Protocol Title: Acceptability of HPV self-sampling tools for cervical cancer prevention in Jamaican women: A theory-based approach to culturally-tailored message design.

Version: 1A

Version Date: April 27, 2018

NCT Number: NCT03613493

1) Protocol Title

Acceptability of HPV self-sampling tools for cervical cancer prevention in Jamaican women: A theory-based approach to culturally-tailored message design.

2) IRB Review History*

N/A

3) Objectives*

The purpose of the proposed study is to increase HPV screening behaviors in Jamaican women by examining the acceptability of HPV DNA self-sampling tools, and determine the most culturally appropriate and effective message design for promoting such a tool in this context.

Specific Aim: Evaluate culturally-tailored HPV DNA self-sampling toolkit.

H1: Women who receive culturally tailored messaging will exhibit improved screening, screening-relevant knowledge, attitudes, and perceived-efficacy.

4) Background*

Low screening coverage is related to health system barriers, as well as women's attitudes and knowledge about cervical cancer screening. In a study conducted by the Ministry of Health and Environment of Jamaica in 2008, lack of uptake was found to be influenced to a significant degree by fears and misconceptions on the part of Jamaican women, including ideas that the human papillomavirus (HPV) test causes damage to the cervix. In addition, other factors impeding women in Jamaica include concerns about privacy, belief that the procedure was embarrassing, ignorance about where to get a pap test, and lack of sufficient information, fear of pain, fear of cervical cancer diagnosis, and lack of sufficient time with their doctors.

The US Food and Drug Administration has designated HPV screening as a best practice in identifying risk of cervical cancer, over and above pap test screening, because of its high efficacy, affordability, and convenience, since it can be adapted for various settings. The HPV self-sampling tool has been shown to address issues such as privacy, and studies have shown that women feel more comfortable with this option and expressed willingness to recommend the tool to others. This adaptability has become a driving force in advocates support for the tool in hard-to-reach and poor areas. HPV self-sampling has been tested in many contexts, including resource-limited countries, and has been found to be efficacious and cost-effective. With this now fairly well-established in the literature, research questions have now focused on the best strategies for diffusion of the tools. It has been suggested that Community Health Workers (CHWs), coupled with Community-based Participatory Research (CBPR) methods are the ideal vehicle to ensure optimal uptake in community-settings. On the other hand, other studies have proposed that a mailed approach is preferred.

This current proposal aims to determine how culturally appropriate messaging within one context (Jamaica), alongside an innovation (self-sampling HPV test), might increase uptake of screening behaviors.

5) Inclusion and Exclusion Criteria*

Rationale for inclusion/exclusion criteria: This study will involve the collection of data from Jamaican women. Eligible participants will be accepted to the study on a first-come- first-serve basis. A prescreening survey in person or over the phone (see Appendix A), as well as the data from the baseline survey (see Appendix B), which will include a demographic section which will include self-reporting of age etc. (listed below) which will be an additional check for confirming eligibility for the study.

Inclusion criteria: Jamaican women, aged 30 to 65.

Exclusion criteria: women who report having had a hysterectomy, have had a history of cervical cancer, Women who are currently up-to-date on cervical cancer screening (have had a Pap in the last 3 years or have had a Pap smear/HPV co-test within the past 5 years), adults unable to consent, children, pregnant women and prisoners.

6) Number of Subjects*

Total expected: approximately 360 participants, (350 for the intervention; 10 interviews)

7) Study-Wide Recruitment Methods*

Jamaican women will be recruited for participation in two different phases of this research project. Efforts will be made to include women from rural areas, urban areas, and varying socio economic and cultural backgrounds. Recruitment will occur in three identified low-screening regions in Jamaica (using national statistical data on screening rates per parish in Jamaica), and enrolment will take place through local community organizations as well as at community events such as health fairs.

8) Study Timelines*

An individual subject in the research is expected to participate up to maximum of 4 months. Enrolling study subjects is expected to not exceed one month prior to the actual study date. The estimated date for the investigators to complete this study is September 30, 2018. The primary data analysis will be completed by October 31, 2018. Other studies that have utilized community and government partners have been successful at recruiting a similar number of participants over a short time. For example (Barrett & Huffman, 2011) collected their entire dataset in 3 weeks in October 2007 (276 Jamaican adolescents). Another example is (Lewis-Bell et al., 2013), a cross-sectional study that

took place in April–July 2010 with 852 sexually-active Jamaican women, 16–49 years of age.

9) Study Endpoints*

The primary study endpoints are:

- Development of messages and design of HPV self-sampling tool kit.

Based on formative results from interviews (see Appendix C for interview script), messages will be designed that are culturally appropriate and tailored for any audience segments which emerge from the data. Feedback will be used to design a culturally adapted HPV DNA self- sampling toolkit for this context.

- Evaluation of culturally-tailored HPV DNA self-sampling toolkit.

Enrolled participants will complete a pre-test/baseline questionnaire which will be based on the theoretical constructs identified, and which will also be assessed in the posttest. The intervention will be considered a success when: 1) the majority of women targeted opt to return their sample, as instructed on the toolkit, for testing and, 2) upon evaluation (posttest - See Appendix C), women report higher levels of, knowledge, self-efficacy and response efficacy or positive changes in attitudes toward screening than at baseline.

10) Procedures Involved*

Interviews

Determination of eligibility: The Jamaica Cancer Society (JCS) will provide support to select 10 individuals for interviews using their database (purposive sampling) from at least 2 of their clinic-based locations. Eligibility will be determined according to the inclusion/exclusion criteria outlined as well as during the pre-screening process (Appendix A).

Procedure: Participants who express an interest will be screened, consented and given the baseline survey to complete, by a local study coordinator or the Co-I. They will then be given the self-sampler tool to use at home. A date, time and location to return the tool and participate in the interview process (within the same week) will be determined with the participant at the time of consent. Participants will be reminded of this by at least one telephone call up to the day of the interview. After the interviews, participants will also complete the baseline survey. The interviews will function as a piloting of the baseline and posttest questionnaires as well as a pretest of the collection of self-samples (described below), since participants will actually use and return a self-sampling tool before conducting the interview. The location for the interviews will be at the JCS. The participants will receive their hpv test results within 6 weeks of the interviews.

Narrative interviews: For the purpose of social science research, narrative interviews are unstructured and in-depth and ask participants to reconstruct a particular event that is important to them and their social context, in the format of a story, for an interviewer (Rohleder & Gibson, 2005). The method seeks to understand how people's narration of stories also demonstrates people's ways of thinking or their "unconscious logic" (Hollway, 2001, p. 15). Moving beyond the traditional question-response format, narrative interviewers have a diminished role. Instead the interview relies on certain expected schema in storytelling to elicit the sought-after rich data. This schema dictates that the respondent will naturally share the most pertinent information, provide sufficient detail, and include a structure that includes a beginning, middle and end of the main situation or occurrence being described. After the participants are asked to tell their story, the interview may not interrupt at any point to ask for further explanations or to express any opinions; the interviewee may only ask what happened next (Rohleder & Gibson, 2005). See Appendix C for interview script.

Tailoring the self-sampler messages (package and instructions): The participant responses will provide insight into local women's' perceptions, language, experience using the tool, which will further aid message design. The interviews will provide insight on the participants experience using the toolkit and how this is expressed linguistically. For example, in their own words how did they use the self-sampler tool. This will inform further the language and wording choices for the culturally-tailored condition.

Collection of Self-Samples:

Determination of eligibility: Participants in the full intervention (350 women) will be screened for eligibility by the CO-I or a local study coordinator. The Co-I/local study coordinator will administer a brief screening questionnaire prior to obtaining informed consent (Appendix A). The screening questionnaire will cover the inclusion/exclusion criteria listed above. For women who screen potentially eligible, the CO-I/local study coordinator will further describe the study. Eligible potential participants will be told that we are conducting a research study to understand how new innovations like an at-home HPV self-sampling tool would be accepted by you and in your community. The study will involve completion of a baseline survey (Appendix B) about their sexual and reproductive practices and cervical self-sampling.

In our research, we plan to use a self-sampling device developed by Preventive Oncology International (POI) and the National Institutes of Health (NIH). The POI/NIH self-sampler is considered a non-significant risk device and has been approved for research conducted by NIH faculty throughout the United States and in various international settings. This device is manufactured by Puritan Medical Products, and is thought to reflect an improvement over other self-samplers, given a larger Collection Swab tip, which enables a woman to collect cells from more of

the cervix's total surface area with less effort. The POI/NIH self-sampler is a 20 cm in diameter, which is similar to a regular-sized tampon. This sampler is easy to use. A woman inserts the device into her vagina until she feels slight resistance. The participant then holds the paddle end of the Collection Swab and rotates it five times. She then withdraws the Collection Swab. Once the Collection Swab is fully removed from the vagina, the participant places the Collection Swab into liquid cell preservative and rotates it five times. The participant can then dispose of the swab in a household trash can and secure the vial lid. The participant should return the vial by mail (she will be provided a pre-addressed, stamped envelope) or in person to a specified return location. The CO-I/local study coordinator will be responsible for storing and shipment of the samples to the SCCC for testing.

Participants will receive the HPV self-sampler at the time they complete the baseline survey with the Co-I/local study coordinator. The HPV self-sampler kit will include the collection swab and the vial for collecting and storing the specimen, and an instructional sheet that visually depicts the steps for self-sampling. 115 women will receive a culturally-targeted, fear appeal message for the HPV self-sampler kit; 115 women will receive only a fear appeal message, not targeted for the Jamaican populace; and 115 women will receive only the self-sampler tool with no message appeal (plain packaging). (Appendix G & J). The Co-I/local study coordinator will offer the HPV self-sampler accompanied by an instruction sheet on how to use the self-sampler. At this point participants will receive some sensitization on the topic, which will include: 1) health education on the importance of cervical cancer screening using a short intervention/educational script (Appendix H) and 2) motivation to encourage women to have screening using the HPV self-sampler. Women will also be informed of the following: 1) HPV infection usually is not detectable or harmful; 2) nearly everyone who has had sexual intercourse has been exposed to HPV and infection is very common; 3) a positive HPV test result does not indicate the presence of cancer and that not all women who test positive for an HPV infection will not develop advanced cancer. It will also be stressed to women that if they have not seen a doctor recently they will still need to see a provider to address other health issues, which may include a gynecologic exam. They will also be advised that if HPV obtained through self-sampling is positive, they will need follow-up medical care at clinical sites (a list of possible sites will be provided). and to package and return it by mail or to the address provided. A brief survey on intentions will then be administered (Appendix K). Participants will be asked to use the tool at home by following the instructions, The local study coordinator will follow up with participants who do not return the kit within 1 week via SMS messaging. All participants will receive the following message: "Please remember to return your HPV self-sampler kit to X location during the following times: X Y, and Z. Please ignore this message if you have already returned the kit. Thank you."

Posttest Interview: All participants will be asked to complete a posttest survey which may be administered by phone or in person, if convenient (Appendix D) upon return of the self-sampler kit.

Compensation: All participants will be provided a one-time small incentive of approximately $21USD ($2,500 Jamaican dollars) immediately upon completion of the narrative interviews (for the interview participants), and upon completion of the posttest interviews (for the message design experiment participants).

Report of HPV Lab Results: The Co-I will receive test results from lab and provide information to the local study coordinator. The Co-I/local study coordinator will call participants within 4-6 weeks to notify them of their test results when they are received.

Participants who test negative will be encouraged to follow-up with their doctor and rescreen in 36 months, based on the US Preventive Services Task Force (USPSTF) guidelines. Participants whose test results indicate insufficient sample (insufficient cellular quantity for analysis) would be asked if they had a hysterectomy. If no, the participant will have the option of providing a second sample if they are located within reasonable distance from a local project partner, and an appointment will be scheduled by Co-I/local study coordinator to either deliver the kit or for the participant to pick up. Participants who test positive for HPV will be navigated to appropriate follow-up care with our community partners and/or The Ministry of Health Jamaica within 30 days of receiving the result. The Co-I will work with Ministry of Health staff to ensure that women with abnormal findings receive timely follow up. The Co-I/local study coordinator will follow up with participants who do not return the kit within 30 days.

For individuals who screen eligible but declined consent/enrollment, the brief demographic information collected during the eligibility screen (age, ethnicity) will be kept without any identifiable information so that we may compare responders versus non-responders. For individuals who choose to participate in the study, the CO-I/local study coordinator will obtain consent (see Appendix F), complete the baseline survey (Appendix B) and give the self-sampling tool (or schedule a time to do so at a time or location convenient for the participant).

11) Data and Specimen Banking*

The local study coordinator will transport any samples from the field then batch-shipped to UM Sylvester Comprehensive Cancer Center (SCCC) via DHL. The study coordinator will be in charge of the logistics related to receiving the samples from the field, storing them and shipping them (this corresponds with other projects that have successfully used these methods in the collection of HPV dna samples (see (Lewis-Bell et al. 2013) . We will ship the self-sampled specimens to the SCCC for high-risk HPV detection and HPV viral genotyping. Cervical specimens will be labeled with a number that matches the number assigned to the participant during the study intake. The specimens will be

processed and results will be reported back to Co-I within 2 weeks, who will obtain signature from Dr. Matt Schlumbrecht. He will sign and date lab result sheet. Copies of results will be filed and kept in locked cabinet and uploaded to REDCap. Copies of analysis will be given to the study team who will be filed and kept in locked cabinet and uploaded to RedCap.

12) **Data Management***

All study data will be captured by REDCap (http://project-redcap.org/), and Velos (velos.med.miami.edu), which provides both secure data capture for clinical research studies. The REDCap (Research Electronic Data Capture) system (project-redcap.org/) is a web-based clinical research management application that is designed specifically for investigators and their research teams. It supports processes for patient recruitment, patient scheduling, budgeting, invoicing, and milestone management, data safety monitoring, adverse event reporting, system integration, data collection and study execution. Data safety checks, redundancy, and skip patterns can all be easily programmed. A major strength for our proposal is that REDCAp allows all study related information to be centralized yet be accessed through the internet from anywhere through encrypted and password protected access granted only to authorized personnel as designated by the study PIs. It is easy to use, reliable, fully HIPAA compliant and completely secure. A major advantage of using this system is that UM provides this important resource to UM and associates (such as non-UM community research partners) at no cost. This includes technical support and effort of REDCap team staff who assists investigators in uploading all their surveys and questionnaires into REDCap. In this study, all of the data collected at the time of interview or site visit by the Co-I/local study coordinator will be uploaded in real time into REDCap system using iPads. However, the Co-I will also have paper versions of the instrument for the anticipated but hopefully rare occasions when technological glitches occur. In these cases the Co-I/local study coordinator would input the data at a later time.

All data will be inspected for quality assurance prior to analysis. Prior to performing statistical analysis on quantitative data, the data will be checked, screened and verified. Data checking is critical to ensure the integrity of the database. Range checks will be routinely performed, and random items from the raw data will be checked against the entered data so that mistakes can be identified. the sampling strategy for our study may be described as purposive and snowball sampling. Women will not be not randomly selected as the study was intended to capture a community-based population that meets specific selection criteria. Data will be analyzed from interviews using the constant comparison method (Corbin & Strauss, 2008). For the message design experiment, a paired t-test will be conducted to determine the difference between pre and posttests in screening behavior after exposure to the self-sampling tool; mediation analyses will be conducted to determine if change in screening knowledge, attitudes and perceived-efficacy mediated changes in screening outcomes. Mediation analyses

will be performed using ordinary least squares regression, using techniques recommended for within-subject designs (Judd, Kenny, & McClelland, 2001).

To maintain participant confidentiality, study specific ID codes are used in all study tracking and analyses. Only the Co-I/local study coordinator will have access to the files linking participants with study ID numbers.

13) Provisions to Monitor the Data to Ensure the Safety of Subjects*

All study data collected will be uploaded into the REDCap system. As previously stated, the Co-I and local coordinator have access to this system to enter participant data using an iPad or paper-based methods during interviews and site visits, and in real time during the evaluation phone call.

Furthermore, quality and completeness of data entry will be systematically checked by a data manager at regular intervals for the duration of the study. Only the Co-I has access to the raw data files entered by the Co-I/local study coordinator. De-identified data files that have been cleaned and appropriately grouped and categorized will be made available to study personnel requesting such data.

Additionally, all study staff and the PI will meet monthly to review study progress, as well as discuss any adverse events and feedback from participants regarding study procedures. Finally, study data is reviewed on a regular basis to ensure proper entry and storage procedures.

14) Withdrawal of Subjects*

Any participant may choose to withdraw from the study at any time. If a participant chooses to withdraw, their data will be destroyed, and their reason for withdrawal recorded. Participants may withdraw by contacting the Co-I/local study coordinator.

15) Risks to Subjects*

Participants in the study will be asked a series of questions about their beliefs, attitudes, and practices related to their sexual and reproductive history and health seeking behaviors. There is no risk of physical injury from answering these questions. However, the topic is sensitive in nature, and participants may feel uncomfortable answering some questions about their personal feelings and beliefs, and about the details of their behavior. Participants may also find themselves opening up about health issues and concerns that they have previously kept private, which may cause some emotional discomfort.

Regarding the cervical self-sampling device, the two most common prior problems of self- sampling were: 1) placing the sampler in an incorrect opening (e.g., the anus); and 2) Injury to the vagina or cervix due to aggressive sampling.

Also, a participant may experience cervical bleeding and inflammation from excessive pressure applied during the rotation of the device. If a participant experiences continuous and heavy bleeding, they are advised to stop using the device and contact the study team immediately. However, both of these hazards are unlikely to occur with the current device. In trials with more than 20,000 women when either problem has occurred, they did not cause serious injury. Rather, they resulted in minimal patient discomfort. Thus, it is considered a non-significant risk device.

There are psychological risks associated with receiving an abnormal test result from self-sampling. Participants may interpret an abnormal result as a diagnosis of cancer rather than an infection with HPV. The participant may feel hopeless in response to an abnormal result, believing that there is nothing that can help. As a member of an underserved group she may feel that adequate health services are not available or accessible to her. She may also feel guilty that she has done something wrong or someone has wished ill health upon her. She may feel embarrassed to tell her friends, family, and other ones, fearful of how they may judge her and reflect upon her diagnosis.

If the participant decides that they do not wish to participate in the study after it has started, they will be advised to tell the Co-I or local study coordinator. They will be advised that there is no penalty imposed if they decide to end their participation early and/or refuse to answer any question.

Adverse Experience Reporting: If any participant who chooses to use the HPV self-sampler indicates to the local study coordinator or Co-I that a discomfort is persistent or something else has occurred, the Co-I should contact directly the Principal Investigator and oversight committee of the study. Participants who experience any adverse effect or study-related injury will be navigated to appropriate follow-up care with our community partners and/or The Ministry of Health Jamaica immediately for follow-up care.

16) **Potential Benefits to Subjects***

A potential benefit for all participants is the opportunity to be screened. There are no other direct benefits to participants from taking part in the study.

17) Vulnerable Populations*

This research does not involve individuals who are vulnerable to coercion or undue influence or vulnerable populations.

18) Multi-Site Research*

N/A

19) Community-Based Participatory Research*

This project shares some elements of community-engaged research. Firstly, the community will be involved in the conduct of the study as participants, to improve the utilization of local knowledge in the development of an effective intervention or program at a national level. Secondly, we will collaborate with local institutions to plan the research project and for assistance in the recruitment of participants.

20) Sharing of Results with Subjects*

After participants return their tests by mail (or do not), results will be analyzed within 6 weeks and sent to the local study coordinator, who will call participants to give the results of their tests. Those who do not return their kit will also be called. All women who test positive for high-risk HPV will receive information on follow-up procedures, which will be available at local health facilities.

In addition to disseminating our findings through journals, conferences, and other standard academic channels, our community partners will oversee the dissemination of research findings within our target communities.

21) Setting

The Co-I/local study investigator will identify and recruit potential subjects at various community venues or NGOs (such as the Jamaica Cancer Society) that they deem appropriate and at which women tend to congregate. These may include, but are not limited to: churches, health clinics, markets health fairs and other events. Parishes that have been identified as low-screening areas will be targeted. Additionally, participants will be asked to refer others to the study by providing the names and phone numbers of up to three additional women.

Interviews will be conducted at a location convenient for the participant or in a private location to be identified (e.g. Jamaica Cancer Society office).

22) Resources Available

- Soroya Julian McFarlane, PhD Candidate, Co- Investigator, School of Communication, University of Miami. Soroya will be responsible for all aspects of the research implementation, including: data collection and/or management, study coordination, data analysis and/or statistics, participant screening/recruitment, social and/or behavioral assessment, interviews.

McFarlane's academic and professional experience has been specifically focused on health communication for health disparity populations in Latin America and the Caribbean. She has a Bachelor's degree in Media and Communication (University of the West Indies, Jamaica), with a specialization in Social Marketing. Her Master's degree is in Public Health: Health Promotion (Leeds Metropolitan University, United Kingdom). For the past 8 years she has worked as a Communications Specialist in public health including topics related to sexual and reproductive health, maternal health and HIV/AIDS. She has worked in Jamaica with international, governmental and non-governmental organizations there. She is keen on properly understanding target audiences in order to develop evidence based, culturally appropriate campaigns and evaluation instruments to implement effective interventions at different levels.

PhD Committee:

- Susan E. Morgan, PhD, Advisor of Co-I, PhD Committee Chair, Associate Provost for Research Development and Strategy, Professor, Department of Communication Studies , University of Miami semorgan@miami.edu

As Associate Provost for Research and as a Professor in the department of Communication Studies at the University of Miami, Dr. Morgan has considerable expertise in conducting research on message design in health communication campaigns for specific audiences. I have a strong track-record of scholarly productivity and over $9 million in federally-funded grants that have led to impactful findings. My previous research has focused on the development of effective health behavior change messages in the area of organ donation. This work has demonstrated consistent and significant population effects as a result of these theory-based campaigns. My current, developing area of research in cancer communication includes a focus on creating information about clinical trials that is easily accessible and understood by limited literacy audiences, as well as communication protocols that can be used by medical professionals and research study staff when recruiting potential participants for clinical trials and research studies.

- Wanhsiu Tsai, Ph.D, Associate Professor, School of Communication, University of Miami, wanhsiu@miami.edu
- Nick Carcioppolo, Assistant Professor, School of Communication, University of Miami n.carcioppolo@miami.edu
- Matthew Schlumbrecht, MD, MPH, FACOG, Associate Director for the Gynecologic Oncology Fellowship and the Co-Director of Cancer Control and Prevention for Gynecologic Oncology within the Sylvester Comprehensive Cancer Center, , University of Miami

mschlumbrecht@miami.edu

Additional oversight:

- Erin Kobetz, Ph.D., M.P.H., Senior Associate Dean for Health Disparities, Associate Director, Population Sciences and Cancer Disparity, UM Sylvester, University of Miami ekobetz@med.miami.edu
- Elizabeth Unger, PhD, MD, Chief of the Chronic Viral Diseases Branch. Centers for Disease Control and Prevention (CDC), Atlanta, GA eru0@cdc.gov
- Kay Rattray, Rattray, MBBS, DM (O&G), FRCOG, FACOG, Head of Department, Department of Obstetrics & Gynaecology, The University of the West Indies, Mona Campus, Jamaica kay.rattray@gmail.com

This project may utilize a study coordinator who is indigenous to Jamaica to recruit participants, to collect, store and ship returned self-samples, and to disseminate results. The local study coordinator will have personal connections and cultural competencies within the Jamaican context, and will be familiar with the norms and nuances associated with discussing sensitive topics like sexual and reproductive health and collecting samples, and can approach the work from a place of understanding and knowledge. Additionally, the local coordinator will be certified to conduct research by the UM Institutional Review Board (IRB).

Finally, the project involves collaboration with local partners. We may work with the Jamaica Cancer Society and the University of the West Indies Department for Gynaecology to ensure that interventions are appropriate for the local context.

23) Prior Approvals

The study will also gain ethical approval from the Ministry of Health Jamaica Ethics Committee.

24) Recruitment Methods

Interview participants will be recruited through purposive sampling from a prior focus group study (IRB #20170802). The CO-I/community volunteer will place a follow up call to each identified interview participant to remind them about the upcoming meeting.

Recruitment for the self-sampler intervention will occur in three identified low-screening regions in Jamaica (using national statistical data on screening rates per parish in Jamaica). Recruitment will take place through local community organizations such as churches as well as at community events such as health fairs, various community venues, including laundromats, health clinics, and flea markets. A desk may be set up at an event

with a recruitment poster to attract women (Appendix I). Alternatively, the Co-I/local study coordinator will approach potentially-eligible individuals at community venues, introduce themselves, and explain their role in the project. The Co-I/local study coordinator will also rely heavily on their own social networks and those of the community leaders, to identify potentially eligible participants. From this initial convenience sample of participants recruited at community locations, they will request referrals (names and phone numbers) for potentially eligible participants. Thus, the sampling strategy for our study may also be described as snowball sampling. We will stop recruiting after 350 eligible women have been consented and enrolled. Partnering organizations and NGOs members may also promote our research agenda through culturally-appropriate communication channels, such as radio and word of mouth, and can help generate community interest in, and support for the proposed research.

25) Local Number of Subjects

A minimum of 350 total subjects is expected to be accrued locally.

26) Confidentiality

Multiple steps will be taken to guarantee confidentiality. All paper-based surveys and forms will be entered and uploaded using REDCap. All REDCap data is securely hosted by the University of Miami's IT Department.

Research IT administers project creation, user account management, and movement of projects from development to production. Authentication is performed via CaneID Authentication Service (CAS), the same institution-wide system used for a variety of applications such as myUM.

Any electronic data will be stored in password-protected files that only the PI-I, Co-I and study staff will be able to access. There are multiple levels of security once placed on the local network. Paper copies will similarly be stored in a locked file drawer that only study staff will be able to access.

All study personnel will be certified to conduct human subjects' research by the University of Miami Institutional Review Board.

The study investigators and their staff will consider all records confidential to the extent permitted by law. The U.S. Department of Health and Human Services (DHHS) may request to review and obtain copies of any records. Records may also be reviewed for audit purposes by authorized University employees or other agents who are bound by the provisions of confidentiality.

27) Provisions to Protect the Privacy Interests of Subjects

Participants will be informed that they do not have to answer a question if they do not want to. They are also allowed to withdraw from the study at any moment. All correspondence with participants will be by direct contact. All electronic surveys

and forms will be entered and uploaded using Research Electronic Data Capture (REDCap), which is securely hosted by the University of Miami's IT Department.

To protect the study's subjects' privacy interests, interviews with participants will take place in a location that offers enough privacy, so that they do not have to worry about being seen entering a place that they feel might stigmatize them, or about being overheard when answering sensitive questions or discussing private medical information with other than their physicians or gynecologists. To make the participants more comfortable with the research, the data collection will be limited to only the minimum amount of information necessary to accomplish the study's purposes. Moreover, the questions will be asked by female researchers to make the subjects feel at ease with the situation.

28) Compensation for Research-Related Injury

All research involves a risk of research-related harm to participants. While we do not expect any physical injury related to this study, we may encounter psychological, social or economic risks, in spite of all safety measures. If such problems occur, the researchers will refer participants to the resources of the Ministry of Health for further care and attention. The University of Miami has not set aside funds to pay for any such reactions, or for any related care.

29) Economic Burden to Subjects

The subjects may be responsible for the local transportation expenses related to arriving to the research locations. Refreshments will be provided for the focus group participants.

30) Consent Process

Written Informed consent will be obtained by the Co-I/local study coordinator after pre-screening. Consent will be obtained in a private area from individuals who are eligible and agree to participate after the Co-I/local study coordinator describes the study. Potential participants will be told that we are conducting a research study to understand how innovations like an hpv self-sampling tool would be accepted by you and in your community.

Participants are given the opportunity to opt out of selected study procedures. Informed consent will be provided in English.

A waiver of signed consent is requested for screening activities. This research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

31) Process to Document Consent in Writing

We will be following the SOP HRP-090 Informed Consent Process for Research when obtaining consent.