Lifespan
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Research Consent and Authorization Form

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

Name of Study Participant(s): _____

Principal Investigator: Justin Berk, MD MPH MBA

Title of Research Study:

Extended-Release Injectable Buprenorphine (XR-B) in Correctional Settings: Qualitative

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. In the sections that follow, the word "we" means the study doctor and other research staff. We 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 your 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?

The purpose of this study is to understand the best way to provide addiction treatment in a jail or prison. Specifically, this study will interview people to ask them about their views on the Medication for Addiction Treatment (MAT) program and the different types of medicines used.

You were chosen for this research study because you have had experience in or around the MAT program.

B. What is experimental/new in this study

We specifically want to learn what people know about "injectable buprenorphine" also known as the Sublocade shot.

What do I have to do in this research?

Individuals with Opioid Use Disorder AND Organizational Stakeholders:

To participate in this study, you will be asked to be interviewed for somewhere between 60 – 90 minutes while a person asks you questions about the MAT program. The interview a one-time only interaction.

Organizational Stakeholders:

In addition to the interview, you will be asked to complete a short survey lasting about 10 minutes. The survey will be a one-time interaction only.

C. What could go wrong?

The risks associated with this study are minimal. The most important potential risks to know about are emotional discomfort in interview questions or discomfort completing the survey. There is also the possibility of a confidentiality breach. The research team has mechanisms in place to limit these risks.

D. What are the benefits?

There are no direct benefits to patients or providers/staff. The most important potential benefits to know about related to improving the quality of the MAT program at the ACI and, potentially, other facilities in the nation. Findings from this study may contribute a public health benefit to the opioid overdose epidemic among people who suffer from opioid use disorder.

E. 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 all participants know as soon as possible.

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

Patients: You do not have to be in this research study to be treated for opioid use disorder. Enrollment in this study will not affect your healthcare in any way. It will not affect your length of incarceration, security status, or parole considerations.
Providers or staff:
You do not have to participate in this study. Enrollment in this study will not affect or change your performance in treating the patients in this study. It will not affect your job status.

- **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 researchers would like to know how to help individuals with opioid use disorder remain safe in the opioid overdose epidemic upon release from jail or prison. We also want to ensure the MAT program optimizes the demands on organizational stakeholders like medical staff. In this study we are trying to learn more about the MAT program and how injectable buprenorphine may fit into the program.

We expect to interview about 20 patients and approximately 12 organizational stakeholders (providers and staff) who will also complete a survey.

2. Explanation of Procedures:

Patients and organizational stakeholders: If you agree to take part in this study, you will participate in an interview with a member of the research time. The interview will last between 60 and 90 minutes and will be completely confidential. It will be recorded on a password-protected digital voice recorder and transcribed into text for the research team to review insights to help answer the research questions. The interviews will take place at the ACI.

Organizational stakeholders (e.g., staff, medical providers) will also be asked to complete surveys that should take less than 10 minutes to complete. This survey will be de-identified and reviewed by research staff only.

Compensation:

Patients You will be compensated $25 for the completion of your participation in the research. Providers or Staff: You will be compensated $25 after the completion of the survey and for those unable to receive direct compensation (due to Union agreements, state employment regulations, etc.), $25 will be donated to a charity of your choice and a receipt will be provided to you within 14 days.

Costs for participating in this study

Taking part in this research study will not lead to any additional costs to any participants.

Contact information

If you have questions or concerns about participation in this study, you can discuss them with the Principal Investigator by writing an in-facility letter addressed to: Justin Berk at Planning and Research or through external mail to Justin Berk c/o RIH 1125 N Main St, Ste 215 Providence, RI 02906.

3. Discomforts and Risks

Emotional discomfort –

All: Some interview questions may be considered sensitive and may cause emotional distress. There is a small chance that you may become upset when discussing their history of substance use disorder or arrest. You can terminate the interview at any time for any reason.

Providers or Staff Members: You may feel uncomfortable answering a survey however you can terminate the survey at any time

Breach of confidentiality – The interview will be conducted in a private place though there is a possibility of your responses being identified as your own. We have taken steps to ensure this doesn't happen (i.e., password-protected digital voice recorders, deletion of audio files once transcribed, using first-name or pseudonym only, removing all identifiable information from transcripts, using password-protected HIPAA-compliant servers, etc.) Surveys will be anonymous and have no identifiable information on the hard copies. Hard copies will be stored in a locked filing cabinet accessible only to the research team. They will be transcribed into a private and secure REDCap database that is password-protected and only accessible by the research team.

4. Benefits

There will be no direct benefits for participating in this study. We hope that findings from this study may contribute a substantial public health benefit to the opioid overdose epidemic among people who suffer from opioid use disorder. We hope that findings may facilitate efficient healthcare delivery by organizational stakeholders.

5. Alternative Therapies

There is no treatment in this study. If you decline to participate in this study, there will be no changes to general treatment for patients. Providers and staff will not have any changes in their role to the patients if they decline to be in this study.

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.

7. Medical Treatment/Payment in Case of Injury

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, Research Protection Office in Lifespan Office of Research, at (401) 444-6246.

The mailing address for the Human Research Protection Program (HRPP) is:
167 Point Street
Coro East, Suite 1A
Providence, RI 02903

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

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.

The following people or businesses/companies might use, release, or receive such information:

- The researcher and their support staff only

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 aged 60 and older to the Department of Elderly Affairs. Similar examples include any act of sex or related behavior that

falls under the standards of the Prison Rape Elimination Act (PREA) which must be reported to the appropriate personnel in the facility. **Confidentiality must be broken in information released in considered a threat to self, facility, and/or community corrections security.**

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 any treatment. If you do not sign, you will not be able to enroll in the research study.

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.

To withdrawal from the study in writing, you can write to Justin Berk c/o RIH 1125 N Main St, Ste 215 Providence, RI 02906.

10. Additional Information

Parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole.

NIH Certificate of Confidentiality

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.

Signature Page for Adult Participants

Adult Participant

- 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 use of associated protected health information as described above (HIPAA). *I also confirm that I have been now or previously given a copy of the Lifespan Privacy Notice.*
- **The Researcher is required to provide a copy of this consent to you.**

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.

Print name of Study Participant

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

Research Investigator /or Designee's Statement & Signature

- I have fully explained the research described above, including the possible risks and benefits, to all involved parties (participant /parents/legal guardian as applicable).
- I have answered and will answer all questions to the best of my ability.
- I will inform all involved parties of any changes (if applicable) to the research procedures or the risks and benefits during or after the course of the research.
- I have provided a copy of the consent form signed by the participant/parent/guardian and a copy of the hospital's privacy notification (if requested).

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

☐ **A copy of this complete 7 signed consent form has been given to the participant.**