Study title: Rhode Island Prescription and Illicit Drug
NCT04372238
Document date: 11/09/2021

Brown University IRB Original Approval: 04/18/2019
Brown University IRB Amendment Approval: 08/10/2020
Brown University IRB Amendment Approval: 02/26/2021
Brown University IRB Amendment Approval: 06/15/2021
Brown University IRB Amendment Approval: 10/05/2021
Brown University IRB Amendment Approval: 12/13/2021
Brown University IRB Amendment Approval: 11/22/2020
Brown University IRB Amendment Approval: 10/15/2020
Brown University IRB Continuing Approval: 03/18/2021
Brown University IRB Amendment Approval: 09/01/2021
Brown University IRB Amendment Approval: 11/09/2021

Rhode Island Prescription and Illicit Drug Study
Responding to Fentanyl and Associated Harms (Screening)
Version 5, 11/09/2021

You are invited to take part in a Brown University research study. Your participation is voluntary. I will read the consent form for you, but if you would like a copy of the form for participating in the screening process, for yourself I can email it to you or text a link to you.

- PURPOSE: This call will help us to establish the eligibility for this study. Information gathered through the eligibility process will be used to ensure that people do not attempt to enter the study multiple times.

- PROCEDURES: You will be asked questions about the town you live in, your age, and your drug use in the past 30 days. Once the screening is complete, you will be assigned a study identification number. Your name and contact information will be stored separately from the rest of your study information. All of this information will be stored in a secured server.
- TIME INVOLVED: Screening will take place over the next 5-10 minutes

- COMPENSATION: There is no compensation for the eligibility screening.

- RISKS: The risks to participating in this screening are small. You may feel uncomfortable answering some of the questions. If you do not want to answer a particular question, you can skip that question, but it may affect your eligibility to participate in the study.
- BENEFITS: You may not directly benefit from screening for this research study.

- CONFIDENTIALITY: Any information you share with us will be confidential. Your name, other personally identifying information, telephone numbers, and tracking information will be recorded in separate files and will not be linked to any of the data. You will be assigned a special identification number that will be used on all study forms in place of your name.

- VOLUNTARY: You do not have to be in this screening if you do not want to be. Even if you decide to start screening, you can change your mind and stop and any time. Completing this screener does not automatically enroll you in this study. If found eligible, you have the right to decide if you want to participate in this study

- CONTACT INFORMATION: If you have any questions about your participation in this study, you can call Dr. Brandon Marshall at (401-863-6427) or email Brandon_Marshall@Brown.edu, the Principal Investigator, or Jesse Yedinak at (401-863- 9770 or Jesse_Yedinak@Brown.edu), Project Director.

- YOUR RIGHTS: If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

Do you agree and understand the information in this document? Do you agree to volunteer as a research participant for this study

Rhode Island Prescription and Illicit Drug Study
Responding to Fentanyl and Associated Harms
(Baseline) Version 5, 11/09/2021

You are invited to join a research study. The purpose of this consent form is to give you information to help you decide whether or not you want to join this research study. Your participation is voluntary.

If you have any questions, please ask.

- RESEARCHER: Dr. Brandon Marshall, Principal Investigator, phone: 401-863-6427, email: Brandon_Marshall@Brown.edu.

- PURPOSE: Researchers at Brown University are conducting a study about overdose prevention in Rhode Island. Funding for this study is provided by the National Institute on Drug Abuse.

- PROCEDURES: We will meet with you six times over the course of the year. At each visit, you will answer questions as part of a survey. You will be asked personal questions about yourself, including the town you live in, your age, your drug use history, and your experiences with overdose.

- You will also be asked give a urine sample. The results of the drug test will not affect your role or eligibility in the study. We will use the results to better understand what drugs people have been exposed to recently, including to accidental fentanyl exposure. Once the urine screening is completed, the sample will be disposed of immediately.

- At three of the six visits, you will be asked to provide a dried blood spot using a finger stick method for the purpose of drug, HIV and hepatitis C testing. These specimens will also be stored for future use related to substance use and infectious diseases. The results of your dried blood spot testing do not affect your participation in the study and will not be linked to your name. You may still participate in the study if you choose not to provide dried blood spot specimens. You may be contacted if positive results are received when testing your dried blood spot specimens for infectious diseases. This may happen within three years of participating in the study.

- You will be given educational trainings about naloxone and how to prevent or stop an overdose. All of your answers and study data will be stored in a secured server, and your name will not be linked to your answers.

o If you take part in this study, you will be randomly assigned, **"randomized"** into receiving one of two groups using current standard-of-care interventions, either a **standard** overdose education and naloxone distribution program or a **fentanyl** overdose education and naloxone distribution program. "Standard of care" means something that usually happens as part of treatment, and "randomization" means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in either of the
two groups.

o One of the groups will be asked to use rapid "Fentanyl Test Strips" from the medical device company BTNX Inc. The Fentanyl Test Strips were originally approved as a urine screening test to find out if fentanyl is in your body. We will be asking one of the groups to use them in a different way, which means we will show you how to use them directly on drug residue, to test if fentanyl is in your drugs.

o We may communicate with you by text message throughout the next year, unless you prefer we call you directly. Either way, this communication may incur a cost depending on what phone plan you have.

- Throughout the study, we may use the survey data that we collect to link to records routinely collected by state agencies such as the Rhode Island Department of Health. These records may include EMS reports related to suspected overdose and overdose fatalities for the purposes of this research study.

- In the event that we do not receive contact from you after 30 days of attempted contact, we may use the survey data that we collect to search publicly available Department of Correction Records in order to determine if you have been recently incarcerated. If the study team is unable to get in contact with you for over 90 days due to incarceration, you will be withdrawn from the study.

- Results of this study may be used to help researchers at the Brown University School of Public Health understand more about fentanyl overdose in Rhode Island.

- It may also help organizations, healthcare providers, and others to develop better prevention for people who are at risk for accidental overdose or accidental fentanyl exposure.

- Data collected for this study will be used to create an intervention to help stop accidental fentanyl overdose.

- Some behavioral intervention sessions will be audio-recorded and will only be reviewed by study staff. This is to help insure that the interventions are designed well and improved upon as needed, and to insure that you receive the same level of care as all other study participants. Recordings may also be transcribed digitally and reviewed to look at themes or concerns among participants, further helping shape the interventions. Names mentioned on the tape will be removed prior to analysis. Recordings will be identified by a study identification number only, and will be stored at Brown University in a secure, password- protected folder on an electronic server. Recordings will be retained for seven years and then destroyed. You may elect not to have your sessions audio-recorded, and may still participate in the study. Additionally, you may ask to turn off the recorder at any point during the sessions.

- For dried blood spot collection, the finger-stick procedure is very similar to the way a person with diabetes checks his or her own blood sugar. It is a routine procedure. In the procedure, the end of one of your fingers will be cleansed with alcohol. Your finger will be stuck once using a sterile single-use lancet (very small with a sharp point) and the first drop of blood will be wiped away (not used). The next 3 or 5 drops will be put on the collection card, and will be used for the tests. If the finger continues to bleed, a band-aid may be applied. It will take about five (5) minutes to complete this collection.

- You will be asked personal questions about yourself, including town you live in, your age, your drug use , your sexual orientation and your experiences of overdose (both your own, and those occurring in your social network)

- TIME INVOLVED: The research study visits will take place in person. You will be asked to complete SIX times in-person visits total in the next 12 months. The first visit will take up to an hour and a half, and the other five visits will take up to one hour of time each.

- COMPENSATION: You will receive a $35 for the first and last two visit and $25 for the three intermediate visits if participate in this study. There are SIX visits total in the next 12 months. If you choose to provide the dried blood spot specimens you will receive an additional $5 for each of the three visits, for a total of an extra $15. You can earn up to $195 if you attend all visits You will only be compensated for the visits you attend. We will provide free garage parking in our office location if you chose to drive to the study visit. For those who are not able to drive and for those who are unable to arrange their own transport, we are able to provide transportation through UberHealth.

- RISKS: The risks to participating in this study may include feeling uncomfortable answering some of the questions. This may cause anxiety or stress. If you do not want to answer a particular question, you can skip that question. You also have the right to leave the study at any time.

- While you may be getting education and support on how to prevent a drug overdose, you may still be at risk for overdose and should take all precautions necessary to avoid an overdose.

- **If you are in the group that receives fentanyl test strips, the test strips do not guarantee your safety against an overdose as they are not always 100% accurate.**

- There is minimal physical risk to you from the routine finger stick(s) used for dried blood spot collection. The finger stick may cause a small amount of pain and bruising, and the site may bleed slightly for a time after the blood is collected. There is also a very rare chance that the stick site could become infected. If this happens, you might require medical treatment

- BENEFITS: It is possible that you will benefit from the study by receiving tools and education about ways to help protect yourself from accidental overdose. This is not an addiction treatment study. The intervention provided by our staff will address overdose prevention only. However, some of the other direct benefits to you may include referrals to addiction treatment programs, as well as medical care and other social services, as appropriate.

  If you are in the intervention group that receives fentanyl test strips, the strips may provide you with additional information about what is in your drugs.

  Finally, at the end of each interview, you will receive a package of educational material regarding overdose prevention as well as a list of substance use treatment services in Rhode Island. At the first session, all participants will also receive a naloxone kit.

- ALTERNATIVES: You may choose not to take part in the study. If you do not participate, we will remove you from our outreach list and no longer contact you.

- CONFIDENTIALITY: Any information you share with us will be confidential. Your name, other personally identifying information, telephone numbers, and tracking information will be recorded in separate files and will not be linked to any of the data. You will be assigned a special identification number that will be used on all study forms in place of your name.

- A description of this clinical trial will be available on the website http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you or anyone else in the research study. At most, the website will include a summary of the results. You can search this website at any time. To help us protect your privacy, the National Institutes of Health has given us a **Certificate of Confidentiality**. We can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena.

- We will use the Certificate to resist any demands for information that would identify you. The exception is that the Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities about harm to yourself or others, child abuse or neglect, and/or elder abuse. In the case that you disclose harm to yourself or others, we have a responsibility to provide that information to the appropriate law enforcement agency.

- The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research.

- Only in the case of an emergency involving danger to yourself or someone else will we break that confidentiality: Brown University staff sometimes review studies like this one to make sure they are

being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

- VOLUNTARY: You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time.

- CONTACT INFORMATION: If you have any questions about your participation in this study, you can call Dr. Brandon Marshall at (401-863-6427) or email Brandon_Marshall@Brown.edu, the Principal Investigator, or Jesse Yedinak at (401-863- 9770 or Jesse.Y@Brown.edu), Project Director.

- YOUR RIGHTS: If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

Do you agree and understand the information in this document? Do you agree to volunteer as a research participant for this study?

o YES
o NO
o REFUSE TO ANSWER

Do you agree to allow us to link your information from the study to overdose-related data routinely collected by the Rhode Island Department of Health, such as information about EMS reports of suspected overdose and fatal overdoses?
o YES
o NO
o REFUSE TO ANSWER

If you are randomized to the intervention, do you agree to have your sessions recorded for quality control purposes?
o YES
o NO
o REFUSE TO ANSWER

Do you agree to allow us to collect, store, and test dried blood spots obtained from you at three of the study visits?
o YES
o NO
o REFUSE TO ANSWER

We would like to contact you about possible future studies, conducted by members of our team or other teams at the Brown University School of Public Health. Do you agree to let us collect your name, telephone number and email address. This information will not be connected to any research data. You can withdraw this permission at any time by telling the research staff.

o YES
o NO
o REFUSE TO ANSWER