Research Consent and Authorization Form

Rhode Island Hospital, The Miriam Hospital, EP Bradley Hospital,
Newport Hospital, and Gateway HealthCare

Name of Study Participant: _____

Principal Investigator: Kirsten Langdon, PhD

139 Point St., Providence, RI, 02903

Title of Research Study: Combined Injectable Treatment for HIV and OUD

Study Key Information

You are being asked to take part in a research study. A research study helps scientists and doctors learn new information to improve medical practice and patient care. This form contains information that will help you decide whether to take part in the research. Taking part in this study is completely voluntary. Even if you decide to take part in the study, you are free to leave at any time if you change your mind. The researcher will explain the study to you and answer any questions you may have. We encourage you to discuss this study with others (your family, friends or other doctors) before you agree to participate in the research. If you agree that you would like to participate in this research study, you will be asked to review and sign this consent. A copy will be given to you.

A. What is the purpose of the research?

You are being asked to take part in a research project because you have a history of being diagnosed with HIV and Opioid Use Disorder; or because you have a history of being diagnosed with HIV and Opioid Use Disorder, and a history of involvement with the criminal justice system within the past five years. The purpose of this research project is to understand patients' knowledge, attitudes, and perceptions of using long-acting injectable medications to treat HIV and Opioid Use Disorder.

B. What is experimental/new in this study

The FDA recently approved new medications to treat HIV and Opioid Use Disorder. These medications are long-acting injectables, meaning that patients typically receive one monthly

injection as part of their treatment. While there is evidence to support the use of these medications, little is known about how potential patients might feel about receiving both medications at the same time. Results of this study may help guide future recommendations for how to provide combined injectable treatment for HIV and Opioid Use Disorder.

C. What do I have to do in this research?

The study is one visit only and will take you a total of approximately 75 minutes to complete. If you decide to join this research study, the following things will happen: You will be asked to complete a baseline survey about your daily experiences, treatment history, opinions about the healthcare system, past substance use, and attitudes and behaviors about HIV. The survey will take approximately 15 minutes to complete. You will also be asked to participate in a one-on-one interview in a private Lifespan office or by phone or videoconference to answer questions about your knowledge, attitudes and perceptions of combining long-acting injectable medications for HIV and Opioid Use Disorder.

If at any time you feel uncomfortable answering any of the questions, you may choose not to respond.

D. What could go wrong?

The most important potential risks to know about are: Since we will be collecting information about you, one possible risk is loss of privacy or breach of confidentiality; however, we will minimize this risk by keeping all information you give us strictly confidential and available only to our research staff. We will assign a unique study ID number to all of the information that we collect from you. Your name and other identifying information will not appear in publications regarding this study. The interview session may include sensitive information about you. We will make every effort to assist you for any discomfort you may feel during this process.

E. What are the benefits?

There is no direct benefit to participants completing the study. Your participation may benefit others by contributing to knowledge about clinically-informed and evidence-based approaches to treating people with HIV and Opioid Use Disorder.

F. Other things I should know about this research?

If we find out about new information from this research that may affect your health, safety or willingness to stay in this research, we will let you know as soon as possible.

G. If I don't want to take part in this research what are my other choices?

You do not have to be in this research study to be treated for HIV or Opioid Use Disorder. Your healthcare provider has discussed with you what your clinical treatment options are and which clinical treatment(s) might be right for you considering your medical history. These clinical

treatment options may include medications, counseling, case management, and peer recovery support. Each of the clinical treatment options has known rates of being effective, known risks, as well as possible drawbacks.

- **Please carefully read this form, additional detail about each item just described is found below.**
- **Please listen to the study team explain the study and this form to you.**
- **Please ask questions about anything that is not clear.**

1. Nature and Purpose of the Study

You are being asked to take part in a research project because have a history of being diagnosed with HIV and Opioid Use Disorder; or because you have a history of being diagnosed with HIV and Opioid Use Disorder, and an involvement with the criminal justice system within the past five years. The purpose of this research project is to understand patients' knowledge, attitudes, and perceptions of using long-acting injectable medications to treat HIV and Opioid Use Disorder. We expect to enroll 55 subjects into this study. This study is sponsored by the National Institute of Health.

2. Explanation of Procedures:

If you agree to take part in this study, you will be asked to complete a baseline survey via REDCap, a secure online platform. A link to complete these surveys will be sent to you via text message and email. The baseline survey asks questions about your daily experiences, treatment history, opinions about the healthcare system, past substance use, and attitudes and behaviors about HIV. You will also be asked to complete a one-on-one qualitative interview via phone, video call, or in-person. If at any time you feel uncomfortable answering any of the questions, you may choose not to respond.

The study is one visit only. We estimate that it will take approximately 75 minutes for you to complete the study – 15 minutes to complete the baseline survey and 60 minutes to complete the interview. The interview session will be audiotaped. The audiotapes will be destroyed at the end of the study. The goal of these interviews is to explore knowledge, attitudes, and perceptions of using long-acting injectable medications to treat HIV and Opioid Use Disorder. This information will be used to inform future recommendations for how best to deliver this type of treatment.

You will receive $40 for participating in the interview and completing the baseline survey. The one-on-one interview will take approximately 60 minutes to complete. Additionally, participants who complete the interview will be given small snacks such as Cheez-Its or small gum packages ($1-$2 in value). For participants completing the interview remotely, they will be given a $2 gift code that will be sent via email or text message. Additionally, all patients will be given a health and wellbeing resource guide containing information about programs and organizations offering recovery and support services to adults throughout Rhode Island.

Parole boards will not take into account your participation in the study when they make decisions about parole. Participation in the study will not affect parole. Your identifiable private information that have been collected as part of the research will not be used or shared with other researchers for future research studies.

Costs for participating in this study

Some of the services you will receive are being performed only because you are participating in this research study. These 'research only' services include the interview. These services will be paid for by the study and will not be billed to you or your health insurance company.

There are other services you will receive during this research study which are considered "routine clinical services" and are not part of the research study. These are services you would receive even if you were not in the research study. Examples are visits with your psychiatrist and therapist or routine lab work. These non-research services will be billed to your health insurance company, but you will be responsible for paying any deductibles, co-payments, or co-insurance that are a normal part of your health insurance plan. If you do not have health insurance, you will be responsible for those costs.

Contact Information:

You can call us with any concerns or questions about the research. Please contact the Principal Investigator Kirsten Langdon, PhD at (401) 606-4198.

3. Discomforts and Risks

Since we will be collecting information about you, one possible risk is loss of privacy or breach of confidentiality; however, we will minimize this risk by keeping all information you give us strictly confidential and available only to our research staff. We will assign a unique study ID number to all

of the information that we collect from you. Your name and other identifying information will not appear in publications regarding this study. The interview session may include sensitive information about you. We will make every effort to assist you for any discomfort you may feel during this process.

4. Benefits

You will not receive any direct benefit from your participation in this study. We hope that your participation may benefit others by contributing to knowledge about clinically-informed and evidence-based approaches to the treatment of HIV and Opioid Use Disorder.

5. Alternative Therapies

If you don't want to take part in this research, there is no penalty to you. There are no alternatives if you decide not to participate.

6. Refusal/Withdrawal

It is up to you whether you want to be in the study. You are not required to enroll or participate. If you decide to participate, you can always change your mind and quit at any time. If you decide not to be in the study, or if you quit later, you will still be able to get the health care services you normally get. If you join, but later the researcher **or your doctor** feels being in the study is no longer good for you, they may choose to take you out of the study before it is over. If new information becomes available that might change your mind about whether you want to stay in the study, the researcher will share this information with you as soon as possible.

Reasons the researchers would take you out of the study even if you wanted to stay in:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is suspended or canceled.

You have the right to change your mind at any time regarding follow-up after withdrawal. If you decide to quit the study, please tell the head researcher Kirsten Langdon, PhD at (401) 606-4198 or 200 Corliss St., Providence, 02904.

7. Medical Treatment/Payment in Case of Injury

A research injury is any physical or mental injury or illness caused by being in the study. If you are injured by a medical treatment or procedure you would have received even if you were not in the study, that is not a research injury. To help avoid research injury and added medical expenses, it is very important to follow all study directions carefully. If you do experience a research injury, Lifespan or the study doctor can arrange medical treatment for you. Such treatment will be paid for as described below.

If you have insurance and have a research injury that is not covered by the study, it is possible that some or all the cost of treating you could be billed to your insurer. If your health insurance will not cover such costs, it is possible you would have to pay out of pocket. In some cases, Lifespan might be able to help you pay if you qualify for free care under Lifespan policy. However, Lifespan has no

policy to cover payment for such things as lost wages, expenses other than medical care, or pain and suffering.

This study does not include any treatment or intervention; therefore, a research related injury/illness is unlikely to occur.

8. Rights and Complaints

Signing this form does not take away any of your lawful rights. If you have any complaints about this study or would like more facts about the rules for research studies, or the rights of people who take part in research studies, you may contact the Director of Research Protection Office in Lifespan Office of Research, at (401) 444-6246.

9. Confidentiality and Research Authorization for Use and Disclosure of Your Health Care Information.

Your research records will be treated as private health care records and will be protected according to Lifespan privacy practices and policies that are based on state and federal law. Federal law requires us to get your permission to use or disclose (release your information to someone outside of Lifespan) your health information for research purposes. If you sign this form, you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research, providing treatment, collecting payment and running the business of the hospital. This permission has no expiration date. You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study, you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

To cancel permission in writing, you can reach head researcher Kirsten Langdon, PhD at (401) 606-4198 or 139 Point St., Providence, RI, 02903.

Generally, the entire research record and any medical records held by the hospital may be used and released for research purposes. The following people or businesses/companies might use, release, or receive such information:

- The researcher and their support staff;
- The study sponsor National Institute of Health;
- Doctors, nurses, laboratories and others who provide services to you or the sponsor in connection with this study;

- The company or section of the U.S. government that is paying for the study and others they hire to oversee, administer, or conduct the research;
- The United States Food and Drug Administration, the Department of Health and Human Services, the Office of Inspector General, the Office of Civil Rights, European Medicines Agency;
- People who volunteer to be patient advocates or research volunteer protectors;
- Members of the hospital's administrative staff responsible for reviewing, approving and administering clinical trials and other healthcare or research activities;
- Accrediting Organizations.

There are times when the law might require or permit Lifespan to release your health information without your permission. For example, Rhode Island law requires researchers and health care workers to report abuse or neglect of children to the Department of Children, Youth and Families (DCYF) and to report abuse or neglect of people age 60 and older to the Department of Elderly Affairs.

All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that, so it is possible they might re-release your information.
You have the right to refuse to sign this form and not participate in the research. Your refusal would have no effect on your treatment, charges billed to you, or benefits at any Lifespan health care site. If you do not sign, you will not be able to enroll in the research study and will not receive treatment as a study participant.

If you decide to quit the study after signing this form (as described in Section 6: Refusal/Withdrawal), no new information will be collected about you unless you gave us permission to do so. However, the hospital or the researchers may continue to use information that was collected before you quit the study to complete analysis and reports of this research. You will not be allowed to see or copy the information described in this form if the research is open. You may see and copy the information when the study is completed.

The National Institutes of Health has issued a Certificate of Confidentiality for this research. This adds special protection for the research information and specimens that may identify you. The researchers may not disclose information that may identify you, even under a court order or subpoena, unless you give permission. However, a Certificate of Confidentiality does not prevent researchers from disclosing information about you if required by law (such as to report child abuse, communicable diseases or harm to self or others); if you have consented to the disclosure (such as for your medical treatment); or if it is used for other research as allowed by law. In addition, the Certificate cannot be used to refuse a request if a governmental agency sponsoring the project wants to audit the research. Any research information that is placed in

your medical record would not be covered under this Certificate. The Certificate will not be used to prevent disclosure for any purpose you have consented to in this informed consent document. The Certificate does not stop you from voluntarily releasing information about yourself or your involvement in this research. If others obtain your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Contact for Future Studies:

Your participation in **any research** is completely voluntary and you should feel no pressure to participate if you are contacted about another research study.
Please check and initial one of the options below regarding future contact about other research done by us or other researchers we are working with (collaborators).

_____ ☐ Yes, I may be contacted about participating in other research projects studying Opioid Use Disorder, HIV, or related conditions. I give permission for my contact information (name and mailing address and/or phone number) to be given to other researchers working with the study investigator.

_____ ☐ No, I do not want to be contacted about other research projects. **Do not** give my contact information to the staff of any other research studies

Contact for Study Updates:

Please check and initial one of the options below regarding future contact about study updates and findings when they are available.

_____ ☐ Yes, I am interested in being contacted about study related events and results when they are available.

_____ ☐ No, I do not want to be contacted about study related events and results.

SIGNATURE

I have read this informed consent and authorization form. ALL OF MY QUESTIONS HAVE BEEN ANSWERED, AND I WANT TO TAKE PART IN THIS RESEARCH STUDY.

By signing below, I give my permission to participate in this research study and for the described uses and releases of information. *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice.*

This informed consent document is approved for use with a valid IRB stamp at the top of each page. The document expires for use on the date listed within the IRB stamp. DO NOT sign this document after this expiration date.

If the expiration date is blank, this document does not expire.

The Researcher is required to provide a copy of this consent to you.

Signature of Adult Study Participant	Date (MM/DD/YEAR)	Time when signed

Signature of researcher or designate	Date(MM/DD/YEAR)	Time when signed

☐ **A copy of this complete (note total number of pages in footer) signed consent form has been given to the participant.**