

Consent Form for Louisiana Re-Entry Initiative (WWAV)

Why Is This Research Study Being Done?

The Louisiana Re-Entry Initiative (LRI) study is trying to find ways to link and keep HIV+ people in health care. We are interested in HIV+ persons who were or are now in jail, prison, or the department of corrections. One agency involved is Women with a Vision, or WWAV.

Medical care is needed to help HIV+ people live long and healthy lives. In the LRI program, a Community Outreach Worker from WWAV will get you into medical care. S/He knows the medical system and will help you get the care you need. Once you are in medical care, the Community Outreach Worker from WWAV will help you stay in medical care by offering any other services you may need, such as housing or transportation help. The LRI study measures the effect of this.

How Many People Will Take Part In This Research Study?

The study can have 390 adults from Louisiana. You must be HIV+ and have spent time in a jail or correctional facility at some point in your life.

What Is Involved In This Research Study?

If you are linked to medical care and get help to stay in medical care by the Community Outreach Worker, you are eligible to be in the study.

For the study, we are asking you to answer some questions, a survey, after we enroll you. We will ask you questions every six months afterwards for 18 months. There are a total of four surveys. It will take 45 minutes to answer the questions in each survey. Your lab results will be used to see if you are in medical care.

You do not have to take part in the study to receive medical and other services. You can receive services without completing any surveys and taking part in the study.

What Are My Rights If I Choose To Take Part?

It is your choice to take part in this study. If you choose not to take part, it will not affect your treatment in any way. It will also not affect your stay in jail/prison or parole status. You may choose not to take part in this study.

What About Confidentiality?

AIDS United in Washington D.C. paid for this study. It is being carried out by the Louisiana Public Health Institute, or LPHI, in New Orleans. We will keep whatever we learn from you in confidence. All staff involved in the study will keep information about you private and safe.

Your information will not be printed or given out. Your name will not appear in any study papers like reports or presentations. All of your information will be kept in a locked safe place. When we put your information in a computer, it will be kept safe, secure, and protected. Your study data may be shared with or reviewed by Louisiana Public Health Institute, Capitol Area Reentry Program, Inc., NO/AIDS Task Force, Women with a Vision and the Institutional Review Board.

The Institutional Review Board, or IRB, is made up of many people. Their job is to look at the plan of a study to see whether the people who are doing the study, like LPHI, follow the federal government rules. They make sure those who take part in the study know what the study is about and you and any information you provide is safe and protected.

Please know we will report to concerned authorities if you plan to harm yourself or others. This is required by law.

What Are The Risks, Benefits, And Options?

There is little to no risk to you when taking part in this study. Some of the questions we ask may cover sensitive topics. You do not have to answer any question that makes you uncomfortable. You can stop answering questions at any time. If you decide to stop answering questions or stop taking part in this study, it will not affect your stay in jail/prison or parole status. If you decide to stop answering questions or stop taking part in this study, you can still get any medical or other services you need. All of your information will be confidential. This means that only people on the study team will see your answers. However, even with these protections, there is a small potential risk for loss of confidentiality.

You can benefit from the study by being linked to health care and other services. If you choose to take part, your answers may help to develop effective ways to link and keep HIV+ people in care.

Will I Receive Any Payment If I Choose To Take Part In This Study?

You will get a \$10 gift card for answering questions after you are enrolled. You will get a \$15 gift card for answering questions 6 months after enrollment, a \$15 gift card for answering questions 12 months after enrollment, and a \$20 gift card for answering questions 18 months after enrollment.

What Are The Costs To Me If I Choose To Take Part In This Study?

If you choose to take part in this study, there is no cost to you.

Whom Do I Call If I Have Questions?

If you have any questions, concerns, injury, or complaints about this study, please call Dr. Russell Brewer with the Louisiana Public Health Institute at 1-504-301-9825. If you feel you have been violated by taking part in this study, have a private question you do not want to speak with Dr. Russell Brewer about, or want to give input, you may call Ethical & Independent (E&I) Review Services at 1-800-472-3241. You can email them at subject@eandireview.com or write to them at 14400 East 42nd Street, Suite 240, Independence, MO 64055. E&I is an IRB, an independent group of people that looks out for the rights and welfare of people taking part in research studies.

Signature:

By signing this document you agree to take part in this study under the conditions described above. You have been given a chance to ask questions. Your questions have all been answered to your satisfaction. You are not giving up any legal rights by signing this form. You will be given a copy of this signed consent document.

I agree to take part in this study:

 Date

 Your Printed Name

 Your Signature

 Date

 Printed Name of Person
Obtaining Consent

 Signature of Person
Obtaining Consent