing relationship between the participant and the researcher (e.g. treatment**

provider/patient; instructor/student; supervisor/employee, etc.):

- [ ] Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion
- [ ] Having an independent advocate (e.g. advocate for decisionally impaired adults, wards) present during the consent / assent discussion
- [ ] Removing physical symbols of authority like white coats or police badges
- [x] **Sitting down beside the participant instead of standing over them**
- [ ] If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to)
- [ ] Moving to a more neutral location like a conference room
- [ ] Obtaining consent / assent after other services/interactions have been completed (e.g. after school or the clinic visit)
- [x] **Having a mandatory wait period for the participant to go home and think before they sign consent /assent**
- [ ] Sharing the consent / assent discussion between two people (i.e. a clinician might be the best person to explain study procedures and risks, but then they could step out and let a research assistant finish the consent process)
- [ ] Other protection(s) not listed here – describe below
- [ ] N/A: Requesting Waiver of Consent

9. * **Describe the other ways the study team will minimize any potential perception of undue influence to participate:**
   Our team will offer enough privacy to let the Muslim women think and join to our study.
   our team is supported by the Mosque and our names and pictures will be on the Ads board to make sure we are trusted by the community.

10. * **How much time will participants be given to make a decision:**
    Two weeks after the first conversation about the study. we will drop the participant from out list if we have not heard back from her.

11. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**

ID: HM20024502 **HM20024502** View: SF_IRB_ConsentPlan_Groups

Consent Groups

1. * **Enter a descriptive name for this consent / assent group:**
   Intervention group consent form

2. * **Select all that apply to this consent / assent group:**

	Name
☑	**Signed Consent by Participant**
☐	Signed Parent/Guardian Permission or Legally Authorized Representative Consent
☐	Signed Assent by Child or Decisionally Impaired Adult
☐	Verbal/Other Indication of Assent by Child or Decisionally Impaired Adult
☐	Short Form Consent (limited applicability)
☐	None of the Above (select waiver below)

3. * **Select all electronic signature platforms that apply to this consent / assent group:**
   - ☐ Not using electronic signature platforms
   - ☐ DocuSign Part 11 (FDA regulated studies)
   - ☑ **DocuSign (standard platform for non-FDA regulated studies)**
   - ☐ REDCap e-Consent
   - ☐ iMedConsent (Veterans Affairs studies)
   - ☐ Other electronic signature platform

4. If Other is selected, explain:

5. * Select any waivers that apply to this consent / assent group:

- [x] **No Waivers Requested**
- [ ] Waiver of All Consent or Some Elements in Consent Form
- [ ] Waiver of Parental Permission or Legally Authorized Representative Consent
- [ ] Waiver of All Assent by Child or Decisionally Impaired Adult
- [ ] Waiver of Signature on Consent/Permission Forms (waiver of documentation of consent)
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6. * Select all study team role(s) that will obtain consent / assent from this group:

- [x] **Principal Investigator**
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [x] **Lead Student/Trainee Investigator (leading their own project)**
- [x] **Research Coordinator**
- [ ] Research Nurse
- [ ] Consultant

- [x] **Research Assistant**
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [x] **Trainee/Student(working on project)**
- [ ] Other
- [ ] N/A: Requesting Waiver of Consent

7. * **Describe the consent procedures used for this group. Address each point below:**

- When and where consent will occur
- What will be covered during the consent discussion
- How the consent discussion will occur (e.g. in-person, phone, video conference)
- How you will reconfirm consent on an ongoing basis, if applicable

When and Where Consent Will Occur:
Consent for the intervention group will be obtained at the Islamic Center during the scheduled education sessions. Participants will have the opportunity to provide consent before engaging in the educational program.

What Will Be Covered During the Consent Discussion:
During the consent discussion, participants will be provided with a detailed explanation of the educational program, including the topics covered, session duration, and expected outcomes. The risks and benefits associated with participation will be clearly explained, along with any potential discomfort or adverse effects that may arise from the educational sessions. Additionally, participants will be informed about their rights as research participants, including confidentiality and the voluntary nature of their involvement. They will have the opportunity to ask questions and seek clarifications before providing consent.

How the Consent Discussion Will Occur:
The consent discussion will occur in-person, allowing for direct communication between the research team and the participants. A designated research team member, such as the research assistant (RA), will conduct the discussion in a private room at the Islamic Center. The participant will have the opportunity to review the consent form, ask any questions, and discuss any concerns before making an informed decision to participate. The RA will be available to provide explanations and guidance as needed to ensure the participant's understanding of the study and their role in it.

How Consent Will Be Reconfirmed on an Ongoing Basis:
Since the intervention group will be participating in a one-day educational program, ongoing reconfirmation of consent is not applicable in this case. However, the research team will ensure that participants are aware of their right to withdraw from the study at any time, even after providing initial consent. Participants will also be provided with contact information to reach out to the research team if they have any questions or concerns during or after the educational program.

8. * **Select the processes for minimizing any potential perception of undue influence to participate, particularly when there is a pre-existing relationship between the participant and the researcher (e.g. treatment provider/patient; instructor/student; supervisor/employee, etc.):**

- [ ] Having a 3rd person (family/friends, another study team member, etc.) present during the consent / assent discussion
- [ ] Having an independent advocate (e.g. advocate for decisionally impaired adults, wards) present during the consent / assent discussion
- [ ] Removing physical symbols of authority like white coats or police badges
- [ ] Sitting down beside the participant instead of standing over them
- [ ] If obtaining consent / assent in a clinical setting, letting patients sit instead of lie down (if they are able to)
- [ ] Moving to a more neutral location like a conference room
- [ ] Obtaining consent / assent after other services/interactions have been completed (e.g. after school or the clinic visit)
- [x] **Having a mandatory wait period for the participant to go home and think before they sign consent /assent**
- [ ] Sharing the consent / assent discussion between two people (i.e. a clinician might be the best person to explain study procedures and risks, but then they could step out and let a research assistant finish the consent process)
- [ ] Other protection(s) not listed here – describe below
- [ ] N/A: Requesting Waiver of Consent

9. * **Describe the other ways the study team will minimize any potential perception of undue influence to participate:**
To minimize any potential perception of undue influence to participate, the study team will employ various strategies. First, participants will be provided with comprehensive information about the study, including its purpose, procedures, risks, benefits, and their rights as research participants. This will allow them to make an informed decision based on their own judgment.

Second, the study team will ensure that participation is voluntary, and participants can choose to withdraw from the study at any time without consequences.

Third, the consent process will be conducted in a private and comfortable setting, allowing participants to freely express their concerns and ask questions.

Finally, the study team will maintain open lines of communication and provide contact information so participants can reach out for further clarification or to voice any concerns they may have throughout the study. These measures aim to create a supportive and unbiased environment, promoting autonomy and safeguarding against perceived undue influence.

10. * **How much time will participants be given to make a decision:**
Participants will be given sufficient time(expecting from a week to two weeks) to make a decision regarding their participation in the study. The exact duration may vary depending on the circumstances and complexity of the study. Typically, participants are encouraged to take as much time as they need to review the provided information, ask questions, and consider their decision.

The study team will emphasize that there is no rush to make a decision and that participants are free to take the necessary time to make an informed choice that aligns with their interests and preferences.

11. **If applicable, describe the procedures for consenting children upon entering adulthood or participants who are no longer decisionally impaired:**

ID: HM20024502 **HM20024502**

View: SF_IRB_StudyLocation_NonVCUSitesDetails

Non-VCU Site Details

1. * **Name of institution or site:**
   The University of Kentucky

2. * **Provide a description of the institution's or site's role in the research and what study activities they will be performing. For example involvement in study design, carrying out research procedures, recruiting subjects, consenting, analyzing data and or specimens (regardless of identifiability), writing manuscripts or publications, solely being a location for VCU investigators to conduct activities, etc.:**
   The University of Kentucky (UK) collaborates with VCU investigators by actively participating in research studies. Their role may observing the recruitment process and contributing to manuscript writing. They are not solely a location for VCU investigators but actively engage in various research activities.

3. * **Describe the adequacy of the institution or site to ensure human participant safety, particularly in event of unanticipated emergency:**
   In the context of research conducted at VCU collaboration with the University of Kentucky (UK) , human participant safety will be observed by VCU and overseen by their Institutional Review Board (IRB). VCU, as the responsible institution, ensures that appropriate measures are in place to protect the safety and well-being of participants in the event of an unanticipated emergency.

   The VCU IRB provides oversight and guidance to ensure that all necessary precautions are taken to safeguard the participants throughout the research process.

4. * **Select the IRB review path the Non-VCU institution or site will follow:**

- ○ Exempt study submission
- ○ Site Engaged -- Has FWA and Will Obtain Own IRB Review
- ● **Site Engaged -- Requests to Rely on VCU IRB Review**
- ○ Site Not Engaged -- IRB Review Not Required
- ○ Site Engaged -- Does not regularly conduct human subject research AND is not required to have a FWA as a recipient of PHS funding.

5. **If the institution or site is engaged and will either 1) obtain their own IRB review OR 2) rely on VCU IRB review, provide the FWA# of the site:**

6. **If this is a foreign site or location, select which individuals and/or groups will be serving as the cultural consultant for the site to ensure that the research will be conducted according to local customs and procedures:**

- ☐ This is not a foreign site/location
- ☐ Foreign IRB or ethics committee (required for foreign sites engaged in expedited and full board research)
- ☐ Foreign site principal investigator
- ☐ Foreign site community advisory board
- ☐ Foreign site community elders or similar governing body
- ☐ Other cultural consultant (select if none of the above options apply; more information will be required about this individual)

ID: HM20024502 **HM20024502** View: Personnel

Personnel

1. * **Name:**
   Tamas Gal

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

- [ ] Principal Investigator
- [x] **Co/Sub-Investigator**
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [ ] Research Nurse
- [x] **Consultant**

- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other

4. * **Study related responsibilities:**

- [x] **Study Design**
- [ ] Data Collection - Lab
- [ ] Data Collection - Clinical
- [ ] Data Collection - Interviews/Surveys
- [ ] Data Collection - Direct Observation
- [ ] Clinical Services
- [ ] Intervention Services
- [ ] Data Entry

- [ ] Data Coding
- [x] **Data Management**
- [x] **Data Analysis**
- [ ] Project Coordination
- [ ] Participant Identification
- [ ] Participant Recruitment
- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
   Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills

- ☐ Trainee
- ☐ Student
- ☐ Other

7. Additional or Emergency Phone:

ID: HM20024502 **HM20024502** View: Personnel

Personnel

1. * **Name:**
   Vanessa Lavene Sheppard

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

☑	**Principal Investigator**
☑	**Co/Sub-Investigator**
☐	Medical or Psychological Responsible Investigator
☐	Lead Student/Trainee Investigator (leading their own project)
☐	Research Coordinator
☐	Research Nurse
☑	**Consultant**

- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other

4. * **Study related responsibilities:**

- [x] **Study Design**
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- [ ] Clinical Services
- [ ] Intervention Services
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- [ ] Data Coding
- [ ] Data Management
- [ ] Data Analysis
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- [ ] Participant Consent
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Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [x] **Experience - Related Skills**

- ☐ Trainee
- ☐ Student
- ☐ Other

7. Additional or Emergency Phone:

Personnel

1. * **Name:**
   Asmaa Namoos

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

- [ ] Principal Investigator
- [ ] Co/Sub-Investigator
- [ ] Medical or Psychological Responsible Investigator
- [x] **Lead Student/Trainee Investigator (leading their own project)**
- [ ] Research Coordinator
- [ ] Research Nurse
- [ ] Consultant

- [x] **Research Assistant**
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [x] **Trainee/Student(working on project)**
- [ ] Other

4. * **Study related responsibilities:**

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- [x] **Data Collection - Clinical**
- [x] **Data Collection - Interviews/Surveys**
- [x] **Data Collection - Direct Observation**
- [x] **Clinical Services**
- [x] **Intervention Services**
- [x] **Data Entry**

- [x] **Data Coding**
- [x] **Data Management**
- [x] **Data Analysis**
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- [x] **Participant Identification**
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- [x] **Participant Consent**
- [x] **Regulatory Management**
- [ ] Other

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   Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [x] **Experience - Clinical**
- [x] **Experience - Related Skills**

- [x] **Trainee**
- [x] **Student**
- [ ] Other

7. Additional or Emergency Phone:

ID: HM20024502 **HM20024502** View: Personnel

Personnel

1. * **Name:**
   Robert Perera

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

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   - (●) **Yes**
   - ( ) No

3. * **Roles:**

- [ ] Principal Investigator
- [x] **Co/Sub-Investigator**
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [ ] Research Nurse
- [x] **Consultant**

- [ ] Research Assistant
- [ ] Pharmacist
- [x] **Statistician**
- [ ] Regulatory Coordinator
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- [ ] Data Collection - Direct Observation
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- [x] **Intervention Services**
- [x] **Data Entry**

- [x] **Data Coding**
- [x] **Data Management**
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- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills

- ☐ Trainee
- ☐ Student
- ☐ Other

7. Additional or Emergency Phone:

ID: HM20024502 **HM20024502** View: Personnel

Personnel

1. * **Name:**
   Jessica LaRose

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

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   - (●) **Yes**
   - ( ) No

3. * **Roles:**

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- [ ] Research Nurse
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- [ ] Research Assistant
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- [ ] Data Collection - Interviews/Surveys
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   Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills

- ☐ Trainee
- ☐ Student
- ☐ Other

7. Additional or Emergency Phone:

ID: HM20024502 **HM20024502** View: Personnel

Personnel

1. * **Name:**
   Sun Jung Kim

2. * **Is this individual a 'COI Investigator'?**

   Conflict of Interest (COI) Investigator - any individual who has a level of independence and responsibility comparable to that of the PI for the design, conduct, or reporting of research.

   Anyone designated as a COI Investigator must have a current Financial Interest Report (FIR) in the Activity and Interest Reporting System (AIRS) (https://airs.research.vcu.edu).

   - (●) **Yes**
   - ( ) No

3. * **Roles:**

- [ ] Principal Investigator
- [x] **Co/Sub-Investigator**
- [ ] Medical or Psychological Responsible Investigator
- [ ] Lead Student/Trainee Investigator (leading their own project)
- [ ] Research Coordinator
- [ ] Research Nurse
- [x] **Consultant**

- [ ] Research Assistant
- [ ] Pharmacist
- [ ] Statistician
- [ ] Regulatory Coordinator
- [ ] Trainee/Student(working on project)
- [ ] Other

4. * **Study related responsibilities:**

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- [ ] Data Collection - Clinical
- [x] **Data Collection - Interviews/Surveys**
- [x] **Data Collection - Direct Observation**
- [ ] Clinical Services
- [ ] Intervention Services
- [ ] Data Entry

- [ ] Data Coding
- [ ] Data Management
- [x] **Data Analysis**
- [ ] Project Coordination
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- [ ] Participant Recruitment
- [ ] Participant Consent
- [ ] Regulatory Management
- [ ] Other

5. * **The PI certifies that if this individual will conduct any clinical activities as part of this study, the individual is appropriately credentialed and privileged to practice within the institution where the research will be conducted:**
Individual has no clinical responsibilities

6. * **Qualifications to carry out study related responsibilities: (you may select multiple answers)**

- [x] **Education and/or Professional Preparation**
- [x] **Experience - Research**
- [ ] Experience - Clinical
- [ ] Experience - Related Skills

- ☐ Trainee
- ☐ Student
- ☐ Other

7. Additional or Emergency Phone:

ID: HM20024502 **HM20024502** View: SF - Community Engaged Research

Community Engaged Research

If this pop-out window fails to respond after you click OK, close the window and email the responses you were trying to enter here to ERAHelp@vcu.edu. This pop-out window has a known system glitch. ERA Help personnel can assist with entering this information for you.

1. * **Name of the organization:**
   Islamic center of Richmond

2. * **Zip code or country of the organization:**
   23060

3. * **Select the role that best describes this community partner/co-researchers:**

- (●) **Provides access to study subjects or project sites only. Partner/Co-researcher is not involved with study design, subject recruitment, data collection, or data analysis**
- ( ) Provides guidance to the researcher about the study design, subject recruitment, data collection, or data analysis. Partner/Co-researcher does NOT make decisions about study design.
- ( ) Makes decisions WITH the researcher about the study's research activities and/or helps conduct those activities (i.e., study design, subject recruitment, data collection, and/or data analysis)

ID: HM20024502 **HM20024502** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Consent form focus group

2. * **Type:**
   Consent/Assent/Information Sheet

3. * **File:**
   Namoos- Consent from of focus group 05.12.2023.pdf(0.03)

ID: HM20024502 **HM20024502** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Consent form - Intervention program

2. * **Type:**
   Consent/Assent/Information Sheet

3. * **File:**
   Namoos- Consent from of Intervention group 05.12.2023 copy.pdf(0.04)

ID: HM20024502 **HM20024502** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Fund Plan

2. * **Type:**
   Funding Proposal

3. * **File:**
   Asmaa -Budget 04.13.2023.xlsx(0.03)

ID: HM20024502 **HM20024502** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Education session

2. * **Type:**
   Other

3. * **File:**
   Asmaa Education session guide , intervention group- 04.07.2023.docx(0.02)

ID: HM20024502 **HM20024502** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Timeline Plan

2. * **Type:**
   Other

3. * **File:**
   Namoos, timeline for PROMIS women Project-.docx(0.02)

ID: HM20024502 **HM20024502** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Conceptual model

2. * **Type:**
   Research Measure

3. * **File:**
   Asmaa Conceptual Model 05.12.2023.docx(0.02)

ID: HM20024502 **HM20024502** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Flayer 2

2. * **Type:**
   Other

3. * **File:**
   Asmaa Flyer Version 05.12.2023.docx(0.01)

ID: HM20024502 **HM20024502** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Namoos-Focus group script guide

2. * **Type:**
   Other

3. * **File:**
   Namoos -Focus Group Script Guide.docx(0.02)

ID: HM20024502 **HM20024502** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Participants -RA communication script

2. * **Type:**
   Other

3. * **File:**
   Namoos- Participants -RA communication script .docx(0.01)

ID: HM20024502 **HM20024502** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Study Survey(Pre-post and satisfactory scales)

2. * **Type:**
   Research Measure

3. * **File:**
   Survey- Promise women project 05.12.2023.docx(0.01)

ID: HM20024502 **HM20024502** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   consent form- focus group

2. * **Type:**
   Consent/Assent/Information Sheet

3. * **File:**
   Consent from -Focus group 02.20.2023.docx(0.01)

ID: HM20024502 **HM20024502** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   VS biosketch

2. * **Type:**
   CV/Biosketch

3. * **File:**
   Sheppard Biosketch for AN 11.14.2022.pdf(0.01)

ID: HM20024502 **HM20024502** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Communication log

2. * **Type:**
   Other

3. * **File:**
   Communication log.docx(0.01)

ID: HM20024502 **HM20024502** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   PRMC approval

2. * **Type:**
   Ancillary Committee Approval

3. * **File:**
   2022-10-10_MCC-22-19873_PRMC Approval Letter.pdf(0.01)

ID: HM20024502 **HM20024502** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Flyer

2. * **Type:**
   Other

3. * **File:**
   Flyer 004.08.2022.png(0.01)

ID: HM20024502 **HM20024502** View: SF_IRB_Summary_Document

Add Document

1. * **Document Name:**
   Namoos Resume

2. * **Type:**
   CV/Biosketch

3. * **File:**
   Dr. Namoos A. Biosketch 06.07.2021.pdf(0.01)