INFORMATION LEAFLET AND INFORMED CONSENT

TITLE: The Prevalence of Oral HPV infection and Oral lesions in People Living with HIV in a HIV Primary Care Clinic

PROTOCOL NO.: MISP #10965
WCG IRB Protocol #20226457

SPONSOR: Vivent Health

INVESTIGATOR: Dr Cynthia (Cindy) S Firnhaber, MD
Vivent Health
5250 Leetsdale Dr Suite 300
Denver C0 80246

STUDY-RELATED PHONE NUMBER: 303-393-8050 (24 hours)

Taking part in this research is voluntary. You may decide not to participate, or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you have any questions, concerns, or complaints or think this research has hurt you, talk to the research team at the phone number(s) listed in this document.

Each **Participant** must receive, read, and understand this document **before** any study-related procedure

INTRODUCTION

Good day, my name is **Dr. Cindy Firnhaber**. I am a physician at Vivent Health and oversee this study at our site. I would like to invite you to consider taking part in this research study because you are living with human immunodeficiency virus (HIV). In this document, called a consent form, we are going to provide you with information regarding this study, to help you decide if you want to be a part of it or not. The study staff will also talk with you about this information. You should feel free to ask any question about this study at any time. You can also take this form at home with you if you prefer to read it at your own convenience. Once you are satisfied with the information you have received, if you decide to take part in this study, you will be asked to sign this consent form (last page), to indicate your consent. After signing it, you will get a copy for you to keep.

Please remember that, even if you agree to participate in this study and sign this form, you will be FREE TO WITHDRAW (interrupt) from the study AT ANY TIME, should you change your mind.

WHY IS THIS STUDY BEING DONE?
There are over 100 types of human papillomavirus (HPV) that infect humans. Many of these types of HPV infect the cervix, anus, and the mouth. The HPV virus can cause the cells in areas of the body to change which may lead to pre-cancer and then cancer if not treated. About fifteen HPV strains are known to cause pre-cancer changes that can lead to cancer, including types 16 and 18 which account for most of the precancerous tissue changes and cancers of the anogenital tract.

The main purpose of this study is to determine how many people in our clinic have the HPV virus in their mouths and to look for any sores or changes in the mouth. This study is investigating if HPV might be related to lesions in the mouth. While HPV has been known to be associated with pre-cancer changes of the cervix and the anus, only cervical samples are routinely co-tested for the presence of HPV in the United States. There is little information about oral HPV infection and associated changes in people living with HIV. This study is to help gather more information regarding oral HPV infection in people living with HIV.

WHAT DO I HAVE TO DO IF I AM IN THIS STUDY?
This visit will show if you are eligible to take part in this study. The study provider will review your medical history and determine if you meet the inclusion/exclusion criteria to participate in the study. To participate in this study, you must be HIV positive, have had at least two visits to the Vivent Health Denver clinic, have a CD4 count above 200 cells/mm^3, be willing to perform an oral swish and spit sample collection, and have an oral exam. A previous history of oral or tongue cancer will exclude you from the study. A brief summary of what you can expect at study visits can be found below.

Study Visit:
If you agree to participate in this study and qualify, we will gather information on your medical history and physical exam will occur.

Medical History and Physical Exam:
The study team will review your demographic and vaccine history in the electronic medical chart (EPIC). You be asked additional questions about your health including information regarding HIV, anal and cervical pap smears, and treatment for any HPV related anal and/or cervical lesions. Further information may be asked regarding substance abuse (such as smoking cigarettes, alcohol, methamphetamine, and other substances) over the counter supplements and prescribed medications. The dentist will ask you about the care of your mouth and teeth.

Swish and Spit Sample:
After the medical history is taken, the study coordinator or your provider will have you swish approximately 3 tablespoons of mouthwash solution (like Scope) in your mouth for 15 seconds and then spit the sample into a cup. Once the sample is collected, the study staff will schedule an appointment with the Vivent dentist.

The oral solution samples will be sent to Dr. Anna R. Giuliano, PhD

Professor and Director Center for Immunization and Infection Research in Cancer (CIIRC) Moffitt Cancer Center in Tampa Bay Florida. Samples will have a unique study identifier and the Moffit laboratory will not have access to your personal identification or information. (See Confidentiality Section). The oral HPV results are for research purposes only and not available to study participants.

Dental Visit

An appointment will be scheduled with the Vivent Health dentist within 30 days at your convenience.

Dental Exam:

For each study participant coming in for a comprehensive head and neck exam, we start by inspecting the area as we discuss medical/dental history and take vitals. The participant is then placed in recline at the 12 o'clock position. Palpation of the angle of the jaw and chewing muscles occurs. Examination of lymph nodes along the jaw, neck, and visualization for any facial abnormality is done. An exam inside the mouth to inspect sides of the tongue, roof, side, and floor of the mouth occurs.

If any lesion is noticed, we will ask the participant for any known history. If they are unaware of the lesion, we will have them return in 2 weeks and try to see if there is any factor that is causing the lesion that can be changed. If the lesion persists, we will either perform the biopsy at our office or ask you to be seen by an oral surgeon or ears, nose, and throat physician if necessary. All lesions are sent to oral pathologist for diagnosis, which is then reviewed with the participant.

The dental exam will be covered by the study. If further evaluation and treatment is needed that is outside of the clinic's scope, referral to an outside specialist that is covered by the participant's insurance will be completed. The study cannot pay for the specialist appointment or any imaging or procedures that might be needed.

SCHEDULE OF EVENTS

The study staff can answer any questions you have about the study and the procedures. The table below can be used as a quick reference.

	Inclusion/Exclusion Criteria	Consent signed	Demographics/health hx/laboratory results collected	HPV sample collected	Oral exam By Vivent dental team *
Clinic Visit	X	X	X	X	X

* Oral exam may be rescheduled for another day within 30 days

HOW LONG WILL I BE IN THIS STUDY?

This study is just one visit for the participant.

WHY WOULD THE DOCTOR TAKE ME OFF THIS STUDY EARLY?
The study doctor may need to take you off the study early without your permission if:

- Your doctor feels it is in your best interest
- The study is cancelled

WHAT ARE THE RISKS OF THE STUDY?

- Minor discomfort of the swish and spit sample taking
- Minor discomfort in the oral exam by HIV provider or the dentist
- Possible loss of confidentiality

ARE THERE BENEFITS TO TAKING PART IN THIS STUDY?.

- Access to a thorough oral exam at Vivent health.
- Further information would be gathered regarding HPV infection in the mouth in the people living with HIV.

WHAT OTHER CHOICES DO I HAVE BESIDES THIS STUDY?
Instead of being in this study, you have these options:

- You may choose not to participate.
- You may choose to have oral exams outside of a clinical trial.

Please talk to your provider about these and other choices available to you. Your provider will explain the risks and benefits of these choices.

WHAT ABOUT CONFIDENTIALITY?
We will do everything we can to protect your privacy. In addition to the efforts of the study staff to help keep your personal information private, we have undergone training to ensure that we understand the best ways to keep your information safe. A study number will be assigned to your file and your identity will be kept confidential. Information that is used in scientific journals will not include any information that identifies you as a participant in this study.

The following are people or organizations who may review your records from this study:

- WCG IRB Ethics Committee
- Government regulatory agencies such as the U.S. Food and Drug Administration (FDA)
- Study monitors
- Merck
- personal doctor.

By agreeing to participate in this study, you hereby agree to allow your medical records to be reviewed by them as part of their obligations relating to the oversight of this clinical study.

Any information uncovered about your test results or state of health from your participation in this study will be kept in strict confidence. The only exception to this rule

will be cases of communicable diseases where a legal duty of notification to the Department of Health is required. In this case, you will be notified of our intention to disclose such information to the authorized state agency.

The results of this research might be published. However, your name and other identifying information will be kept confidential.

Your information will be protected from disclosure to others to the extent required by law. Complete secrecy cannot be promised.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WHAT ARE THE COSTS TO ME?
The HPV oral sample and testing will be provided to you at no cost. This study will not provide you with HIV drugs. Your insurance company, or your health care system will need to assume the cost of any HIV drugs that are prescribed to you by your doctors. The study is not able to pay for any oral imaging or procedures ordered by the oral specialist. If you become pregnant while on this study, the study will not cover any cost related to your pregnancy, the delivery of your baby, or the care of your baby.

WHAT HAPPENS IF I AM INJURED DURING THE STUDY?
A study related injury is one that occurs as a direct result of the administration of the study medication or of study specific procedures. You must notify a member of the study staff immediately of any complications, side effects, and/or injuries you experience during the study. If a research-related injury occurs, you have not given up any of your legal rights by signing this consent form.

Additional information on the payment of medical treatment and compensation due to injury can be obtained from any of the study staff. A copy of the ABPI Guidelines and the insurance certificate is available should you wish to review them.

The insurance does not pay for:
- Medical treatment of other injuries or illnesses
- Injuries caused by not following the study requirements (protocol)

WILL I RECEIVE ANY PAYMENT?
There will be $50.00 compensation provided to you for completing the study measures.

There will be no cost to you for:
- Study-related visits (including dental visits)
- Physical examinations
- Laboratory tests or other procedures
- Money for transportation to an Ears, Nose, and Throat specialist if needed in relation to this study

Treatment for other medical conditions including HIV will be done at your usual medical clinic and will not be paid for by the study.

WHAT ARE MY RIGHTS AS A RESEARCH PARTICIPANT?
Taking part in this study is completely voluntary. You may choose not to take part in this study or leave this study at any time. You do not need to give a reason if you want to leave the study. Your decision not to participant or to leave the study will not have any impact on your access to other medical care.

You must inform study staff if you wish to leave the study and the study staff will supervise the process of discontinuation with your health needs as first priority.

Study staff will disclose new information from this or other studies that may affect your health, welfare, or willingness to stay in this study. If you want the results of the study, let the study staff know. If you decide to withdraw from the study, your HPV swish and spit sample will be removed from storage (either at Vivent or at Dr. Anna Giuliano's laboratory in Florida) and destroyed.

WHAT DO I DO IF I HAVE QUESTIONS OR PROBLEMS?
While you are in the study, you will be under the care of **Dr. Cindy Firnhaber and other Vivent health providers**. If at any time between your visits, you feel that any of your symptoms are causing you any problems or you have any questions during the study, please contact Dr. Firnhaber or any other providers working on this study.

Dr. Cindy Firnhaber and other study personnel can be reached at **303-393-8050 (24 hours)**. This number includes weekends or nights if there are any complications or questions.

This study was submitted to the WCG IRB and written approval was granted by the committee for this study to be done by Vivent Health. This study has been structured in accordance with the Declaration of Helsinki (updated October 2008), which deals with the recommendations guiding doctors in research involving human participants. A copy of this document is available should you wish to review it.

For questions about your rights as a research participant or questions, concerns or complaints regarding the conduct of this study, you can contact WCG IRB at:

By Mail:

WCG IRB
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 855-818-2289
E-mail: researchquestions@wcgirb.com

PARTICIPANT QUESTIONS
Did the participant raise any questions? YES / NO

If yes, what were they?
_____
_____
_____

CONSENT:
If you have read this consent form (or had it explained to you), all your questions have been answered and you agree to take part in this study, please sign your name below.

_____
Participant's Name (print)

_____ _____
Participant's Signature Date and Time

_____
Study Staff Conducting the Consent Name (print)

_____ _____
Study Staff Conducting the Consent Signature Date and Time

_____
Witness' Name (print), (As appropriate)

_____ _____
Witness Signature Date and Time