IRB APPROVAL OF MODIFICATION

May 31, 2022

Dear German G. Gornalusse:

On 5/31/2022, University of Washington IRB Committee B reviewed the following application:

Type of Review:	Modification / Update
Title of Study:	Comparing immune activation and latent HIV reservoir size between people living with HIV (PWH) on tenofovir-containing versus NRTI-sparing ART
Investigator:	German G. Gornalusse
STUDY ID:	STUDY00011699
MOD ID:	MOD00012497
Funding:	Name: National Institutes of Health (NIH), Grant Office ID: A124241, Funding Source ID: R01AI134293 Funding Title(s): "Identification of drug-targetable IFN-stimulated genes mediating immune activation during ART-treated HIV-1 infection"

IRB Approval

Under FWA #00006878, the IRB approved modifications to your research. The expiration of the current IRB approval period remains 12/13/2022.

- COVID NOTE: See the HSD website for the latest COVID guidelines for conducting human subjects research.
- This approval applies only to the activities described in your application (including any references to specific grant sections). It does not include other activities that may be described in your grant or contract.

Location of documents

Use the revised consent form that was approved by the IRB. It can be downloaded from the Final column under the **Documents tab** in Zipline.

Thank you for your commitment to ethical and responsible research. We wish you great success!

Sincerely,

Shawn Query, CIP
Senior Administrator, Committee B
squery@uw.edu
206.221.0265

UNIVERSITY OF WASHINGTON
HARBORVIEW MEDICAL CENTER

CONSENT FORM

Comparing immune activation and latent HIV reservoir size between people living with HIV (PWH) on tenofovir-containing versus NRTI-sparing ART

Researchers:

German Gornalusse, PhD	Research Assistant Professor, OB/GYN	(206) 326-9555
Florian Hladik, PhD, MD	Research Associate Professor, OB/GYN	(206) 221-0585
Romel Mackelprang, PhD	Research Assistant Professor, OB/GYN	(206) 685-8576
H. Nina Kim, MD, MSc	Professor, Medicine	(206) 744-5130
Lindsay Legg, LPN	Research Referral Nurse	(206) 744-8748

Emergency 24-hour number **Page ACTU AIDS researcher on call** **(206) 744-3000**

RESEARCHER'S STATEMENT

We are asking you to be in a research study. This form gives you information to help you decide whether or not to be in the study. Being in the study is voluntary. Please read this carefully. You may ask any questions about the study. Then you can decide whether or not you want to be in the study.

KEY INFORMATION ABOUT THIS STUDY

The purpose of this study is to learn whether the type of HIV medication you have been prescribed by your physician influences how large your HIV reservoir is. The HIV reservoir is the cells where HIV hides in your body. We also want to learn how activated your immune system is. This page is to give you key information to help you decide whether or not to participate. Please ask the research team or study coordinator questions. If you have questions later, our contact information is shown on top of this page.

WHY ARE WE DOING THIS STUDY AND WHAT WILL YOU BE ASKED TO DO IF YOU PARTICIPATE?

People living with HIV take different HIV medications. Many of them contain a type of drug named NRTIs (for "nucleoside reverse transcriptase inhibitors). No one knows if NRTI-containing treatments are better or worse than other types. For example, we don't know if there are differences in how they affect the immune system. Also, we don't know if these treatments differ in how they affect the number of cells that contain HIV in a dormant stage (also known as the HIV reservoir). By doing this study, we hope to improve the quality of life of people living with HIV. If you agree to participate:

- You will continue taking HIV meds as prescribed by your primary physician.
- You will have two research clinic visits during the study.

In the first visit, we will:

-ask you to fill out a survey about your medical history, sexual history and substance abuse. You may refuse to answer any question in this survey.
-do a targeted physical exam, where we will focus on body parts related to your immune system.
-draw ~4 teaspoons of blood from your arm.
If your lab results show you meet the eligibility criteria (mainly if we do not detect HIV in your blood or if the levels are very low), you will be invited to come in for a second visit.

In this second visit, we will:
-repeat the physical exam,
-ask you more questions about your health,
-perform a pregnancy test (if you are a woman who could be pregnant),
-draw about 7 teaspoons of blood and
-perform two medical procedures to obtain samples from your rectum and your duodenum (part of your intestines, near your stomach). For the rectal biopsies, we will insert a small tubular instrument into your rectum and collect five small samples. . For the duodenal biopsies, a nurse under the supervision of a trained GI doctor(endoscopist) will administer sedating medication(s) such as Sublimaze Midazolam, and potentially Benadryl through your arm vein to achieve light (conscious) sedation and allow you to tolerate the EGD procedure. We will then insert an endoscope through your mouth down to the esophagus, stomach, and first and second portion of the duodenum. ;We will take several small samples from the duodenum.

WHY MIGHT YOU **NOT** WANT TO BE IN THIS STUDY?

You might not want to participate if you are planning to change your HIV meds or if you are having side effects. There are risks involved in study participation. For example, the biopsy procedures might cause bleeding, pain, infection, tearing of the lining of intestines, or reaction to the medication used to sedate you.
You will need a ride home after the second visit due to effects of the sedating medication.
You will need to abstain from receptive anal sex for 7 days after the second visit.
You may not want to have your samples and data (which are coded and had identifying information removed) made available to other researchers.
The detailed consent (pages 5 and 6) provides a list of possible risks that are associated with the study as well as potential social harm that can result for situations when confidentiality may be breached.

WHY MIGHT YOU WANT TO BE IN THIS STUDY?

This is a preliminary study and it will have no direct benefit to you. However, information learned from this study may help other people living with HIV. The results may someday lead to new and better HIV meds or even a cure.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. If you decide not to take part, you will not lose any services, benefits, or rights you would normally have. You will still

receive treatment for HIV and your decision will not affect the medical care provided by your primary physician. You can choose to withdraw at any time during the study.

WHAT IF YOU WANT MORE INFORMATION?

The rest of this document gives you more information about the study, like:
- What will be done at the research visits
- The risks (side effects) of study procedures
- Who will pay for treatment if you are injured from the study procedures
- How we will protect your privacy
- Who to talk to if you have problems, suggestions or concerns

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PURPOSE OF THE STUDY

Current treatments for HIV (known as antiretroviral treatment or ART) are extremely effective in controlling HIV reproduction. In many patients, these drugs suppress the number of viruses measurable in the blood to undetectable levels. Nevertheless, whenever ART is stopped, HIV levels rebound due to viruses that are hiding in reservoirs in the body.

The purpose of this study is to learn whether the type of HIV medication (antiretroviral treatment) you have been prescribed by your physician influences how large your HIV reservoir is. In the HIV reservoir, the HIV does not replicate (is not active) and remains in a dormant state. The latent HIV reservoir results from HIV DNA integration into the chromosomes of your immune cells.

Additionally, we want to learn how activated your immune system is. We believe that it may be possible in the future to develop a treatment to completely eliminate HIV from a person who has a small HIV reservoir and a calm immune system. Thus, this current study is motivated by finding and implementing a cure for HIV infection in the future.

Specifically, we want to determine the size of the HIV reservoir and the magnitude of immune activation in the blood and in the intestinal tract of HIV-infected people who take one of two types of antiretroviral treatment. The first one is an ART regimen that contains a type of drugs named NTRIs (for "nucleoside reverse transcriptase inhibitors); a compound called "tenofovir" is an example of NRTI. The second one is an ART regimen that does not contain NRTIs (we call it "NRTI-free treatment). The former type of combination ART has been available for many years under several brand names. The latter, tenofovir-free combination ART, has been available as an oral tablet since 2017 under the brand name Juluca® and as a depot (long acting) intramuscular injection under the brand name Cabenuva® since 2020.

We plan to recruit 20 HIV-infected people using tenofovir-containing ART and 20 HIV-infected people using either Juluca or Cabenuva. This study is being conducted by the AIDS Clinical Trials Unit (ACTU). The study will be done at the University of Washington AIDS Clinical Trials Unit (UW ACTU) at Harborview Medical Center (HMC), and the Gastroenterology Clinic at HMC.

We have identified you as potentially eligible for this study using Leaf, a self-service tool for University of Washington investigators to search the electronic health system records within UW Medicine. We obtained approval by UW's Institutional Review Board to access identified data.

About 40 people locally will take part in this study. After a screening visit, if you participate in the study, you will have a single study visit where we will take samples from your blood, and from the upper and lower gastrointestinal tract.

STUDY PROCEDURES

Screening Visit (at UW ACTU) – up to 90 minutes

The screening visit is to see if you meet the requirements for joining the study. At this visit, we will:

- Ask you to sign a consent form for screening and study participation, and a release for us to obtain your HIV test results and HIV-related immune status from your primary care physician
- Fill out a survey with questions related to your sexual history and substance abuse. There will be questions such as "Are you currently having sex of any kind—so, oral, vaginal, or anal— with anyone?", "Do you use alcohol, heroin, meth, cocaine or marihuana and if so, how much and how often? or "Have you ever shared a needle or injection equipment with another person for any reason? You may refuse to answer any question in this survey or in any questionnaire.
- Do a targeted medical history. "Targeted medical history" means we will ask you questions that focus on specific aspects of your health. We will ask you questions related to your immune system, your history on past and current infections and use of medications, for example. You may refuse to answer any question in this survey or in any questionnaire.
- Do a targeted physical exam. "Targeted physical exam" means we will examine specifically the body parts directly involved with your immune system. The medical staff may take your vital signs (blood pressure, temperature, breathing rate, weight, pulse), listen to your heart and feel your abdomen and lymph nodes.
- Draw about 19ml (or about 4 teaspoons) of blood from a vein ("venipuncture") to perform the following laboratory tests (if not documented within the prior month):
    - HIV plasma viral load testing (to measure the level of HIV in your plasma)
    - Peripheral blood CD4+ T cell count (to measure the level of a type of immune cells in your blood)
    - Complete blood count (to measure the cells that make up your blood: red blood cells, white blood cells, and platelets)
    - PT/PTT (for blood clotting function)
    - Renal (kidney) function panel

You will potentially be recruited into this study if you meet these criteria: your viral load (level of HIV in your plasma) is very low or undetectable (less than 40 copies/ml), you have been taking ART for more than 1 year, you do not have chronic hepatitis, and your blood clotting tests show normal results.

If You Do Not Enter the Study

If you decide not to take part in this study or if you do not meet the eligibility requirements, we will still use some of your information. As part of this screening visit, some demographic (for example, age, gender, race) will be maintained in the ACTU database.

Study Medications

Your antiretroviral treatment will be prescribed by your primary care physician. All prescription refills and monitoring will occur through that mechanism. THE DRUGS WILL NOT BE PROVIDED BY THE STUDY.

Procedure Visit (at UW ACTU and HMC Gastroenterology Clinic) – up to 4 hours

The procedure visit must occur within 30 days of the Screening Visit

For all participants at this visit we will:

- Perform a targeted medical history and physical exam
- Perform a urine pregnancy test (in women who can be pregnant)
- Draw 40 ml (about 7 teaspoons) of blood by venipuncture for:
    - Stored blood for later testing as part of this or future studies. We will collect 3 tubes with 10 ml of blood each for plasma and white blood cells.
    - Special testing of the DNA of blood cells for HIV DNA, and of the RNA of blood cells for signs of immune activation. We will collect 4 tubes with 2.5 ml of blood each. The DNA is a genetic material made up of genes and the RNA made up of molecules your cells need to "read" your genes.
- Perform an **anoscopy** with biopsies

  Anoscopy is an examination using a small, rigid, tubular instrument called an **anoscope** (also called an anal speculum). This is inserted a few inches into the rectum to collect some small samples of mucosal tissue. We will collect 5 biopsies and use one cytobrush (a small soft brush used to collect cells). You may feel pressure during the examination, and the anoscope will make one feel as if he or she were about to have a bowel movement. There may be mild pain, but many patients do not feel any pain from anoscopy.
- Perform an **esophagogastroduodenoscopy (EGD)** with biopsies

  This procedure will be done at the HMC Gastroenterology Clinic and involves looking at the esophagus, stomach, and first and second part of the duodenum.. This will also involve the use of an endoscope, which is a long flexible tube, to remove small tissue samples. The endoscope contains a tiny camera on the end to help the doctor examine your gastrointestinal tract. We will collect 5 biopsies and use one cytobrush (a small soft brush used to collect cells). This procedure uses light sedatives given by a vein in your arm. The procedure will take about 1½-2 hours, including time for recovery. You will need to have someone drive you home.

  In both cases (anoscopy and EGD), we will preserve some samples in a solution called "RNA later" (for RNA and DNA analysis) and some biopsies may be dry frozen (for potential study on proteins and determination of drug levels). contain a type of drugs named NTRIs (for "nucleoside reverse transcriptase inhibitors).

If You Stop Taking Your ART Medication Between the Screening and Procedure Visit

If you stop taking your ART medication between the screening and procedure visit, you are no longer eligible for this study. Please contact the study coordinator or nurse if this is the case.

RISKS, STRESS, OR DISCOMFORT

Risks of Anoscopy

There are few risks. With the biopsies, there is a slight risk of bleeding and mild pain. You should not have receptive anal intercourse for 7 days after anoscopy or until no blood is found.

Risks of EGD

There is a small chance of a hole (perforation) in the stomach, duodenum or esophagus from the scope moving through these areas. There is also a small risk of infection or bleeding at the biopsy sites. We quote risk of any of these happening to be less than 0.01%. These complications, should they occur, may require hospitalization, surgery, repeat EGD and/or a blood transfusion.

Risks of Sedating Medications

You could have a reaction to the medicine used during the procedure, which could cause:

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- Nervous System: Sedation, sleepiness, blurred vision, dizziness (lightheadedness), headache, disturbed coordination, rigidity, abnormal sweating, transient memory loss (amnesia), agitation, rapid involuntary muscle jerking or twitching (including tonic/clonic movements and muscle tremor), hyperactivity and combativeness
- Gastrointestinal System: nausea, vomiting, abdominal cramping
- Respiratory System: hiccoughs, thickening of bronchial secretions (sputum or expectorated mucus), respiratory depression, airway obstruction, laryngospasm (sudden spasm or closure of vocal cords), oxygen desaturation (lower percentage of oxygen in your blood), apnea (not breathing), coughing, If these effects remain untreated, respiratory arrest can occur.
- Cardiovascular: low blood pressure (hypotension), high blood pressure (hypertension), bradycardia (slow heart rate)
- Local effects at intravenous injection site: pain (burning and stinging), induration (hardening of the skin), redness, tenderness
- Anaphylaxis (severe allergic reaction) with red rash and itching (hives).
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- Heart attack or stroke. We quote this risk to be less than 0.01%.

Thus, less than 0.02% is the estimated incidence rate of having any adverse event considering the combined risk of the EGD procedure and sedating medications.

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Risks of Drawing Blood

Having blood drawn may cause some discomfort, lightheadedness, bleeding, swelling, or bruising where the needle enters the body, and in rare cases, fainting, or infection.

Risks of Social Harm

Although the study site will make every effort to protect your privacy and confidentiality, it is possible that your involvement in the study as a participant could become known to others (if it is not already) and that social harm may result (because you could become discriminated or singled out as being infected with HIV). For example, you could be treated unfairly or discriminated against by family members, friends, and/or the community. Likewise, the breach of confidentiality may make your

relatives or acquittances discriminate against you based on the information you provided about your history of illegal substance use (if any) and your sexual history.

ALTERNATIVES TO TAKING PART IN THIS STUDY

You may choose not to participate in this study if you don't want to. Your decision will not affect the medical care provided by your primary physician.

BENEFITS OF THE STUDY

This is a preliminary study and there will be no direct benefit to you from participating in this study. However, information learned from this study may help other people living with HIV. For example, we may learn which medications to treat HIV infection produce less inflammation and keep the number of latently infected cells (known as the HIV reservoir) smaller, which can be important when searching for an HIV cure.

SOURCE OF FUNDING

This study will be supported by grants from the National Institutes of Health.

CONFIDENTIALITY OF RESEARCH INFORMATION

The information we will gather about you is confidential. We will label your samples and the information about you with a number, not your name. We will keep your name and other information that might identify you (called the "identifiers") separate from your sample. The identifiers and links between the results obtained from your samples and your identifiers will be kept by the University of Washington researchers indefinitely because they may be valuable for future studies. .If we publish the results of this study, we will not use your name.

Your participation in this study will be noted in your UW medical record. Although we will make every effort to keep your information confidential, no system for protecting your confidentiality can be completely secure. It is possible that unauthorized persons might discover that you are in this study or might obtain information about you. University and government oversight offices such as the University of Washington Regulatory Offices, National Institutes of Health (NIH), the federal Office for Human Research Protections (OHRP), and study staff sometimes review studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

We will not release any information that identifies you without your written permission, except as required by law. We will ask you to sign a medical release of records form. This will allow us to obtain information from your primary care physician and to send study information, like your test results, to that provider using our hospital's electronic medical records system. We will need to have access to your medical records for this study. For example, we may need to look at records of previous illnesses and blood tests or records about illnesses that occur during the study. If you are not eligible for the study after completion of all screening tests, your results will be kept indefinitely in a confidential file at the ACTU.

Persons who have access to your medical record will have access to any research-related information or documents that are in your record. Access to your medical records is governed by Washington State law (RCW 70.02) and by the federal HIPAA law.

Should study personnel learn that you have acquired a new notifiable infection, they will report this to the King County Department of Health by confidential communication.

We have a Certificate of Confidentiality from the National Institutes of Health (NIH). This helps us protect your privacy. The Certificate means that we do not have to give out information, documents, or samples that could identify you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the institution(s) conducting the research, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- individuals who want to conduct secondary research if allowed by federal regulations and according to your consent for future research use as described in this form;
- King County or Seattle Police Department authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

The Certificate expires when the NIH funding for this study ends. Currently this is 31-May-2023. Any data collected after expiration is not protected as described above. Data collected prior to expiration will continue to be protected.

USE OF INFORMATION AND SPECIMENS

Commercial Profit

The specimens we collect as part of this research will not be used for commercial profit.

Genetic Sequencing

We will determine the copy number of HIV and its structures in the samples we will obtain from your immune cells and from your duodenal and rectal biopsies. We will also obtain data on gene expression from all the biological samples we take from you. We may obtain DNA genomic sequencing data from immune cells to map HIV integration sites or we may perform whole genome DNA sequencing to analyze whether certain genetic variants you have are associated with certain immune traits.

Returning Results to You

It is possible that some of the study evaluations may reveal previously unknown health conditions like new infections (e.g., hepatitis B, hepatitis C or other sexually transmitted infections) or new conditions (e.g. low white blood cell counts, high blood pressure, etc.). Your lab results containing information on your immune system/liver/kidney function and pregnancy test as well as observations made by the physician or nurse in any of the clinic visit(s) will be placed in your medical record as soon as they are available. You should be able to access them after they are posted, which typically takes between 1-2 weeks after the samples are collected. If we find abnormal results you will be referred to your primary

health care provider for treatment or management. The study coordinator or staff will contact you by phone and you will be asked to make an appointment with your primary health care provider. You and/or your insurance will be responsible for the cost of this follow-up visit or subsequent visits with your primary provider(s). We do not anticipate finding clinically urgent (life-threating) results. However, if this happens, we will notify you and your primary health provider by phone as soon as the results are available.

Using Your Data in Future Research

The information and/or specimens that we obtain from you for this study might be used for future studies. We may remove anything that might identify you from the information and specimens. If we do so, that information and specimens may then be used for future research studies or given to another investigator without getting additional permission from you. It is also possible that in the future we may want to use or share study information that might identify you. If we do, a review board will decide whether or not we need to get additional permission from you.

We may submit your de-identifiable genomic data to unrestricted repositories (i.e. the data will be made accessible to anyone via a public website). However, the data submitted will not have your name or any identifiable information like your date of birth or address. The purpose of this is to allow other researchers to perform complementary analyses ("secondary analyses") and discover new genomic associations between DNA variants, gene expression and traits or diseases.

GENOMIC DATA SHARING

We will obtain genetic information about you. Specifically, we will obtain information about messenger ribonucleic acid (RNA) molecules in your blood and tissues. We may also obtain parts of the genetic code of your chromosomes. We will not use your genetic material to grow new or genetically modified cells..

The National Institutes of Health (NIH) has developed data (information) banks that collect genomic study data. The NIH will store your de-identified information in these data banks for other researchers to use in future studies on any topic. This will include de-identified information about your HIV status. The researchers could be from government, academic, or commercial institutions.

The information from this study will be stored in a public unrestricted data bank that anyone can use. This public information will not include your name or other information that could identify you. It is possible that your genomic information could be used to identify you when combined with information from other public sources, but we believe this is unlikely to happen.

You will not be able to withdraw your information after it has been submitted to the NIH data banks. However, if you decide not to consent, you can write to the study Principal Investigator (Dr. Gornalusse) within 6 (six) months after recruitment and request not to submit the genetic information to the data banks. The email address of Dr. Gornalusse is: germag@uw.edu.

There is a risk that others will be able to trace this information back to you or close biological relatives. The current risk of this happening is very small but may grow in the future as new technologies are developed. If this should happen, someone might use this information to learn something about your health or genetic heritage. If linked to a medical condition and inappropriately shared with someone, it could affect your ability to get or keep some kinds of insurance. There is a possibility that this information could affect family members because certain conditions and traits run in families and are

inherited through genes. This could hurt family or other relationships. There is a risk that your information could become known to the public, employers, or law enforcement agencies. The information may be used to enforce negative stereotypes. There may also be other risks that are not yet known.

COSTS

There will be no cost to you for the study-related visits, physical examinations, required laboratory tests or other procedures. This study will not provide you with antiretroviral treatment. You, your insurance company, or your health care system may need to assume the cost of drugs not provided by the study. In some cases, it is possible that your insurance company or health care system will not pay for these costs because you are taking part in a research study.

COMPENSATION FOR PARTICIPATION

You will receive $100 for the anoscopy and $300 for the EGD in the form of a gift card. We will provide the compensation after the procedural visit (after you participated in the anoscopy and/or the EGD protocol). For each visit, you will also receive compensation for parking or transportation. This compensation will be given in a form of pre-paid parking vouchers or tickets or adult ORCA card (up to $30/visit); in both cases, vouchers and card will be given to you when you meet with the study coordinator at the time of the first or second visit. The compensation you receive for being in this study may be considered taxable income. The study staff may collect your name, address and social security number for tax purposes.

RESEARCH-RELATED INJURY

What to do

For a life-threatening problem, call 911 right away or seek help immediately. Contact one of the study clinicians (Lindsay Legg, Dr. Nina Kim at the numbers listed at the top of page 1 when the medical emergency is over or as soon as you can. For all other study-related problems, please also contact them. If you are injured because of being in this study, necessary medical treatment will be offered at a UW Medicine facility.

The costs of the treatment for an injury or illness thought to be related to this study may be billed to you or your health insurance just like other medical costs, or it may be covered by the UW's discretionary Human Subjects Assistance Program (HSAP), depending on several factors. The researcher may request HSAP coverage by following established procedures. If you wish to request HSAP coverage yourself, contact the researcher or the UW Human Subjects Division at hsdinfo@uw.edu or 206-543-0098. Ask the researcher if you would like information about the limits and conditions of the HSAP. The UW does not normally provide any other form of compensation for injury. However, the law may allow you to seek payment for injury-related expenses if they are caused by malpractice or the fault of the researchers. You do not waive any right to seek payment by signing this consent form. We will bill your health insurance for treating problems that result from your HIV or from standard clinical care. If you have no health insurance or your insurance refuses to pay, we will bill you. There is no program for compensation through the NIH for research related injury.

YOUR RIGHTS

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. The care that you would normally receive will not be affected if you decide not

to take part. Your decision will not have any impact on your participation in other studies conducted by NIH and will not result in any penalty or loss of benefits to which you are otherwise entitled. If you wish to withdraw, please contact the researcher listed on page 1 of this consent form.

You will need to register to get a hospital number if you don't already have one. A hospital medical record number is needed when visits occur at the UW ACTU or Harborview Medical Center. This means that you will have a chart with registration information. It is possible that unauthorized persons might discover that you are in this study, or might obtain information about you. When you come to a UW Medicine study location, like Harborview, you may be asked to sign a consent for care form. This allows UW Medicine to provide care for you in emergency situations. If you want to be in this study, you must sign the consent for care form. You will be asked for information such as your social security number when you register. This medical record will be permanent. It will be stored with all other UW Medicine medical records. We will send a copy of this consent to the hospital chart if you get your medical care at Harborview Medical Center.

We will discuss the study with you and answer all your questions. If you agree to take part, we will ask you to sign this consent form. You won't lose any other benefits just because you don't want to be in this study. You will not be giving up any of your legal rights by signing this consent form.

A copy of the consent form will be given to you or emailed to you at an email address that you provide. It will be a "PDF" document. Most computers already have PDF viewer software installed, which will allow you to open, read, or print the consent form. The email we send you will include a link to PDF viewer software (such as Adobe Acrobat Reader) in case your computer doesn't already have it. If you would prefer to receive a paper copy of the consent form at no cost to you, please contact the researcher listed on page 1 of this consent form.

Consent Presenter Statement

I have provided this participant with information about this study. The participant has been given sufficient time to consider participation and I have answered any questions they had. The participant indicated that they understand the nature of the study, including risks and benefits of participating.

Printed name of study staff obtaining consent Date

Subject's statement

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I give permission to the researchers to use my medical records as described in this consent form. I will receive a copy of this consent form.

Printed name of subject Signature of subject Date

Copies to: Researcher

Subject
Subject's Medical Record (if applicable)