INFORMATION SHEET
FOR AIM 3 FOCUS GROUP/INDIVIDUAL INTERVIEW

Study Title:	**Adaptation of an HPV education resource to promote HPV vaccination among Latino Young Men who Have Sex with Men in Puerto Rico and Florida** **Proyecto Hombres Previniendo el VPH (Proyecto HPV)**
Protocol Number:	**MCC 20819**
Sponsor:	**National Cancer Institute (NCI)**
Principal Investigator:	**Shannon Christy, PhD**
Telephone:	[redacted]
Address:	[redacted]

You are being asked to take part in a research study. The information in this document should help you to decide if you would like to participate.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of the study is to assess Human Papillomavirus (HPV) and HPV vaccination knowledge, awareness, attitudes, health beliefs, and behaviors as well as educational preferences for learning more about HPV and HPV vaccination and to receive feedback on and adapt HPV educational materials for young Latino men who have sex with men.

The purpose of the current part of the study is to conduct focus groups and individual interviews with 24 Latino sexual minority men in Puerto Rico and Florida to gain feedback on Human Papillomavirus (HPV) education materials so that they are understandable, relevant, and engaging.

WHAT IS INVOLVED IN THE STUDY?

For this phase of the study, we are asking you to participate in a one-time focus group or an individual interview that will be audio digitally recorded and transcribed verbatim. The focus group/individual interview will take about 90-120 minutes. You will also be asked to complete a brief sociodemographic survey either online or in-person, prior to the focus group or individual interview.

WHY AM I BEING ASKED TO TAKE PART IN THE STUDY?

You are being asked to take part because you are a Latino man between the ages of 18-26, live in Puerto Rico or Florida, and identify as being sexually to men.

HOW MANY PEOPLE WILL BE IN THE STUDY?

About 24 participants in Florida and Puerto Rico will participate in this phase of the study.

WHAT HAPPENS IF I DO NOT WANT TO BE IN THIS RESEARCH STUDY?

Your participation is voluntary, and you may stop your participation at any time. There will be no penalties or loss of benefits or opportunities if you do not participate or decide to stop once you start. The Investigator or the sponsor can end your participation in the study without your consent.

ARE THERE BENEFITS TO ME IF I AM IN THE STUDY?

This study is for research purposes only. There is no direct benefit to you from your participation in the study. Information learned from the study may help other people in the future.

ARE THERE RISKS TO ME IF I AM IN THE STUDY?

The primary risk of the study is related to privacy. All reasonable measures will be taken to protect your personal information so that it does not get shown to someone who is not permitted to see it. You might feel uncomfortable sharing your sexual practices or sexual orientation experiences. You do not have to answer any question that makes you uncomfortable. Even if we publish the findings from this study, we will keep your study information private and confidential. Anyone with the authority to look at your records must keep them confidential. There may be risks which are currently unknown.

WILL IT COST ANYTHING TO BE IN THE STUDY?

There is no cost to be in the study.

WILL I GET PAID?

Each participant will receive a $50 gift card after participating in the focus group/individual interview.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment and because of federal law, we must obtain your authorization before we use or disclose your information for this study.

By agreeing to participate, you are permitting researchers at Moffitt Cancer Center to use personal health information for research purposes within its organized health care arrangements. You are also allowing the Moffitt Cancer Center to disclose your personal health information to outside organizations or individuals that participate in this study. We may publish what we find out from this study. If we do, we will not let anyone know your name. We will not publish anything that would directly let people know who you are.

Identifiers might be removed from your identifiable private information collected during this study and could then be used for future research studies or distributed to another investigator for future research studies without additional informed consent.

HIPAA AUTHORIZATION FOR USE OR DISCLOSURE OF PROTECTED HEALTH INFORMATION FOR RESEARCH

Who will disclose, receive, and/or use your information?
Your records are confidential and they will be kept in a secure environment and protected to the full extent of the law.

To do this research, the following people and/or organization(s) will be allowed to disclose, use, and receive your information, but they may only use and disclose the information to the other parties on this list, to you or your personal representative, or as permitted by law:

- Every research site for this study, including the Moffitt Cancer Center, and each site's study team, research staff and medical staff.
- Any person who provides services or oversight responsibilities in connection with this study.
- Every member of the Moffitt Cancer Center workforce who provides services in connection with this study.
- The person who is responsible for the study nationwide or worldwide (study chairperson).
- Any laboratories, individuals, and organizations that use your health information in connection with this study.
- Any sponsor of the study, including the following sponsors: National Cancer Institute
- Any federal, state, or local governmental agency that regulates the study (such as the U.S. Food and Drug Administration (FDA) and Florida Department of Health (FDH). The U.S. Department of Health & Human Services (DHHS), Office for Human Research Protections (OHRP).
- Other government agencies in this or other countries.
- The designated Protocol Review and Monitoring Committees, Institutional Review Boards such as Advarra IRB, Privacy Boards, Data and Safety Monitoring Board and their related staff that have oversight responsibilities for this study.
- The National Cancer Institute in evaluating the ongoing research of the Moffitt Cancer Center as a Comprehensive Cancer Center.

The organizations and people listed above may employ or pay various consultants and companies to help them understand, analyze and conduct this study. All of these people may not be known now, but if you would like to have more specific information about this at any time during the study, you may ask the study investigator and your questions will be answered.

Moffitt Cancer Center cannot guarantee the privacy of your information, or block further use or distribution, after the information has left the Moffitt Cancer Center. Others listed above may further disclose your information, and it may no longer be covered by federal privacy

regulations. If all information that does or can identify you is removed from your records, the remaining information will no longer be subject to this authorization and may be used or shared for other purposes. You might have the right to see and copy your health records related to this research. You might not be able to see or copy some of your records until after all participants finish the study. If it is necessary for your care, your records will be provided to you or your regular doctor.

WHAT INFORMATION WILL BE USED OR DISCLOSED?

By agreeing to participate, you authorize the use and disclosure of your entire study record and any medical or other records held by Moffitt Cancer Center, including, but not limited to, HIV/AIDS, mental health, substance abuse or genetic information. The purpose for the uses and disclosures you are authorizing is to conduct the study explained to you in this information sheet and to ensure that the information relating to that study is available to all parties who may need it for research purposes.

Your authorization to use your health information will never expire unless and until you expressly revoke it in writing to the study investigator listed on the first page of this information sheet.

Any data collected before your letter will continue to be used as necessary to preserve the integrity of the study, however no additional information will be collected after you withdraw your authorization.

You do not need to agree to this authorization, but if you do not, you cannot participate in this study.

CERTIFICATE OF CONFIDENTIALITY

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) There is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);
2) You have consented to the disclosure, including for your medical treatment; or
3) The research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project or for information that is required by the Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the

researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

ALTERNATIVES TO PARTICIPATION

This research study is for research purposes only. The only alternative is to not participate in this study.

WHOM TO CONTACT ABOUT THIS STUDY

During the study, if you have questions, concerns or complaints about the study, please contact the Investigator at the telephone number listed on the first page of this consent document.

An institutional review board (IRB) is an independent committee established to help protect the rights of research participants. If you have any questions about your rights as a research participant, and/or concerns or complaints regarding this research study, contact:

- By mail:

  Study Participant Adviser
  Advarra IRB
  6100 Merriweather Drive, Suite 600
  Columbia, MD 21044

- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Participant Adviser: Pro00046114.

By participating in the focus group/individual interview, I am giving my consent to participate.