# Informed Consent Form

## HIV Clinical Trials Networks Red Ribbon Registry

## Key Information

The Red Ribbon Registry is a tool to screen potential volunteers who want to take part in current or future research for HIV treatment or prevention. Participation involves completing a short online intake survey that includes some personal questions. Participation is voluntary. The risks of joining this registry are minimal, as described below.

## Introduction

The Clinical Trials Networks funded by the Division of AIDS (DAIDS) at the National Institute of Allergy and Infectious Diseases (NIAID) are doing research to learn more about the prevention and treatment of the human immunodeficiency virus (HIV). This virus causes AIDS. The HIV pandemic is a public health emergency. About 37 million people worldwide are now living with HIV. Since the start of the epidemic in the 1980s, over 70 million people have become infected with HIV, and over 35 million people have died of AIDS. World-wide, AIDS has become the leading infectious disease cause of death, and the sixth leading cause of death overall. We need to keep doing research to find vaccines, other prevention methods, and treatments that can work for people of all ages. We are working with researchers and companies around the world to make this happen. Our funding comes from the NIAID of the U.S. National Institutes of Health (NIH), an agency of the U.S. Department of Health and Human Services (HHS).

## About the Red Ribbon Registry

The purpose of the Red Ribbon Registry is to create a list (or registry) of adults living in the United States who want to take part in current or future HIV studies. To sign up, we will ask you to fill out an online survey to find out more about your interest and provide us with details about yourself. This will help us find out if we can match you to a study. It is expected that about thirty thousand people will take part in this registry.

## Being in the Red Ribbon Registry

The survey includes some personal questions. You will be asked about where you live, your past and current health, and your contact information so that we can reach you. Your answers will help us figure out if you meet the basic requirements for current or upcoming studies. Your information will not be used for any medical care. It should take less than 10 minutes to complete the survey. We may follow up with you to ask additional questions to learn about your interest in HIV clinical trial research. We may also contact you yearly to update your health information if anything has changed. It is completely up to you if you want to answer all the questions. Choosing not to answer any questions will not result in any penalty or loss of benefits to which you are otherwise entitled.

You may get contacted by researchers who can tell you more about specific studies. Any study you are contacted about will already have been reviewed by an Institutional Review Board (IRB). IRBs

make sure we protect your rights, follow the study plans, and keep you safe. If we do not contact you, that means there is no study that we can match you with right now.

We may also periodically ask you about your experience, motivation, and thoughts on joining the registry, so that we can improve both the tool and our messaging about HIV studies.

**Risks**

Joining this registry has very little risk, but it is not risk-free. You may feel uncomfortable answering questions about yourself. You do not have to answer any questions you do not want to, and you can stop at any time.

The other risk is to your privacy. There is a very small risk that that your personal information could be given to someone who should not have it.

**Benefits**

There are no direct benefits for being in the Red Ribbon Registry. By joining, you may become part of a group of volunteers who help find ways to improve people's health.

**Confidentiality**

We will do all we can to protect your privacy, but this cannot be guaranteed. Your information will be stored in our secure system. This information can only be seen by people who have permission to see it. These groups include:

- The DAIDS Networks and people who work for them
- Clinical researchers doing DAIDS Network studies
- Fred Hutchinson Cancer Center, which is the center that coordinates the registry
- Government agencies that provide support for the registry:
    - Your information may be shared with other approved partners (NIH, the US Office for Human Research Protections, and the US Centers for Disease Control and Prevention) in these same nationwide efforts to understand and respond to the HIV pandemic. The information shared will not contain your name.

- Institutional Review Boards (IRBs)
- A small number of Oracle employees who will have access to the registry to keep it working well.

**Certificate of Confidentiality**

We have a Certificate of Confidentiality from the US government to help protect your privacy. With the certificate, we generally do not have to release information about you to someone who is not connected to the Red Ribbon Registry, such as the courts or police. Sometimes we can't use the certificate. Since the US government funds this project, we cannot withhold information from it. Also, you can still release information about yourself and your participation to others.

**Payment for Participation**

You will not be paid for joining the Red Ribbon Registry. There is also no cost to you to join the Registry.

**Updating Your Preferences**

If you no longer want to participate in the registry, you can remove your information at any time. You can do this by going to your profile and selecting the "Registry Participation" option. If your information has already been accessed by some researchers, removing yourself from the registry does not mean that your contact information will be removed from those researchers. It only means that future researchers and studies will no longer have access to your profile when looking for interested volunteers.

You may also choose to stop receiving general communications that are not related to joining a specific study. You can "Unsubscribe" from these communications at any time. This does not remove you from the registry, and the researchers may still contact you for a study.

**Questions about Your Rights or the Red Ribbon Registry**

The Red Ribbon Registry has been reviewed by the Fred Hutchinson Cancer Center Institutional Review Board (IRB). They are an independent committee established to help protect the rights of people in research. For questions about your rights, contact the Director at 206-667-5900 or irodirector@fredhutch.org. Please reference Study Investigator James Kublin, MD, MPH. If you have any questions about this study, you may send an email to R3assist@fredhutch.org.

**Consent to Join the Red Ribbon Registry**

If you have read and understand this informed consent form, are at least 18 years old and agree to complete this survey, please begin the survey by entering your information below. You may stop this survey at any time. If you stop before the end of the survey, any information you already entered will be saved. You do not give up your legal rights by joining. You can save or print a PDF copy of this consent form if you wish.