Informed Consent Form
ULACNet-104: CAMPO Global Cancer Health Disparities Supplement

Relationship between high-risk HPV infection, high-grade squamous intraepithelial anal lesions, and anal microbiome among three distinct populations of Hispanic people living with HIV in California, Mexico, and Puerto Rico.

Objectives of the study
We are inviting you to participate in a research study that seeks to answer the question: Is there a relationship between the types of bacteria that live in the anus (also known as the anal microbiome) and the risk of high-risk human papillomavirus infection or HPV-related premalignant lesions in Hispanic people living with HIV in Puerto Rico, Mexico and California? The investigators responsible for this study are Dr. Jorge Salmerón (Condesa Clinics in Mexico, National Institute of Public Health), Dr. Ana Ortiz (Hospital del Centro Comprensivo de Cáncer de la Universidad de Puerto Rico) and Dr. Joel Palefsky (ANCRE Center, University of California, San Francisco). This study is funded by the U.S. National Cancer Institutes (Grant: U54CA242646).

Voluntary participation
You have a choice whether or not to participate in this study, or to change your mind at any time. If you decide to withdraw participation, let the study team and the principal investigator know as soon as possible. No matter what you decide, you won't lose access to health care or any legal rights. Before you decide whether to participate in this study, it is important that you understand all of the procedures. Read all the information provided carefully, take your time to discuss it with anyone you want, and ask all the questions you need.

This informed consent form contains key information to help you make a decision. Please take the time to read it carefully. We are inviting you to participate in this research study because you are already part of the ULACNet-101 study and are eligible to participate in this new project.

Procedures
Your doctor, nurse, or study coordinator will take you to a private office where you will be asked to answer a diet and lifestyle questionnaire, which will take approximately 30 minutes. You do not need to answer questions that make you uncomfortable, but we ask that you be as honest as possible in answering the questionnaire. We will not subject you to any other procedures, as no additional samples will be required to those already provided by you in the ULACNet-101 project.

Contact us for information about your rights as a study participant
If you have questions about your rights during this research study, you may contact the Chair of the Ethics and Research Committee of the National Institute of Public Health, Dr. Angélica Ángeles Llerenas [redacted] or if you prefer, you may write to her [redacted]

Contact us for questions and information about the study
If you have any questions related to the study, you can contact the study coordinators in Mexico at the Condesa Iztapalapa and Cuauhtémoc clinics, Paula Saldaña-Rodríguez [redacted] and Thalía Garcés-Jurado [redacted] and/or Dr. Jorge Salmerón [redacted]

Simplified Privacy Notice:
The National Institute of Public Health (INSP) [redacted] is responsible for the processing of the personal data provided by any person who participates in this research study, which will be protected in accordance with the provisions of the General Law on the Protection of Personal Data in Possession of Obligated Subjects and will be used exclusively for the purposes set forth in this document. You may request the correction of your data, that your data be deleted from our databases or withdraw your consent. For any of these requests, we ask you to contact the responsible researchers, Dr. Leticia Torres and Dr. Jorge Salmerón, [redacted] You also have the right to know who and for what purpose your data will be used. To request corrections or additions to your data, as well as to cancel or decline use of your data (ARCO rights) you may contact the Head of the Transparency Unit of the INSP, Dr. Edgar Leonel González González [redacted]

[redacted], or at the INSP offices, [redacted].

As part of the collaboration of this study, their information will be shared with the group of researchers from the following institutions: the University of California, San Francisco, the Comprehensive Cancer Center of the University of Puerto Rico and the National Institute of Public Health of Mexico, which are the organizations that are conducting this study within the CAMPO consortium; the sponsor of the study, the U.S. National Cancer Institutes, who will obtain information from this research under the data collection authority Title 42 U.S.C.284; the INSP Research Ethics Committee to protect the people who participate in this study. If you do not agree to the sharing of your data with these bodies, please let us know by sending a message to the Principal Investigators to the following email address: leticia.torres@insp.mx or jorge.salmeron@insp.mx.

Comprehensive Privacy Notice: Information regarding the comprehensive privacy notice for study participants can be found at the web page of the Institute National of Salud Publica at the following link: https://www.insp.mx/resources/images/stories/Transparencia/docs/Aviso_de_privacidad_integral_microbioma.pdf

We thank you for your participation in this project.

Informed Consent Statement

I have been adequately informed about this study, as well as the contents of this Informed Consent Form that has been given to me. I was given the opportunity to carefully read the information provided and my questions were answered satisfactorily. I have received a copy of this consent form. By signing this document, I consent to participate in the study described here.

_____

Participant Name

_____ _____

Participant Signature **Date**

I have explained to the participant all the information pertinent to this study and answered all of their questions. In my opinion, they fully understood the information described in this document and freely consent to participate in this study.

_____

Name of the person obtaining informed consent

_____ _____

Signature of the person obtaining informed consent **Date**