Protocol Title: Rhode Island Prescription and Illicit Drug Study (RAPIDS)
Principal Investigator: Brandon DL Marshall PhD
Department: Epidemiology, Centers for Epidemiology and Environmental Health (CEEH)
Funding Source (if no external funding for the project, enter "University")**:** NIDA

If externally funded, Coeus Institute Proposal # for the project:
(TBD - JIT Request in-process)

Is this an undergraduate student project? Yes **No ☒**

Attach to this form the information required for a complete protocol, as outlined beginning on page 3 of this form, Instructions & Information. Additional information about preparing a protocol can be found here.

1. Select the appropriate type and category number of review. See descriptions of Expedited categories. If no expedited categories completely describe the proposed research, select "Full Board.") ☆ **Expedited #** ☒ **Full Board**

2. **Investigator Conflict of Interest Statement:**
   The *Brown University Conflict of Interest Policy for Officers of Instruction and Research* *("COI Policy")* defines the term "Investigator" as "the project director or principal investigator and any other person, regardless of title or position (e.g., full or part-time faculty member, staff member, student, trainee, collaborator, or consultant), who is **responsible** for the **design, conduct, or reporting** of sponsored research." Using this definition of "Investigator," please ensure that all Investigators on this protocol answer questions 3(a) and 3(b) below [attach additional sheets for any Investigators who are not the PI; they only need to answer 3(a) and 3(b)]:
   a. Have you completed a conflict of interest disclosure (i.e. *Annual COI Assurance Form* **or** *COI Reporting Form*) within the past 12 months and is it accurate and up-to-date as of the time of this submission, as required by the COI Policy? (You may access the system here to confirm.) ☒ **YES** ☆ **NO**

   b. Do you have a significant financial interest (SFI) that is related to this research protocol? "Related" could mean the research involves products, technology, intellectual property, or services made, owned, or provided by the entity/ies in which you have an SFI and/or that the SFI could be affected by the proposed research or its results. ☆ **YES** ☒ **NO**

Principal Investigator certifies to the following: ***(1)*** The rights and welfare of the participants are adequately protected. ***(2)*** The risks to an individual are outweighed by the potential benefits to him/her or by the importance of the knowledge to be gained. ***(3)*** This protocol is accurate and complete; if the project scope or design is later changed, the PI will resubmit for review. ***(4)*** All research personnel, including the PI, has been, or will be, adequately educated in human research protections prior to beginning work on the project.

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Principal Investigator signature:

Date: 03/31/2019

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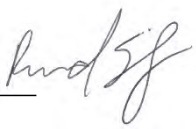
(Advisor's signature is required for all graduate/medical student projects.)
Advisor certifies to the following: Advisor has read the protocol and approves of the project.

Advisor' name:

Advisor's signature:_____ **Date:** _____

For IRB Use Only

Signature of the Authorized Official of the IRB: 

Date of IRB approval: *4/18/2019*

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Protocol component	Included?	Page number(s):
1. IRB Form #1	**Yes**	Cover Page
2. Lay Summary	**Yes**	4
3. Protocol Narrative:		5-18
Aims & Methodology	**Yes**	5
Informed consent procedure	**Yes**	16
Consent/Assent documents/scripts	**Yes**	See Attachment A
Risks and Benefits	**Yes**	17
4. Attachments:		19
a) Informed Consent & Survey Instruments (combined)	**Yes**	**Attachment A**
b) Education handouts for participants	**Yes**	**Attachment B**
c) Recruitment materials (online & community-based)	**Yes**	**Attachment C**
d) NIDA R01 Funding application	**No**	**Attachment D (upon request)**
*Other IRB approvals***	**NA**	***Will be submitted to RIDOH for an IAA once Brown IRB approval is in place*
e) Data Use Agreements (RI Dept of Health)	**Yes**	**Attachment E**
f) Data & Safety Monitoring Plan (DSMP)	**Yes**	**Attachment F**
g) Stronghold MOU	**Yes**	**Attachment G**
h) IDE Checklist and NSR Justification	**Yes**	**Attachment H**
i) Safety Protocol	**Yes**	**Attachment I**
j) Community Based Resources and Referrals	**Yes**	**Attachment J**
k) Investigator Self-Evaluation Checklist	**Yes**	**Attachment K**

2. LAY SUMMARY: The Rhode Island Prescription and Illicit Drug Study (RAPIDS)

This study will test the efficacy of a novel drug-checking intervention to prevent fatal and non-fatal overdose among people who use drugs (PWUD), who are 18-65 years old at the time of enrollment. We will evaluate whether the incorporation of rapid fentanyl testing into a theory-driven overdose education and prevention intervention reduces rates of overdose compared to standard overdose education and naloxone distribution. Results from this study will significantly improve public health efforts to address the fentanyl overdose epidemic and reduce harms associated with exposure to drugs contaminated with fentanyl. This is a full clinical trial, building on our previously approved fentanyl-test-strip pilot study (2016-2017), the results of which have recently been published.[1]

1. [1]Krieger MS, Yedinak JL, Buxton JA, et al. High willingness to use rapid fentanyl test strips among young adults who use drugs. Harm Reduct J 2018;15(1):7.
2. Krieger MS, Goedel WC, Buxton JA, Lysyshyn M, Bernstein E, Sherman SG, Rich JD, Hadland SE, Green TC, Marshall BDL. Use of rapid fentanyl test strips among young adults who use drugs. Int J Drug Policy. 2018 Nov;61:52-58. doi: 10.1016/j.drugpo.2018.09.009. Epub 2018 Oct 18.

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THE RAPIDS CLINICAL TRIAL:
Appendix B: RAPIDS Protocol

PROTOCOL NARRATIVE Aims & Methodology

3.1a. Specific Aims & Methodology

In light of the urgent need for research on novel interventions to prevent illicitly-manufactured fentanyl (IMF) exposure and overdose, we will determine whether a brief, theory-driven overdose prevention intervention incorporating “take home” rapid fentanyl testing decreases overdose among adults. We will enroll up to 550 PWUD at risk of overdose in a randomized trial, hereby referred to as the **Rhode Island Prescription and Illicit Drug Study (RAPIDS)**.

In **Aim 1,** we will assess the efficacy of the RAPIDS intervention on preventing overdose among PWUD. In **Aim 2,** we will determine whether the intervention effects are mediated through our model constructs, including knowledge, motivation, behavioral skills, and self-efficacy to use the fentanyl test strips and engage in overdose risk reduction practices. In **Aim 3,** we will determine whether there is heterogeneity of treatment effect related to key participant characteristics, including age, baseline motivations to use the test strips, as well as type and frequency of drug use. By determining the sub-groups for whom intervention efficacy is highest, these findings will guide optimal implementation of this brief intervention to reduce overdose among PWUD.

Eligibility criteria include reported use of heroin, illicit stimulants, counterfeit prescription pills, or injection drug use in the past 30 days, regardless of treatment status (see **Table 1**). An overview of the study design is included in section **3.1.d** below. Participants will be randomized 1:1 to receive the RAPIDS intervention or the attention-matched control condition.
Experimental arm participants will receive the RAPIDS intervention, which includes education about the dangers of IMF, motivational interviewing to increase willingness to use fentanyl test strips and engage in overdose risk reduction behaviors, hands-on training to use the test strips, and opportunities to plan and role- play how to implement overdose risk reduction behaviors upon receipt of a positive or negative test result. In addition, intervention participants will receive ten test strips for personal use. Motivational interviewing “booster” sessions will occur at 1, 2, and 3 months post-randomization, with additional test strips provided on an as needed basis. In the attention-matched control arm, participants will receive standardized overdose education and naloxone distribution (OEND) training, with attention-control visits at 1, 2, and 3 months.
Participants in both arms will receive a naloxone kit after completion of the first session, and information regarding where to obtain additional naloxone at subsequent visits. Follow-up interviews will occur at 6 and 12 months. The primary endpoint will be the rate of self- reported overdose over the follow-up period. Secondary endpoints (e.g., accidental overdose death and suspected EMS runs for overdose) will be ascertained by data linkage to statewide overdose surveillance databases maintained by the research team. Consistent with recruitment rates in our prior studies, we aim to enroll 20 participants per month starting in Year 1 until target

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enrollment is reached.

During the baseline visit, participants in both the experimental and control arms will be given a naloxone kit that includes two doses of intranasal naloxone along with a wallet card with information about fentanyl and the educational flyer in a discreet pouch or bag. At all other assessment visits participants will be referred to community locations for no-cost or low-cost naloxone access. We have created a flyer (see **Attachment B**) that provides specific information about locations where naloxone can be obtained, as well as a link to a page that contains this information on www.PreventOverdoseRI.org. In Rhode Island, naloxone is available via pharmacies and community organizations to anyone in the state via standing order authorized by Dr. Rich (RAPIDS co-investigator). Additionally, all participants will be asked to provide a urine sample for a 12-drug panel rapid urine screen plus fentanyl rapid urine screen (one sample) at each study visit. The urine screens are not meant to determine a participant's eligibility based on their self-reported drug use. The urine screens will measure fentanyl and other recent drug exposure among participants to determine if there was unintentional exposure to fentanyl. Once a urine screen is completed, the sample will be disposed of immediately. Finally, participants will be asked to provide dried blood spots at three study visits (i.e., baseline, 6 months and 12 months) to confirm results from urine screening in the 12-drug panel above, in addition to detection of novel synthetic opioid and other psychoactive substances. Testing of dried blood spots will be undertaken routinely throughout and at the end of the study, and will not be used to determine a participant's eligibility. After the samples have been analysed for the study endpoints as specified in the protocol, remaining samples will be stored for use in future Institutional Review Board approved substance use and infectious disease (e.g., HIV, hepatitis C, and COVID-19) related research. Additional consent will not be sought for this storage and future use.

Table 1. RAPIDS Clinical Trial Summary

Brown Investigative Team	**PI: Brandon Marshall, PhD** Associate Professor, Department of Epidemiology **Co-I: Katie Biello, PhD** Associate Professor, Behavioral and Social Sciences
Total Enrollment	*n*= 550 (maximum for all activities)
Proposed Timeline	Recruitment begins 12/01/2019 and continues until target enrollment is reached
Clinicaltrials.gov status	Approved: NCT043772238
Intervention Name	The RAPIDS Intervention (2 arm study)
Inclusion/Exclusion Criteria	● 18 to 65 years of age; ● reside in Rhode Island; ● are able to complete interviews in English; ● self-report past 30 day use of heroin, illicit stimulants (e.g., powder cocaine, crack, methamphetamine), counterfeit prescription pills, or injection drugs, regardless of treatment status; and ● Participants who refuse consent to participate, are unable to provide informed consent due to altered mental status, or who cannot adequately hear and/or comprehend either consent process, will not be enrolled. ● Participants who exclusively misuse medications obtained from a physician or diverse of someone else's prescription will not be enrolled
Number of study visits	**7 total over 12 months** Baseline (60 minutes) + follow-ups (60 minutes) (Follow-ups at 1mo, 2mo, 3mo, 6 mo, 12mo)
Compensation	$35 for the first and last two visits, and $25 for the three intermediate visits, and an opportunity to earn an additional $5 at the visit at 3,6, and 12 months, up to $195 total if participant attends all sessions

3.1 b. Detailed description of the RAPIDS intervention (Experimental Arm)

The intervention is based on two behavioral frameworks: the **Information-Motivation-Behavior (IMB) model**, and the **self-efficacy model** as applied to addictive behaviors.

The RAPIDS intervention provides (see also **Figure 4** from grant proposal)**:**

1. education about the dangers of IMF and how to prevent overdose (information);
2. motivational interviewing to encourage risk reduction behaviors (motivation) and to assess and improve participants' confidence in implementing these behaviors (self

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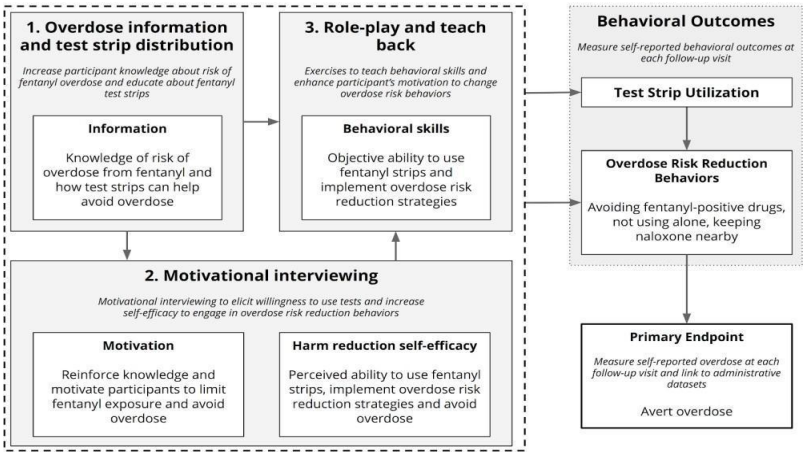
efficacy);

3. hands-on training demonstrating how to use and interpret fentanyl test strips (behavioral skills), including opportunities to practice using the test strips; and
4. provision of BTNX Rapid Fentanyl test strips[1] (see **Attachment B)** for personal harm reduction use.

Specifically, the intervention will directly increase engagement in the target overdose risk reduction behaviors, and indirectly through fentanyl test strip utilization. In other words, **we hypothesize that fentanyl test strip utilization is an important, but not exclusive, behavioral mediator through which the intervention will prevent overdose among PWUD.**

Figure 4: RAPIDS Intervention Conceptual Model



Survey Assessment Description (for complete survey instrument see **Attachment A):**

Information: Participants will be assessed on their knowledge of fentanyl and overdose prevention strategies with multi-item scales (e.g., agreement with statements such as, “Someone is more likely to overdose when using fentanyl-laced drugs than when using drugs that aren’t laced with fentanyl,” and, “Do you know where you buy or get Narcan™, a medication sometimes called naloxone?”).

Motivation: Participants will be assessed on their motivation to use the rapid fentanyl tests (e.g., agreement with a statement reading, “I am concerned about my drugs being contaminated with fentanyl”) and engage in overdose risk reduction behaviors (e.g., agreement with a statement reading, “I am confident that I can ask someone to check on me after I use drugs and call 911 if they think I am overdosing”).

Behavioral Skills: Participants will be assessed on their behavioral skills related to use of the rapid fentanyl tests (e.g., “I feel confident in my ability to use the test strips to detect if there is fentanyl in my drugs”) and engagement in overdose risk reduction behaviors (e.g., “What do you do to avoid an accidental overdose?” and, “Have you ever given Narcan/naloxone to someone who you thought was overdosing?”).

Self-Efficacy: Questions about harm reduction self-efficacy will be used to assess participants’ confidence to employ specific health-preserving skills in different types of high-risk situations

[1] https://www.btnx.com/files/BTNX_Fentanyl_Strips_Harm_Reduction_Brochure.PDF

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(i.e., when experiencing withdrawal, when feeling depressed, when feeling social pressure to use drugs in a less safe manner). This scale has shown good internal consistency and construct and discriminant validity.

Behavioral Outcomes: Participants in the intervention arm will be asked a series of questions regarding fentanyl test strip utilization at all follow-up assessments. These questions were used successfully in our pilot study, and include items such as, “Of the 10 tests we gave you, how many tests did you use?” and, “What did you do when you found out your drugs were laced with fentanyl?” As an additional measure of test strip utilization, participants will be asked to return unused tests to the study office. We will also assess motivations for using the test strips, including a desire to avoid IMF-contaminated drugs or purposely identifying fentanyl.

At each time point, participants will be asked about the practices they engage in to avoid accidental overdose. Strategies to avoid overdose include the target overdose risk reduction behaviors:

1. discarding IMF-contaminated drugs,
2. not using alone (and staggering drug use with another person who is able to administer naloxone and call 911 in the event of an overdose), and
3. keeping naloxone nearby.

We will also assess other harm reduction practices, including taking a “tester” or lower initial dose, avoiding injection drug use, and purchasing drugs from a consistent source.

Standard of Care (Attention-Matched Control Arm). Existing research suggests that training people who are at risk for overdose and their peers on how to respond when witnessing an overdose is a feasible and effective strategy for preventing overdose death. Given that this represents current overdose prevention practice, participants in the control arm will receive the standardized OEND training that occurs in Rhode Island. This program is based on the common components of many community-based overdose prevention interventions in the US, and includes information on risk factors for overdose, recognizing an overdose, performing rescue breaths, administering naloxone, and recommendations to call 911. **To ensure equivalent attention to the RAPIDS arm, control arm participants will return for retention visits at 1, 2, and 3 months,** and will answer a series of questions regarding substance use and overdose risk behaviors.

Potential Moderators/Other Key Measures: The RAPIDS survey instrument will contain additional behavioral, psychological, and clinical assessments asked of everyone in the study. Many of these questions have been piloted successfully in our prior research.

> <u>Consideration of Sex, Biological Variables, and Other Sociodemographic Characteristics:</u> Participants will report their age, sex at birth, current gender identity, sexual orientation, race, ethnicity, educational attainment, employment status, and recent and lifetime experiences of housing instability and homelessness, involvement

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with the criminal justice system, and participation in sex work.

Substance Use Experiences: Participants will report on recent and lifetime substance use patterns (i.e., age at first use, frequency of use, polysubstance use, binge use, social context of use, route of administration), and perceptions towards fentanyl (i.e., intentional use of fentanyl, suspected exposure to fentanyl-contaminated drugs). The questionnaire will also incorporate a number of standardized instruments, including the Addiction Severity-Index Lite (drug and alcohol section), and the Short Opiate Withdrawal Scale (SOWS).

Healthcare Utilization: Participants will report on health insurance status; prior mental health diagnoses, past treatment experiences, use of medications (buprenorphine, naltrexone, or methadone), and barriers to substance abuse treatment. We will administer a modified version of the Circumstances, Motivation, and Readiness (CMR) scale, which has been used to assess motivation to engage in substance use treatment.

Rapid Urine Screen Tests, Dried Blood Spot and Survey Administration Procedures: Participants will check in at the Brown University School of Public Health Lobby - 121 South Main Street and be escorted to a private interview room by *Research Assistant A*. All consenting procedures and surveys/interviews will be conducted in the private interview room. Each visit will last 60 minutes.

Two trained *Interventionist Research Assistants* (RAs) will manage the visits to 121 South Main St.:

- The first RA, *Research Assistant A*, will be responsible for the informed consent protocol and conducting the survey assessment with the participant. They will also be responsible for administering the RAPIDS intervention for participants randomized to the intervention, which includes the provision of 10 BTNX Rapid Test Strips for take-home, personal harm reduction use.
- The second RA, *Research Assistant B,* will be responsible for conducting the rapid drug screen with the participant. Participants will provide a urine sample for a 12-drug panel and fentanyl baseline urine screen.
- *Research Assistant B* will record the results of the urine screen using the participant number identifier; results will not be shared with the participant.
- *Research Assistant B* will be responsible for the collection and storage of dried blood spots using capillary finger-stick methods for the purposes of toxicology screening and future use related to substance use and infectious diseases, results of which will not be shared with the participant. *Research Assistant B* will complete required specimen collection logs detailing the date and quantity of dried blood spot specimens collected.

Rapid Testing and Dried Blood Spot Quality Control:

Research Assistant B will follow the relevant items on the *Checklist for Good Testing Practices*[2]

[2] https://wwwn.cdc.gov/clia/Resources/WaivedTests/pdf/FINAL_Self-Assessment%20Checklist%20for%20Good%20Testing%20Practices.p

to ensure all procedures are followed accordingly.

- Prior to conducting urine screens, all *Research Assistants* will complete an online CLIA Testing Best Practices training through the Centers for Disease Control and Prevention, *Ready? Set? Test! Patient Testing is Important. Get the Right Results. CE Course Number: WB2639.*
- Testing will be done in accordance with the manufacturer's guidelines, and the Centers for Disease Control and Prevention guidelines: *Good laboratory practices for waived testing sites.*[3]MMWR 2005;54(No. RR-13).
- Dried blood spots collected using capillary finger-stick methods will be undertaken according to the *WHO guidelines on drawing blood: best practices in phlebotomy* (ISBN: 978 92 4 159922 1) and the *WHO manual for HIV drug resistance testing using dried blood spot specimens* (WHO reference number: WHO/HIV/2012.30).
- Prior to collection of dried blood spots, all *Research Assistants* will complete "Qualified Professional Testing Counselor" training as required in the state of Rhode Island.

3.1.c Participant Population

The target population for this trial are adults aged 18 to 65 who are at risk of overdose due to consumption of IMF-contaminated illicit substances.

Eligibility Criteria: Participants will be enrolled in the RAPIDS trial if they are: (a) 18 to 65 years of age; (b) reside in Rhode Island; (c) are able to complete interviews in English; (d) are able to provide informed consent; and (e) self-report past 30 day use of heroin, illicit stimulants (e.g., powder cocaine, crack, methamphetamine), counterfeit prescription pills, or injection drugs, regardless of treatment status.

These criteria are consistent with our pilot study, and were selected to capture a population of PWUD who are at risk of being exposed to IMF-contaminated illicit substances, based on our prior epidemiologic research and other studies. We expect that the racial and ethnic composition of our target population will be similar to that of the samples recruited for our prior research studies involving the target population (approximately 60% white, 20% Black or African American, and 15% mixed race). We also anticipate that males will be over-represented among our target population (approximately 60%). Section **3.1.d** below, outlines the methods for ensuring wide recruitment, in addition to partnering with community-based organizations to increase enrollment.

We will exclude: persons who report exclusive misuse of medications obtained from a physician or diversion from someone else's prescription (e.g., family members), since these sources are unlikely to be associated with IMF exposure.

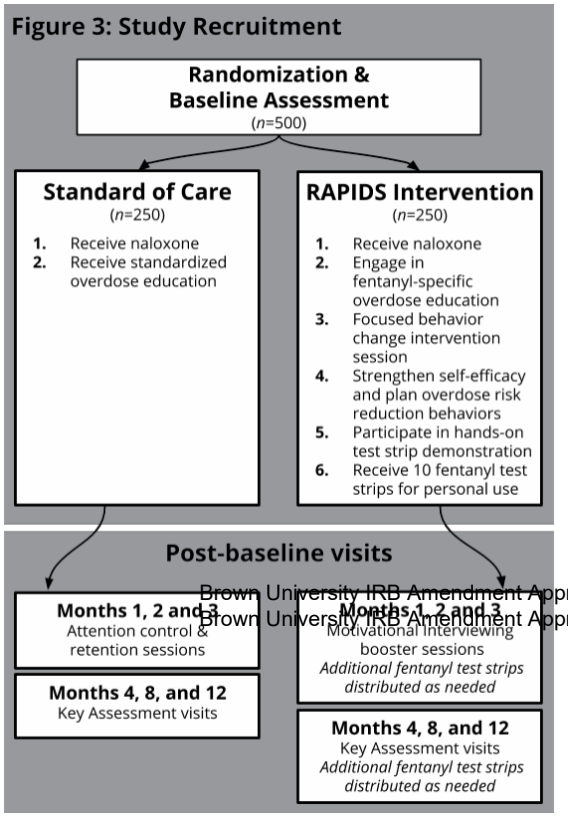
[3] https://www.cdc.gov/mmwr/PDF/rr/rr5413.pdf

3.1d. Recruitment, Enrollment, Randomization, and Retention procedures

Recruitment: Consistent with our previous research, we will employ a combination of field-based recruitment techniques (e.g., targeted canvassing, word of mouth) and Internet-based advertising to recruit potential study participants. Our team successfully identified locations for targeted canvassing in our pilot work. Project staff will conduct outreach and post study flyers in public and semi-public community venues (e.g., bus stops, parks, community organizations, drop-in centers, shelters, needle and syringe programs) in which PWUD are known to congregate. In addition, a recent spatial analysis conducted by our study team found that, between 2014 and 2017, fentanyl-involved overdose deaths have occurred in 37 of 39 municipalities in RI. As such, recruitment will occur throughout Rhode Island; for example, we will purchase advertising on bus routes and radio stations that operate throughout the state. Internet-based recruitment will include advertising on drug information websites used by PWUD (e.g., erowid.org, drugs-forum.com), online classifieds (Craigslist), and social media websites (e.g., Facebook), as well as Today at Brown.

Communication resources: Sufficient iPhones, so that each research assistant has access to one, will be purchased through Brown University's Computing & Information Services (CIS) to be used by research assistants. Throughout the study, study cell phones will only be used by authorized research assistants and staff members involved with participant communication. At the start and end of the day, the primary cell phone will be turned on or off and be checked in and out of a locked desk within the study office. Each cell phone will be encrypted using a custom alphanumeric code, with settings enabled to destroy all data on the phone after 10 failed attempts. The second cell phone will be also be used for field visits as necessary

Both cell phones used in the study will be insured to include repairs through accidental damage, replacement, and theft protection. In addition, all cell phones will be installed with an application which allows for the remote GPS tracking of each device. Each cell phone will have encrypted backups of information stored on iCloud. In the event that a cell phone is lost, stolen, or otherwise not returned, the iPhone will be remotely wiped of data. At the end of the study, all encrypted cell phone data will be destroyed and all cell phones will be wiped of data and returned to Brown University's Computing & Information Services (CIS).



Enrollment and assessment will occur in two stages: First, potential participants will text message, email, or call a study hotline, at which point a study staff member will screen for eligibility. If eligible, the staff member will then schedule an interview at the Brown University School of Public

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Health. At this time, all assessments will occur at our study offices, which are centrally located and easily accessible to members of the study population. In some circumstances, the interviews may occur at a semi-private location outside of BUSPH (ex. Public library study rooms, clinics or other community partner agencies) (see **Attachment I,** Safety Protocol, for field-based safety measures).

Randomization: Randomization: Participants will be randomized 1:1 using a randomization table generated in SAS by the study's Biostatistician,
which will be operationalized using the Randomization Generator Module in REDCap. Randomization will be assigned during the baseline visit.[4] Intervention allocations will be maintained in REDCap by authorized users only, such as the study Statistician, and revealed only through REDCap by prompts during the baseline survey visit and post-baseline visits (See **Figure 3**).

Blinding: Staff conducting the baseline and follow- up assessments will be blinded to intervention assignment until completion of the STUDY ENROLLMENT INFORMED CONSENT FORM at
the Baseline visit. Intervention allocations will be maintained in REDCap by authorized users only, such as the study Statistician, and revealed only through REDCap by prompts during the baseline survey visit and post-baseline visits.

Retention: To maximize retention, we will employ retention strategies that are effective with PWUD.

For example, we have found that text messages are the preferred mode of communication: over 95% of participants in our pilot study owned a cell phone and used it daily. We have included study cell phones in the budget so project staff can text participants at least monthly to update contact information. Additional retention strategies to be employed include: (1) maintaining a tracking database of contact information (e.g., phone numbers, email addresses, social media handles, physical addresses for sending appointment reminder postcards); (2) conducting regular outreach in areas that participants are known to frequent; (3) providing honoraria for all study visits; (4) providing free parking to participants visiting the study office by validating garage parking passes; (5) searching the public RI Department of Corrections database to determine if a participant is incarcerated for a period of longer than 90 days, at which point they will be withdrawn from the study. These strategies were used effectively in our RAPIDS pilot study, resulting in a 90% follow-up rate.

3.1 e How confidentiality of data will be maintained (where data is kept, who has access to it, and how it is kept secure). The Principal Investigator, Brandon Marshall, PhD is ultimately responsible for data safety and monitoring of the study. This process will be monitored on a weekly basis by his team, including the Project Director, Data Analyst, and Senior Research Assistant, with quarterly updates to the entire team of Co-Investigators. The project team will be responsible for ensuring that all policies and processes outlined in the Data Use Agreement (with Rhode Island Department of Health, **Attachment E**) are followed accordingly, and that data are

[4] http://cri.uchicago.edu/wp-content/uploads/2015/12/REDCap-Randomization-Module.pdf

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transferred and shared on the agreed-upon timeline.

This study includes a Data and Safety Monitoring Board (DSMB) and Plan (DSMP).The DSMB will meet on a semi-annual basis with the PI and Project Director to review the DSMP and protocol adherence (see **Attachment F**). The DSMB will also review any adverse or severe adverse events as outlined in the DSMP.

Stronghold computing environment: We will obtain a central storage service hosted by Brown University's Computing & Information Services (CIS) Stronghold project (see **Attachment G,** Stronghold MOU). Stronghold is a HIPAA-aligned, secure computing environment developed for housing, sharing, and analyzing sensitive data. The project's Data Analyst will oversee the database architecture, dataset storage, and all input/output (i.e., RIDOH data transfer) regulations. Stronghold is highly secure computer and storage Windows-exclusive environment for research needs that involve very sensitive data needing special handling, data usage agreements, etc.

All Stronghold users must: Be approved by the Principal Investigator, authorized in writing to Brown University Computing & Information Services (CIS), and:

- complete appropriate training for working with sensitive data (e.g. CITI training);
- be in compliance with all relevant Institutional Review Board protocols;
- be in compliance with any data use agreements or other agreements governing the use of the data stored on Stronghold;
- complete an on-boarding process led by the Principal Investigator or Senior Research Assistant, which includes a review of data security protocols and a guided walkthrough of accessing the Stronghold virtual environment.

Data Transfers – there are select methods to import data, including but not limited to:

- Select Rhode Island state agencies and other offices using a secure VPN tunnel
- Encrypted USB drives
- Secure transfer through firewall exception
- Import and export servers

For the proposed project, we will conduct and automate secure data transfer of administrative overdose records with RIDOH on a monthly basis (according to the timeline outlined in our existing data use agreement, see **Attachment E**). Any matching between personally identified data sources is done within a secured area prior to any data (de-identified) being exported. After the baseline survey, a separate consent procedure will be used to gain permission to obtain information regarding overdose events (to be submitted as a future amendment, upon RIDOH approval). To conduct the probabilistic, confidential data linkage with the RIDOH administrative surveillance records, we will first create an encrypted, password-protected file containing the linkage variables (e.g., sex, date of birth, zip code of residence). We will link these surveillance datasets with participant data using a probabilistic linkage with the following combination of identifiers: first and last name, date of birth, and sex. To conduct the probabilistic match, we will use The Link King software. All linkages will be conducted within

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Stronghold, a HIPAA-aligned secure computing environment at Brown University. Matched records will then be transferred to and stored on computers at the CEEH using secure data-transfer and storage protocols.

Survey data will be collected on password-protected tablets and computers within the Centers for Epidemiology and Environmental Health (CEEH) at the Brown University School of Public Health. The REDCap™ platform exceeds patient confidentiality and data security requirements for clinical trials, and are both HIPAA compliant and fully validated for FDA 21 CFR Part 11.

REDCap™ is a secure and web-based platform that allows input data from anywhere with secure web authentication, data logging, and Secure Sockets Layer (SSL) encryption. For remote data entry during field-based interviews, staff will be given iPads with data connectivity that allow for direct and secure data entry into REDCap™.[5]

Access to project data will be restricted to individuals who are authorized to work on the project. Access to data with identifiers is further restricted to the Systems/Data Manager alone. Data are de-identified before analytic files are created, providing an additional level of protection.
Furthermore, Center employees have signed an oath of confidentiality, and its violation is sufficient grounds for immediate termination. All of our research assistants are CITI certified, and will receive comprehensive orientation and intervention training for this research study prior to interacting with participants or study data.

3.1f Analytic Plan

Assessing intervention efficacy in reducing emergency department (ED) presentation for an overdose or overdose death (Aim 1, secondary endpoint). First, we will compare the overall rate of patients experiencing this composite outcome over the 12-month follow-up period in each group. Next, we will examine the time to first ED presentation or death using a Kaplan- Meier analysis. Patients will be censored as of the first date of either of these outcomes or at the end of the 12-month period. We will use Breslow's method to test if the time to either outcome differs between the groups, since this approach gives greater emphasis to shorter time elapsed after the intervention, which has greater clinical significance. Third, Cox proportional hazards modeling will be used to estimate hazard ratios for the treatment effect. Multivariable models will be constructed to adjust for possible post-randomization confounding.

Examine whether the treatment effect is mediated by differential uptake of risk reduction behaviors in the intervention arm (Aim 2). If the RAPIDS intervention shows efficacy in reducing overdose rates among the sample (Aim 1), we will explore the extent to which this relationship works through several possible mediators (see Figure 4). For mediation analyses, first, we will examine, in multivariable regression models, which mediators, if any, are significantly changed by the intervention (i.e., the rate of change differed by treatment

[5] https://rc.partners.org/research-apps-and-services/collect-data#redcap

assignment). For those that are significantly impacted by the intervention, we will conduct path analysis using structural equation modeling to determine whether the effect of the intervention on overdose is through the hypothesized mediator(s). Structural equation modeling (SEM) allows for the simultaneous estimation of total, direct, mediated and indirect effects of a causal variable (i.e., the intervention) on the outcome (i.e., overdose) through a set of mediator variables. SEM can handle outcomes and mediators with a variety of distributions (including, Gaussian, Poisson and Binomial). Inferences for indirect effects can be estimated using bootstrapped confidence intervals.

Determine whether intervention efficacy varies across participant subgroups (Aim 3). We will examine if heterogeneity of intervention effect is modified by key baseline characteristics of interest, including: age; sex; type, frequency, and route of drug use; baseline level of overdose risk (e.g., lifetime history of overdose); and pre-intervention motivations for fentanyl test strip utilization. We will perform stratified subgroup analyses to determine if treatment effects vary between groups of individuals.

3.1 g COVID-19 procedures and precautions

In response to the COVID-19 pandemic, a number of cleaning, social distancing, and contact tracing procedures are being implemented. These procedures are discussed in detail in Attachment J, Reopening Plan. In short, research staff will take extensive measures to clean the study space at the beginning of each day, between participants and at the end of each day. Research staff and participants and staff will wear masks and maintain adequate distance from each other when a door cannot be closed between them. The only time participants and staff will be closer than 6 feet from each other is for the collection of the dried blood spot. The finger prick will take a matter of minutes, and during that time, the research staff will wear a face shield.

On the day prior to a study visit and on the day of, participants will be screened for COVID exposure and risk. During the visits, surveys will be conducted over zoom with participants and staff sitting in nearby, but separate rooms. This will ensure that staff and participants are not in a closed space for longer than necessary.

Contact tracing logs will be kept and maintained in REDCap. In the event of participant or staff COVID exposure, the research team follow Rhode Island Department of Health contact tracing procedures.

We recognize that as guidance changes, safety procedures may have to be modified. At any point, if Brown University issues additional guideless, the staff will follow those procedures in addition to or in place of the guidelines proposed on **Attachment J**.

3.2 Informed Consent Procedure

We will obtain verbal informed consent from participants at the start of the Screening process, and e-signed informed consent for the interviewer-administered surveys at the Baseline enrollment visit (see **Attachment A** for consent forms). Participants will be asked if they would like a copy of the consent form emailed to them. The enrollment consent form will be reviewed with the subject in a quiet, private location at the Brown University School of Public Health at the start of the Baseline Visit. All participants will be given detailed explanations of their rights as human subjects, including the purpose of the study, length of time for the interview process, study requirements, and risks and benefits of the interventions.

Participants who refuse consent to participate, are unable to provide informed consent due to altered mental status, or who cannot adequately hear and/or comprehend either consent process, will not be enrolled.

Participants will be asked to sign electronic copies of completed consent forms that will be stored in the Stronghold Environment; however, if necessary, paper consent forms will be retained by the Principal Investigator in a secure, double-locked environment. Participants will be offered a copy of the informed consent form via email or by texting them a link to the form online.

3.4 Risks & Benefits

Potential Risks: We recognize that participants will be asked potentially sensitive information, including illicit drug use and injection drug use history, and therefore may experience discomfort, anxiety, or stress in responding to certain study questions. As such, as part of the informed consent procedure, participants will be advised that their answers will be confidential, and issues discussed will in no way impact their ability to obtain or be referred to medical care or social services. In addition, at the start of the interview, participants will be informed that they can skip and refuse to answer any questions that they may find uncomfortable or embarrassing. If concerns arise prior to, during, or after the interview, or if participants request further information, they will be referred either to the toll-free study number, or if they prefer, will be given the contact information of the project PI.

Among participants enrolled in the RAPIDS intervention arm, additional risks include mistakenly believing that a substance does not contain fentanyl or a related potent analogue after self- testing is complete. We will make every effort (through training, teach-back, and automated text reminders) to ensure that participants understand the limitations of the rapid tests, and specifically that a negative self-test result does not necessarily mean that overdose risk is negligible. Interviewers will discuss and role-play how to implement overdose risk reduction activities upon receipt of a positive or negative test. Risks and benefits of the fentanyl test strips will also be addressed in the consent form at enrollment.

The risks to human subjects also include potential breaches of confidentiality. No names or other identifying information will be included in the analytic files. The risk of breach of

confidentiality will be minimized to the greatest extent possible, including through the use of Brown's research protection resource, Stronghold.

There is minimal physical risk to participants 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, participants might require medical treatment.

Alternatives to enrollment in the trial may include not participating in the trial.

Protection Against Risks

Possible risks to participants will be minimized in several ways. All members of the research team will treat all data with strict confidentiality. Questionnaires will not include participants' name or any other identifying information. Participants' names, other personally identifying information, telephone numbers, and tracking information will be recorded in separate files and will not be linked to any of the participants' data. Access to these files will be encrypted, password-protected and locked; access will be restricted to essential study personnel only. No data will be reported on an individual basis; all findings will be reported in summary statistical form only. All analyses will be presented in aggregate form with minimum cell sizes so that individuals cannot be identified. Data will be stored and linked in the Stronghold environment.

Dried blood spots will be held in long-term storage using ultra-low temperature freezer facilities (-70°C) managed and temperature-monitored by Brown University staff. Dried blood spot specimens will be identified using the RAPIDS Participant ID, study visit number, date of study visit. Multiple separate identifiers are necessary to minimize the risk of errors in specimen handling and testing, e.g., transcription errors during specimen labelling or retrieval. As these specimens are not collected in a clinical setting, these identifiers are not considered Protected Health Information. Study personnel will attempt to contact participants that have preliminary reactive results for infectious diseases from dried blood spot samples with a recommendation for follow-up testing with a healthcare provider. Participants will be provided with a resource list with information about where to get tested for infectious diseases at enrolment and if contacted following infectious disease testing. A number of harm reduction and primary care services in Rhode Island provide confidential and anonymous testing for HIV and hepatitis C virus for free or at low cost. We will use the study retention tracking database for contact information, and will provide participants with referral resources related to infectious disease screening during enrolment and when reporting preliminary reactive results. At no time will participant infectious disease and contact information be combined.

All interviews will be conducted by our Research Assistants; these staff who are trained in issues relevant to engaging the target population such as risk reduction and drug user stigma.

Additionally, staff will go through specific training for the purposes of the intervention, including motivational interviewing, overdose recognition and response, and naloxone administration.

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These trainings will be conducted by the Project Director, who has previous experience as a state and national trainer in motivational interviewing and other relevant topics. All research personnel involved in the project will have successfully completed the Collaborative IRB Training Initiative (CITI) at Brown University, an online human subject research protections education program.

Individuals participating in the intervention arm will receive rigorous, comprehensive one-on-one training regarding the procedures and limitations of the BTNX Inc. Rapid Response™ fentanyl test strip. Participants will be informed that the test provides only a qualitative, preliminary analytical result. We will also emphasize that the accuracy of the test's result may be compromised by technical or procedural errors, adulterants in the sample, or the presence of novel fentanyl analogues that are not captured by the test. **During the study follow-up period, automated text messages will be used to remind all participants of their next follow-up visit.**

The proposed text of these messages are as follows:

- **"**Don't forget! You have plans at [time] on [date] at Brown University School of Public Health. Does this time still work for you?" Text us if you have any questions."

Benefits: The direct benefits to participants will include facilitated referrals to overdose prevention services, addiction treatment programs, as well as medical care and other social services, as appropriate. Risk reduction and motivational interviewing provided by trained interviewers may also help individuals who may not otherwise understand how to protect themselves from the harms of illicit drug use to elicit change behaviors and facilitate utilization of the provided overdose education, naloxone, and (in the intervention arm) fentanyl test strips. Finally, at the end of each interview, all study participants will receive a package of educational material regarding overdose prevention (e.g., how to identify an overdose, where to obtain naloxone) (see **Attachment B**), as well as a list of substance abuse treatment services in Rhode Island. After the first session, all participants will also receive a naloxone kit.

Attachment A: Study Scripts, Consent Forms & Surveys

Attachment B: Educational Handouts for Participants

- **BTNX Fentanyl Test Strips for Harm Reduction Use brochures**
- **PreventOverdoseRI.org Fentanyl Test Strip testing instructions**
- **Test Strip Labels (applied directly to the Rapid Test Strips)**
- **BTNX Product Insert**

Attachment C: Recruitment materials (online & community-based)

Attachment D: NIDA R01 Funding application (Upon Request, not included)

Attachment E: BAA - Rhode Island Department of Health

Attachment F: Data & Safety Monitoring Plan

Attachment G: Stronghold / Marshall - MOU

Attachment H: IDE Checklist and NSR Justification

Attachment I: Safety Protocol (staff and participants)

Attachment J: Community Based Resources and Referrals

Attachment K: Investigator Self-Evaluation Checklist

Attachment L: Reopening Plan

Attachment M: Dried Blood Spot Protocol

Attachment N: Use of devices for Dried Blood Spot Protocol

*****Attachments not applicable at this time:***

Letters of support/permission (NA)
Other IRB approvals - RIDOH (To be submitted upon Brown IRB approval)
Protocol addenda/appendices (NA)

THE RAPIDS CLINICAL TRIAL:
Attachment A: Study Scripts, Consent Forms & Surveys

[Project Overview – Information not shown to participants]

Last Updated: 02/01/2021

IRB History: Approved *04/18/2019,* Amendment 1 Submitted *10/31/2019,* Approved 11/22/2019. Administrative amendment submitted 12/12/2019, Amendment 2 Approved 08/17/2020, Amendment 3 submitted *09/30/2020,* Amendment 3 Approved 10/15/2020, Amendment 3 submitted 02/01/2021

Principal Investigator:

Brandon DL Marshall, PhD
Associate Professor
Department of Epidemiology
Brown University School of Public Health

About this Research:

This study will test the efficacy of a novel drug-checking intervention to prevent fatal and non-fatal overdose among adults who use drugs. We will evaluate whether the incorporation of rapid fentanyl testing into a theory-driven overdose education and counseling program reduces rates of overdose compared to standard overdose education and naloxone distribution. Results from this study will significantly improve public health efforts to address the fentanyl overdose epidemic and reduce the harms associated with exposure to drugs contaminated with fentanyl among adults ages 18-65. This is a full clinical trial, building on the results of our fentanyl-test-strip pilot study (2016-2017). This study is funded by the National Institute on Drug Abuse (R01-DA047975).

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These research materials are the property of the principal investigator and are not to be shared or used outside of the study without specific and written permission of the Principal Investigator, Brandon DL Marshall, PhD <brandon_marshall@brown.edu>

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SECTION 1a: PARTICIPANT SCREENING: SCRIPT (Prior to Enrollment)

[Introductory Script for Potential Participants]

Hi, this is [RA name] at Brown University. Thanks for reaching out to us for more info.

Our latest study is about helping stop drug overdose in Rhode Island. People who join our study will help us by answering questions on a survey and going through our short training on ways to help stop accidental drug overdoses.

The research study visits will take place in person, and take up to an hour of your time at each visit. You will be asked to visit our office SIX times total in the next 12 months, and you will be given a survey each time. You will be asked to give a urine sample for a rapid drug screen at each visit. The results of your drug screen do not affect your participation in the study and will not be linked to your name.

If you qualify, you will receive $35 for the first and last visit and $25 for the four intermediate visits visit to participate in the study. Again, there are SIX visits total that we are asking you to do in the next 12 months. You will earn a total of $170 after all six visits. You will only be compensated for the visits you attend.

Would you like to answer a few questions to see if you qualify? Your responses are completely confidential. It will take about ten minutes, including the time I need to go over our consent form with you. I will go over the consent form with you, but if you would like a copy of the form for yourself I can email it to you or text a link to you.

[If YES, proceed to ELIGIBILITY SCREENING – INFORMED CONSENT SCRIPT & FORM]

[If NO, thank them for their time and end the communication]

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SECTION 1c:
PARTICIPANT SCREENING QUESTIONS (REDCap)

1.a Participant ID

(R0001-R1000)

_____

1.b Interviewer ID *(All CAPS, INITIALS ONLY)*

_____

1.1 Are you between the ages of 18 to 65 years old? *[AGE]*
Yes
No

1.3 Are you able to complete a survey in English? *[ENGLISH]*
Yes
No

1.5 Do you currently reside in Rhode Island? *[RESRI]*
Yes
No

1.6 In the past 30 days have you used pills that were purchased on the street? *[USEDPILLS]*
Yes
No

1.7 In the past 30 days, have you bought any pills on the street? *[BOUGHTPILLS]*
Yes
No

RA PROMPT: Participants who exclusively misuse medications obtained from a physician or diverted from someone else's prescription should not be enrolled

1.8 In the past 30 days have you used heroin? *[HER]*
Yes

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No

1.9 In the past 30 days have you used cocaine, crack, or methamphetamine? *[CCM]*
Yes
No

1.10 In the past 30 days have you injected any drugs? *[INJ]*
Yes
No

[END SCREENING]
{PPT IS ELIGIBLE IF 1.1-1.5 = YES, AND, IF ANY ONE OF 1.6-1.10 =YES}
[If YES, proceed to PARTICIPANT CONTACT AND SCHEDULING]
[If NO, thank them for their time and end the communication]

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SECTION 1d:
PARTICIPANT CONTACT AND SCHEDULING (REDCap)

It looks like you qualify for the study! At this time we are going to ask you a few more questions.

[Programmer note, after screening, do not store name with eligibility information, assign participant study identification number and auto-generate randomization. These responses are stored in the Participant Database]		
1.10	**Phone Number/Preferred method of contact**	
1.11	**Preferred email address**	
1.12	**Alternate phone number where we can leave a basic/non-detailed reminder about study visits**	
	If we cannot reach you by phone is there a different messaging application (e.g., Facebook Messenger, Instagram) that we can reach you through - note we will not mention the study directly	
1.13	**First Name**	
1.14	**Last Name**	
1.15 a	**An address we can send a postcard with a basic/non-detailed reminder about study visits**	
1.15	**City of Residence**	

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1.16	**Current Zip Code**	
1.17	**Date of Birth**	
1.18	**First Study Visit**	
1.19	**How did you hear about this study (read out list; check all that apply)**	Craigslist, Twitter, Facebook, Flyer posted outside, Bus ad, A friend told me about it, A family member told me about it, Flyer given to me at an organization:_____, Another study:_____, Other:_____, DK/R

Confirm the date and time of their first visit
Interviewer prompt: That's it for questions. Just a reminder that we have you scheduled for an interview with us on {DATE} at {TIME} at 121 South Main Street. Please bring a photo ID.
[If scheduled same day] We will see you soon. Would you like directions to our office?
[If scheduled a different day] We will be in touch before the interview to confirm. In the meantime, let us know if you have any questions. Thanks!

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SECTION 2a:
BASELINE SURVEY BEGINS (REDCap)
(VISIT 1 ONLY – Baseline)

1.1 Participant ID

_____ *(R0001-R1000)*

1.2 Interviewer ID

_____

Survey started (hidden)
(system-captured as mm/dd/yyyy hh:mm:ss AM/PM)

Survey ended (hidden)
(system-captured as mm/dd/yyyy hh:mm:ss AM/PM)

Did participant sign consent? [*CONSENT*]
- o Yes
- o No

To which did the participant consent?
- o Agreed to this Study Visit *(must be checked to continue)*

ARM ASSIGNMENT *[PIPE FROM SCREENER, RA SEES ARM ASSIGNMENT]*
- **ARM 1 (Control)**
- **ARM 2 (Experimental)**

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SECTION A: DEMOGRAPHICS

Interviewer prompt: Thank you for taking the time to complete our survey. If at any time you feel uncomfortable responding to a question, tell the interviewer that you don't want to answer.

A1. What is your age? *[pptage]*

_____

A2. What was the sex were you assigned at birth on your original birth certificate? *[sexbirth]*

Male
Female
DK/R

A3. What best describes your current gender identity? *(Read out list; check only one) [gend]*

Male *[1]*
Female *[2]*
Transgender Male/Trans Man/Female-to-male (FTM) *[3]*
Transgender Female/Trans Woman/Male-to-Female (MTF) *[4]*
Genderqueer, neither exclusively male nor female *[5]*
Something else *[77]*
DK/R *[99]*

A3a. If GEND = something else [77], What best describes your current gender identity?
_____ *[gend_oth]*

A4. Are you of Hispanic or Latino descent? *[ethnic]*

Yes
No
DK/R

A5. How would you describe your racial background? *(Check only one) [race]*

American Indian or Alaska Native
Asian
Black, African, Haitian, or Cape Verdean
Native Hawaiian or other Pacific Islander
White
Mixed, bi-racial, or multi-racial
Something else: _____
DK/R

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A5a. Do you speak a language other than English at home? *[english]*

Yes
No
DK/R

A5b. *If english= "yes":* **What is this language?** *[homeland]*

_____

A6. Do you consider yourself to be... *(Read out list; check only one) [orie]*

Straight
Gay
Lesbian
Bisexual
Queer
Something else: _____
DK/R

A7. What is your current relationship status? *(Read out list; check only one). [relation]*

You have a spouse/partner whom you live with
You have a regular partner whom you do not live with
You are dating or seeing someone
You are single
DK/R

A8. What is the highest level of education that you have received? *(Read out list; Check only one). [educ]*

Elementary or grade school
Some high school
Finished high school or GED
Some college
Trade or technical school
College or university degree
DK/R

A9. Are you currently enrolled in… *[stud]*

High school or a GED program
Trade or technical school
College or university degree program
None of these
Other
DK/R

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A9a. *If stud= "other"*: **Are you currently enrolled in:_____** *[stud_oth]*

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SECTION B: HOUSING, EMPLOYMENT & INCOME

B1. What type of place are you living in right now? *(Read all that apply, check only one). [hous]*

An apartment or house that you rent or own
A parent or family member's apartment or house
Someone else's apartment or house short-term (like couch-surfing)
College dorm
Recovery or residential treatment center
Transitional housing program
Corrections halfway house
Drop-in center or emergency shelter
Car, abandoned building, or some other indoor public place
On the street or in another outdoor public place (like a park)
Other
DK/R

B1a. *If hous= "other":* **What type of place are you living in right now:____** *[hous_oth]*

What town do you currently live in? *[town]*

_____

B1a. What is your current zip code? *[zip]*

_____
No fixed address
DK/R

Interviewer prompt: We would now like to ask you about your experiences of homelessness. By homelessness, we mean not having a regular place to stay, and living in a shelter because of nowhere else to go, or living in a place not ordinarily used for sleeping, like an abandoned building, car, or park.

B2. Have you <u>ever</u> been homeless? [*hlevr*]

Yes
No → skip to B4
DK/R → skip to B4

B3. *If hlevr= "yes":* **Have you been homeless <u>in the last month</u>?** *[hlm1]*

Yes
No

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DK/R

B3a. *If hlm1= "yes":* **Are you currently homeless?** *[hlcr]*
Yes
No
DK/R

B4. Are you <u>currently</u> employed full-time or part-time doing legal work for pay? This includes work that is full-time, part-time and temporary work? [*employ*]
Yes
No
DK/R

B5. *If employ= "yes":* **Which of the following is closest to your occupation** *(Read out list; check all that apply). [occu]*
Manufacturer *[1]*
Retailer *[2]*
Wholesaler *[3]*
Service Provider *[4]*
Construction *[5]*
Mining *[6]*
Farming/Fishing/Forestry *[7]*
Government *[8]*
Other *[77]*
DK/R *[99]*

B5a. *If occu= "other*: **Which of the following is closest to your occupation: _____** *[occu_txt]*

B6. *If employ= "no":* **If you are not employed, are you…** *(Read out list; check all that apply) [unemploy]*
On temporary layoff from a job *[1]*
Looking for work *[2]*
Retired *[3]*
Disabled *[4]*
A student *[5]*
A homemaker/caretaker *[6]*
Unable to work (primary reason?) *[7]*
Other *[77]*
DK/R *[99]*

B6a. *If unemploy= "unable to work":* **Unable to work, primary reason:_____** *[unepmploy_una]*

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B6b. *If unemploy= "other":* **If you are not employed, are you:_____** *[unemploy_ot]*

B7. Have you ever been turned down for a job because of current or past drug use? *[nojob]*
Yes
No
DK/R

B8. Are you currently receiving any disability benefits (such as workman's compensation or SSDI)? *[incomedis]*
Yes
No
DK/R

B9. What is your average take home monthly income, including public assistance or family support (like from cash assistance, welfare, or TANF)? *[income]*
$0
< $1 - $500
$501 - $1500
$1501 - $3000
> $3000
DK/R

B9a. Have you <u>ever</u> received <u>any of the following</u> in exchange for sexual activities of any sort (like a hand job, blowjob, or sex)? *(Read out list; check all that apply) [sext]*
Gifts or other goods *[1]*
Food *[2]*
Housing *[3]*
Clothes *[4]*
Drugs *[5]*
No, none of the above *[6]*
DK/R *[99]*

B9b. Have you <u>ever</u> received <u>money</u> in exchange for sexual activities of any sort (like a hand job, blowjob, or sex)? *[sexmoney]*
Yes
No

B10. Have you <u>ever</u> been arrested? *[evrarr]*

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Yes
No
DK/R

B11. *If evrarr= "yes":* **Have you been arrested <u>in the last month</u>?** *[m1arr]*
Yes
No
DK/R

B12. *If evrarr="yes":* **Have you <u>ever</u> been incarcerated in an adult jail or prison?** *[evrinc]*
Yes
No
DK/R

B13. *If evrinc= "yes":* **Have you been incarcerated in an adult jail or prison in the last month?** *[m1inc]*
Yes
No
DK/R

B14. *If m1inc= "yes":* **Have you <u>ever</u> been on probation or parole?** *[evrprob]*
Yes
No
DK/R

B15. *If evrprob = "yes":* **Have you been on probation or parole in the <u>past month</u>?** *[m1prob]*
Yes
No
DK/R

B16. *If m1prob= "yes":* **Are you currently on probation or parole?** *[curprob]*
Yes
No
DK/R

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SECTION C: DRUG USE

Interviewer prompt: We are now going to move on to talk about your current and past drug use. As a reminder, your participation is voluntary and you have the right to refuse to answer a question. All responses are strictly confidential and will not be shared with anyone outside of the study team.

C1. Have you ever snorted, smoked, swallowed, or used any of the following drugs without a prescription or not as doctor directed? Please note that we will ask about other drugs and injection drug use separately. *(Read out list and time increments) [evpilnon]*

		Ever (Y/N) *[All NO]* → skip to C5
C1a	Prescription opioids such as Percocet, OxyContin, Dillaudid, Vicodin	
C1b	Medications used for opioid use disorder such as Methadone, buprenorphine/Suboxone	
C1c	Benzodiazepines/Benzos such as Xanax, Ativan, Valium, Klonapin	
C1d	Prescription stimulants such as Adderall, Ritalin, Focalin, Concerta, Dexedrine	

C2. How old were you when you first snorted, smoked, swallowed, or used any of the following drugs without a prescription or not as doctor directed? Please note that we will ask about other drugs and injection drug use separately. *(Read out list and time increments) [yrpilnon]*

C2a. Prescription opioids, such as Percocet, OxyContin, Dillaudid, Vicodin? _____ *[yrpilnon_po]*

C2b. Medications used for opioid use disorder such as Methadone, buprenorphine/suboxone? _____ *[yrpilnon_moud]*

C2c. Benzodiazepines/Benzos such as Xanax, Ativan, Valium, Klonapin? _____ *[yrpilnon_bz]*

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C2d. Prescription stimulants such as Adderall, Ritalin, Focalin, Concerta, Dexedrine? _____ *[yrpilnon_ps]*

C3. How many times in the past 30 days have you snorted, smoked, swallowed, or used any of the following drugs without a prescription or not as doctor directed? Please note that we will ask about other drugs and injection drug use separately. *(Read out list and time increments) [m1pilnon]*

C3a. Prescription opioids, such as Percocet, OxyContin, Dillaudid, Vicodin? _____ *[m1pilnon_po]*

C3b. Medications used for opioid use disorder such as Methadone, buprenorphine/suboxone? _____ *[m1pilnon_moud]*

C3c. Benzodiazepines/Benzos such as Xanax, Ativan, Valium, Klonapin? _____ *[m1pilnon_bz]*

C3d. Prescription stimulants such as Adderall, Ritalin, Focalin, Concerta, Dexedrine? _____ *[m1pilnon_ps]*

C4. Have you first snorted, smoked, swallowed, or used any of the following drugs without a prescription or not as doctor directed in the past <u>7 days</u> or past <u>3 days</u>? Please note that we will ask about other drugs and injection drug use separately. *(Read out list and time increments)*

		Past 7 days (Y/N) *[d7pilnon]*	Past 3 days (Y/N) *[d3pilnon]*
C4a	Prescription opioids such as Percocet, OxyContin, Dillaudid, Vicodin		
C4b	Medications used for opioid use disorder such as Methadone, buprenorphine/Suboxone		
C4c	Benzodiazepines/Benzos such as Xanax, Ativan, Valium, Klonapin		

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C4d	Prescription stimulants such as Adderall, Ritalin, Focalin, Concerta, Dexedrine		

C4e. ***If yes to any of C2a to C2:*** **<u>In the last month</u>, who's usually around when you're using these drugs without a prescription or not as a doctor directed?** (*Read out list; check all that apply). [pepil]*

I use alone *[1]*
A close friend *[2]*
A casual friend or acquaintance *[3]*
A sex partner *[4]*
An immediate family or household member *[5]*
An extended family member *[6]*
A Dealer *[7]*
Strangers/people I don't know *[8]*
DK/R *[99]*

C5. <u>In the last month</u> have you used Suboxone/Subutex/Buprenorphine or methadone to manage opioid withdrawal without a prescription? *[bupself]*

Yes
No
DK/R

C6. *If bupself= "yes":* **<u>In the last month</u>, how did you get Suboxone/Subutex/Buprenorphine or methadone without a prescription?** *(Read out list, check all that apply) [bupbuy]*

Purchased from a dealer or on the street *[1]*
A close friend *[2]*
A casual friend of acquaintance *[3]*
A sex partner *[4]*
An immediate family or household member *[5]*
An extended family member *[6]*
Purchased from the internet or "dark web" *[7]*
Other *[77]*
DK/R *[99]*

C6a. *If bupbuy= "yes":* **In last month, how did you get Suboxone/Subutex/Buprenorphine or methadone without a prescription:_____** *[bupbuy_oth]*

C7. *If bupbuy= "yes":* **<u>In the last month</u>, how have you used Suboxone/Subutex/Buprenorphine without a prescription.** *(Read out list, check all that apply) [buptyp]*

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A film or tablet that dissolves under your tongue *[1]*
Skin patch *[2]*
Pills (orally) *[3]*
Snorting *[4]*
Smoking *[5]*
Injecting *[6]*
Other *[77]*
DK/R *[99]*

C7a. *If buptyp = "yes":* **In the last month, how have you used Suboxone/Subutex/Buprenorphine without a prescription:_____** *[buptyp_oth]*

C8. Have you ever snorted, smoked, swallowed, or used any of the following drugs? Please note that we will ask about other drugs and injection drug use separately. *(Read out list and time increments) [evdrgnon]*

		Ever (Y/N) *[All NO]* → skip to C5
C8a	Marijuana or hash oil, including edibles and synthetic marijuana	
C8b	Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine	
C8c	Psychedelics, such as Mushrooms, Acid, LSD, DMT	
C8d	Crystal methamphetamine (crystal meth, glass, tina, crank, ice)	
C8e	Powder cocaine	
C8f	Crack cocaine	
C8g	Heroin	
C8h	Alcohol	
C8i	Alcohol to intoxication	

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C8j	Other:	

C9. How old were you when you first snorted, smoked, swallowed, or used any of the following drugs? Please note that we will ask about other drugs and injection drug use separately. *(Read out list and time increments) [yrdrgnon]*

C9a. Marijuana or hash oil, including edibles and synthetic marijuana:_____ *[yrdrgnon_m]*

C9b. Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine:_____ *[yrdrgnon_cd]*

C9c. Psychedelics, such as Mushrooms, Acid, LSD, DMT:_____ *[yrdrgnon_p]*

C9d. Crystal methamphetamine (crystal meth, glass, tina, crank, ice):_____ *[yrdrgnon_cm]*

C9e. Powder cocaine:_____ *[yrdrgnon_pc]*

C9f. Crack cocaine:_____ *[yrdrgnon_cc]*

C9g. Heroin:_____ *[yrdrgnon_he]*

C9h. Alcohol:_____ *[yrdrgnon_alc]*

C9i. Alcohol to intoxication:_____ *[yrdrgnon_alix]*

C9j. Other:_____ *[yrdrgnon_oth_age]*

C9k: Other drug mentioned:_____ *[yrdrgnon_oth_drg]*

C10. How many times in the past 30 days have you snorted, smoked, swallowed, or used any of the following drugs? Please note that we will ask about other drugs and injection drug use separately. *(Read out list and time increments) [M1DRGNON]*

C10a. Marijuana or hash oil, including edibles and synthetic marijuana:_____ *[m1drgnon_m]*

C10b. Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine:_____ *[m1drgnon_cd]*

C10c. Psychedelics, such as Mushrooms, Acid, LSD, DMT:_____ *[m1drgnon_p]*

C10d. Crystal methamphetamine (crystal meth, glass, tina, crank, ice):_____ *[m1drgnon_cm]*

C10e. Powder cocaine:_____ *[m1drgnon_pc]*

C10f.. Crack cocaine:_____ *[m1drgnon_cc]*

C10g. Heroin:_____ *[m1drgnon_he]*

C10h. Alcohol:_____ *[m1drgnon_alc]*

C10i. Alcohol to intoxication:_____ *[m1drgnon_alix]*

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C10j. Other:_____ *[m1drgnon_oth_age]*

C10k: Other drug mentioned:_____ *[m1drgnon_oth_drg]*

C11. Have you snorted, smoked, swallowed, or used any of the following drugs without a prescription or not as doctor directed in the past 7 days or past 3 days? Please note that we will ask about other drugs and injection drug use separately. *(Read out list and time increments) [daydrgnon]*

		Past 7 days (Y/N) *[d7drgnon]*	Past 3 days (Y/N) *[d3drgnon]*
C11a	Marijuana or hash oil, including edibles and synthetic marijuana		
C11b	Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine		
C11c	Psychedelics, such as Mushrooms, Acid, LSD, DMT		
C11d	Crystal methamphetamine (crystal meth, glass, tina, crank, ice)		
C11e	Powder cocaine		
C11f	Crack cocaine		
C11g	Heroin		
C11h	Alcohol		
C11i	Alcohol to intoxication		
C11j	Other:		

C12. ***If yes to number indicated for any C10a to C10j:*** **In the last month, who's usually around when you're using these drugs?** *(Read out list; check all that apply). [pepdrg]*

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I use alone *[1]*
A close friend *[2]*
A casual friend or acquaintance *[3]*
A sex partner *[4]*
An immediate family or household member *[5]*
An extended family member *[6]*
A Dealer *[7]*
Strangers/people I don't know *[8]*
DK/R *[99]*

C12a. Of all the drugs that you have snorted, smoked, swallowed or used in the last month, which do you use most often? *[mostnoninj]:*_____

C13. Of all the drugs that you have snorted, smoked, swallowed, or used in the last month, which is the one you prefer to use most? *[prefnoninj]:*_____

Interviewer prompt: Now we would like to ask you some questions about injecting drugs. Your responses will be kept completely confidential and will never be shared with anyone outside of the study team.

C14. Have you <u>ever</u> seen anyone inject drugs? *[ijsee]*
Yes
No → skip to C15
DK/R → skip to C15

C14. *If ijsee= "yes":* **Who have you seen inject drugs?** *(Read out list; check all that apply) [ijw]*
A close friend *[1]*
A casual friend or acquaintance *[2]*
A sex partner *[3]*
An immediate family or household member *[4]*
An extended family member *[5]*
Dealer *[6]*
Strangers (like people on the street) *[7]*
DK/R *[99]*

C15. Do you have a sex partner who currently injects drugs? *[ijsexp]*
Yes
No
DK/R

C16. Do you have close friends who currently inject drugs? *[ijfriend]*
Yes

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No
DK/R

C17. Have you <u>ever</u> used a needle to chip, fix, muscle, or inject drugs even once? *[ijevr]*
Yes
No
DK/R

C18. *If ijevr= "yes":* **The <u>first</u> time you injected any drug, how old were you?** *[ijage]*
_____ years old [max = age reported as in A1]

C19. *If ijevr= "yes":* **Have you ever injected any of the following prescription drugs?***(Read out list and time increments) [evpilij]*

		Ever (Y/N) *[All NO]* → skip to C5
C19a	Prescription opioids such as Percocet, OxyContin, Dillaudid, Vicodin	
C19b	Medications used for opioid use disorder such as Methadone, buprenorphine/Suboxone	
C19c	Benzodiazepines/Benzos such as Xanax, Ativan, Valium, Klonapin	
C19d	Prescription stimulants such as Adderall, Ritalin, Focalin, Concerta, Dexedrine	

C20. How old were you when you first injected the following prescription drugs *(Read out list and time increments) [yrpilij]*

C20a. Prescription opioids, such as Percocet, OxyContin, Dillaudid, Vicodin? _____ *[yrpilij_po]*

C20b. Medications used for opioid use disorder such as Methadone, buprenorphine/suboxone? _____ *[yrpilij_moud]*

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C20c. Benzodiazepines/Benzos such as Xanax, Ativan, Valium, Klonapin? _____ *[yrpilij_bz]*

C20d. Prescription stimulants such as Adderall, Ritalin, Focalin, Concerta, Dexedrine? _____ *[yrpilij_ps]*

C21. How many times in the past 30 days have you injected any of the following prescription drugs. *(Read out list and time increments) [m1pilij]*

C21a. Prescription opioids, such as Percocet, OxyContin, Dillaudid, Vicodin? _____ *[m1pilnij_po]*

C21b. Medications used for opioid use disorder such as Methadone, buprenorphine/suboxone? _____ *[m1pilij_moud]*

C21c. Benzodiazepines/Benzos such as Xanax, Ativan, Valium, Klonapin? _____ *[m1pilij_bz]*

C21d. Prescription stimulants such as Adderall, Ritalin, Focalin, Concerta, Dexedrine? _____ *[m1pilij_ps]*

C22. Have you injected any of the following prescription drugs in the past 7 days or past 3 days? *(Read out list and time increments) [daypilij]*

		Past 7 days (Y/N) *[d7pilij]*	Past 3 days (Y/N) *[d3pilij]*
C22a	Prescription opioids such as Percocet, OxyContin, Dillaudid, Vicodin		
C22b	Medications used for opioid use disorder such as Methadone, buprenorphine/Suboxone		
C22c	Benzodiazepines/Benzos such as Xanax, Ativan, Valium, Klonapin		
C22d	Prescription stimulants such as Adderall, Ritalin, Focalin, Concerta, Dexedrine		

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C23. Have you ever injected any of the following drugs? We will not be asking about fentanyl use right now. We will be asking about that separately later on. *(Read out list and time increments) [EVDRGIJ]*

		Ever (Y/N) *[All NO]* → skip to C5
C23a	Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine	[EvCD]
C23b	Psychedelics, such as Mushrooms, Acid, LSD, DMT	[EvP]
C23c	Crystal methamphetamine (crystal meth, glass, tina, crank, ice)	[EvCM]
C23d	Powder cocaine	[EvPC]
C23e	Crack cocaine	[EvCC]
C23f	Heroin	[EvHE]
C23g	Alcohol	[EvALC]
C23h	Other:	[EvOT]

C24. How old were you when you injected any of the following drugs? We will not be asking about fentanyl use right now. We will be asking about that separately later on. *(Read out list and time increments) [YRDRGIJ]*

C24a. Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine:_____ *[yrdrgij_cd]*

C24b. Psychedleics, such as Mushrooms, Acid, LSD, DMT:_____ *[yrdrgij_p]*

C24c. Crystal methamphetamine (crystal meth, glass, tina, crank, ice):_____ *[yrdrgij_cm]*

C24d. Powder cocaine:_____ *[yrdrgij_pc]*

C24e. Crack cocaine:_____ *[yrdrgij_cc]*

C24f. Heroin:_____ *[yrdrgij_he]*

C24g. Alcohol:_____ *[yrdrgij_alc]*

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C24h. Other:_____ *[yrdrgij_oth_age]*

C9i: Other drug mentioned:_____ *[yrdrgij_oth_drg]*

C25. How many times in the past 30 days have you injected any of the following drugs? We will not be asking about fentanyl use right now. We will be asking about that separately later on. *(Read out list and time increments) [M1DRGIJ]*

C25a. Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine:_____ *[m1drgij_cd]*

C25b. Psychedelics, such as Mushrooms, Acid, LSD, DMT:_____ *[m1drgij_p]*

C25c. Crystal methamphetamine (crystal meth, glass, tina, crank, ice):_____ *[m1drgij_cm]*

C25d. Powder cocaine:_____ *[m1drgij_pc]*

C25e. Crack cocaine:_____ *[m1drgij_cc]*

C25f. Heroin:_____ *[m1drgij_he]*

C25g. Alcohol:_____ *[m1drgij_alc]*

C25h. Other:_____ *[m1drgij_oth_age]*

C25i: Other drug mentioned:_____ *[m1drgij_oth_drg]*

C26. Have you injected any of the following drugs in the <u>past 7 days</u> or <u>past 3 days</u>? We will not be asking about fentanyl use right now. We will be asking about that separately later on. *(Read out list and time increments)*

		Past 7 days (Y/N) *[d7drgij]*	Past 3 days (Y/N) *[d3drgij]*
C26a	Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine		
C26b	Psychedelics, such as Mushrooms, Acid, LSD, DMT		
C26c	Crystal methamphetamine (crystal meth, glass, tina, crank, ice)		

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C26d	Powder cocaine		
C26e	Crack cocaine		
C26f	Heroin		
C26g	Alcohol		
C26h	Other:		

C27a. Of all the drugs you have injected in the last month, which is the one that you use the most? (*Read out list; check only one*) *[ijmost]:*_____

C27b. Of all the drugs you have injected in the last month, which is the one you prefer to use the most? (*Read out list; check only one*) *[ijpref]:*_____

C27c. Have you <u>ever</u> shared a syringe, or drug using supplies like cookers water and cottons, with someone else? *[syrshare]*

Yes
No
DK/R

C28. *If syrshare= "yes":* **In the <u>last month</u>, how often have you shared syringes or those supplies with someone?** *[syrsharem1]*

Never
Once or a couple times
At least every week
Every day
Multiple times per day
DK/R

C29. *If syrsharem1= "yes":* **<u>In the last month,</u> who have you shared syringes or supplies with?** *(Read out list; check all that apply) [syrsharewho]*

A close friend *[1]*
A casual friend or acquaintance *[2]*
A sex partner *[3]*
An immediate family or household member *[PAR]*
An extended family member *[4]*

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Dealer *[5]*
Strangers (people I don't know) *[6]*
DK/R *[99]*

C33. Have you ever needed someone to help you inject? *[helpijevr]*
Yes
No
DK/R

C34. *If helpijevr= "yes":* **<u>In the last month</u>, how often did you need someone to help you inject** *[helpijm1]*
Never
Once or a couple times
At least every week
Every day
Multiple times per day
DK/R

C35. *If helpijm1= "yes":* **<u>In the last month</u>, who helped you inject?** *(Read out list; check all that apply) [helpijm1_who]*
A close friend *[1]*
A casual friend or acquaintance *[2]*
A sex partner *[3]*
An immediate family or household member *[4]*
An extended family member *[5]*
Dealer *[6]*
Strangers (people I don't know) *[7]*
DK/R *[99]*

C35a. Have you ever gone on a run or a binge, as in used a larger amount of drugs as usual over a short amount of time? *[drgbngevr]*
Yes
No
DK/R

C35b. *If drgbngevr= "yes":* **In the last month, did you go on a run or a binge?** *[bngm1]*
Yes
No
DK/R

Interviewer prompt: Some other countries have Supervised Consumption Rooms, which are places where people can legally bring their own drugs, get supplies like clean needles, and use their drugs in

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front of staff in case they overdose. There are no places like this in the US. If there was a <u>legal</u> service you could go to <u>for free</u> to use drugs safely indoors…

C36. **Would you use this service?** *[sifuse]*
Yes
No
DK/ R

C37. *If sifuse= "yes":* **<u>How often</u> do you think you would use this service?** *[siftimes]*
Once or a couple of times
About once a month
At least every week
Every day
DK/ R

C38. *If sifuse= "yes":* **What is the <u>longest time</u> you would be willing to travel to use this service?** *[siftra]*
1-5 minutes
6-10 minutes
11-20 minutes
21-30 minutes
More than 30 minutes
DK/R *[DK]*

C39. *If sifuse= "yes":* **When would you be <u>most likely</u> to use this service?** *(Read out list; check all that apply) [sifpref]*
Mornings, like 8am-12pm *[1]*
Afternoons, like 12pm-4pm *[2]*
Evening, like 4pm-8pm *[3]*
Late evenings, like 8pm-12midnight *[4]*
Other *[77]*
DK/R *[99]*

C39a. *If sifpref= "other":* **When would you be <u>most likely</u> to use this service: _____** *[sifpref_oth]*

C40. Do you think that your friends (or other people you know) would use this service? *[sifptp]*
Yes
No
DK/ R

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Interviewer prompt: We are now going to ask about drug dealing. By dealing, we mean giving drugs to someone in exchange for money, food, shelter, or other goods. Please remember that all responses are strictly confidential and will not be shared with anyone outside of the study team.

C41. Have you <u>ever</u> dealt drugs? *[dealt]*

Yes
No
DK/R

C42. *If dealt= "yes":* **What is the main reason you've dealt drugs?***(Read out list; check only one) [dealw]*

Income for drugs
Income for other purposes
To clear debts
For food or shelter
Another reason
DK/R

C42a. *If dealw="another reason":* **What is the main reason you've dealt drugs:_____** *[dealw_oth]*

C43. *If dealt= "yes":* **<u>In the last month</u>, have you dealt drugs?** [*dealtm1*]

Yes
No
DK/R

C44. *If dealtm1= "yes":* **<u>In the last month</u>, have you dealt drugs that you suspected or knew had fentanyl in them?** *[fentdeal]*

Yes
No
DK/R

C45. *If dealt= "yes":* **Are you concerned about fentanyl contaminating your supply?** [*fentdeal_concern*]

Very concerned
A little concerned
Neutral
Not concerned
DK/R

C46. *If dealt= "yes":* **If given the choice, would you prefer not to deal drugs that had fentanyl in them?** *[fentindrg]*

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Very concerned
A little concerned
Neutral
Not concerned
DK/R

C47. Has your drug use changed in any of the following ways because COVID-19? (*Read out list; check all that apply)* [*cov_use*]

I use more (frequency or amount) than I did before [1]
I use less (frequency or amount) than I did before [2]
I use alone more often [3]
I use alone less often [4]
I use when naloxone is available more often [4]
I use when naloxone is available less often [5]
I taste or check drugs first more often [6]
I taste or check drugs first less often [7]
I have used different drugs because my normal supply has changed or dried up [8]
I have started methadone, buprenorphine or some other form of treatment [9]
I have stopped methadone, buprenorphine or some other form of treatment [10]
I have changed how I have used drugs (for example you have switched from inhalation to injection) [11]
No difference [12]
Something else [77]
DK/R [99]

C47a. *If covid_use*="77"*;* **Is there something else that has changed about how you use drugs because of COVID-19?_____** [*cov_use_oth]*

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SECTION D: FENTANYL

Interviewer prompt: Now we are going to ask you questions about fentanyl. Please answer True, False, or Don't know/Refuse for the next 6 questions.

D1. Fentanyl is an opioid *[info1]*
True
False
DK/R

D2. Fentanyl is not as strong as heroin *[info2]*
True
False
DK/R

D3. Fentanyl acts more quickly than heroin *[info3]*
True
False
DK/R

D4. Drugs that are mixed with fentanyl look different than drugs that are not mixed with fentanyl *[info4]*
True
False
DK/R

D5. Someone is more likely to overdose when using drugs that contain fentanyl than when using drugs that do not contain with fentanyl *[info5]*
True
False
DK/R

D6. In Rhode Island, fentanyl now causes more overdoses than heroin *[info6]*
True
False
DK/R

D7. Have you <u>ever</u> been <u>prescribed</u> fentanyl by a doctor? *[fentrx]*
Yes
No
DK/R

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D8. *If fentrx= "yes":* **In what forms have you been prescribed fentanyl?** *(Read out list; check all that apply) [fentform]*

Skin patch *[1]*
Pills *[2]*
Nasal spray *[3]*
Lozenge/lollipop *[4]*
A film that dissolves under your tongue *[5]*
A spray that goes under your tongue *[6]*
Other: *[7]*
DK/R *[99]*

D8a. *If fentform= "other":* **In what forms have you been prescribed fentanyl: _____** *[fentform_oth]*

D9. Have you <u>ever</u> used <u>prescription fentanyl</u> in a way that was not prescribed by a doctor (without a prescription, or different route or different dose than as prescribed by a doctor)? *[fentnorx]*

Yes
No
DK/R

D10. *If fentnorx= "yes":* **<u>In the last month</u>, how often have you used <u>prescription fentanyl</u> in a way that was not prescribed by a doctor?** *[fentdiv6]*

Never
Once or a couple times
At least every week
Every day
Multiple times per day
DK/R

D11. *If fentnorx= "yes":* **<u>In the last month</u>, what forms of <u>prescription fentanyl</u> have you used in a way that was not prescribed by a doctor?** *(Read out list; check all that apply) [fentdivform]*

Skin patch *[1]*
Pills (orally) *[2]*
Nasal spray *[3]*
Injecting *[4]*
Snorting *[5]*
Smoking *[6]*
Lozenge/lollipop *[7]*
A film that dissolves under your tongue *[8]*
Other: *[77]*

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DK/R *[99]*

D11a. *If fentdivform= "other":* **In the last month, what forms of prescription fentanyl have you used in a way that was not prescribed by a doctor: _____** *[fentdivform_oth]*

D12. *If fentnorx= "yes":* **In the last month, how did you get fentanyl without a prescription?** *(Read out list; check all that apply) [fentbuy]*

Purchased from a dealer or on the street *[1]*
A close friend *[2]*
A casual friend of acquaintance *[3]*
A sex partner *[4]*
An immediate family or household member *[5]*
An extended family member *[6]*
Purchased from the internet or "dark web" *[7]*
Other: *[77]*
DK/R *[99]*

D12a. *If fentbuy= "other":* **In the last month, who did you get fentanyl without a prescription:_____** *[fentbuy_oth]*

Interviewer prompt: Now we are going to be talking about drugs that contained fentanyl. For example, you thought you were buying heroin, but it was contained fentanyl.

D13. I am confident that I have used a drug that contained fentanyl that was not sold as fentanyl. *[fentconfevr]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

For responses *Strongly Disagree, Disagree, Neutral, DK/R* → skip to D19

D14. In the last month, how often have you used fentanyl or drugs you were confident contained fentanyl? *[fentfreq]*

Never
Once or a couple of times
About once a month
At least every week
Every day
DK/R

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D15. *If fentfreq = "Once or a couple of times" or "About once a month" or "At least every week" or "Every day":* **What drugs have you used that you were confident contained fentanyl in the past...** *(Read out list; check all that apply) [fentconfevr]*

		Past month (Y/N)	Past 7 days (Y/N)	Past 3 days (Y/N)
D15a	Marijuana or hash oil, including edibles and synthetic marijuana			
D15b	Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine OR Molly/MDMA/Ecstasy *[MO]*			
D15c	Psychedelics, such as Mushrooms, Acid, LSD, DMT OR Mushrooms *[MU]*			
D15d	Crystal methamphetamine (crystal meth, tina, crank, ice)			
D15e	Powder cocaine			
D15f	Crack cocaine			
D15h	Heroin			
D15j	Prescription Opioid Pills (Vicodin, Percocet, etc.)			
D15k	Prescription Benzodiazepines (Xanax, Klonopin, etc.)			
D15l	Prescription Stimulants (Adderall, Ritalin, etc.)			
D15 m	Other:			

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D15n	DK/R			

D16. *If fentfreq = "Once or a couple of times" or "About once a month" or "At least every week" or "Every day":* **The last time you used a drug you were confident contained fentanyl, did you know that the drug that contained fentanyl before you used it?** *[fentconf]*

Yes
No
DK/R

D17. *If fentfreq = "Once or a couple of times" or "About once a month" or "At least every week" or "Every day":* **The last time you used a drug you were confident contained fentanyl, why were you confident that it contained fentanyl?** *(Read out list, check all that apply) [fentwhy]*

A dealer told me *[1]*
A sex partner told me *[2]*
A friend told me *[3]*
I overdosed *[4]*
A sex partner overdosed *[5]*
A friend overdosed *[6]*
I had a bad reaction *[7]*
Quicker onset of high *[8]*
Different high *[9]*
Differences in appearance, smell or taste *[10]*
Other: *[77]*
DK/R *[99]*

D17a. *If fentwhy= "Other":* **The last time you used a drug you were confident contained fentanyl, why were you confident that it contained fentanyl:_____** *[fentwhy_oth]*

D17a. *If fentfreq = "Once or a couple of times" or "About once a month" or "At least every week" or "Every day":* **The last time you used a drug that you were confident contained fentanyl, how did you get it?** *[fentobt]*

Purchased from a dealer or on the street
A close friend
A casual friend of acquaintance
A sex partner
An immediate family or household member
An extended family member
Purchased from the internet or "dark web"
Other
DK/R

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D17b. *If fentobt = "other":* **The <u>last time</u> you used a drug that you were confident contained fentanyl, how did you get it:_____** *[fentobt_why]*

D18. *If fentfreq = "Once or a couple of times" or "About once a month" or "At least every week" or "Every day":* **The <u>last time</u> you used a drug you were confident contained fentanyl, what did you do when you found out you?** *(Read list out loud; check all that apply) [skill1]*

Took them as I usually would *[1]*
Threw them out *[2]*
Gave them away *[3]*
Sold them *[4]*
Went slower *[5]*
Used less *[6]*
Did a tester *[7]*
Used with someone else around *[8]*
Other: *[77]*
DK/R *[99]*

D18a. *If skill1= "other":* **The <u>last time</u> you used a drug you were confident contained fentanyl, what did you do when you found out:_____** *[skill1_oth]*

Interviewer prompt: Now that we have asked you what you've done in the past when you had drugs that contained fentanyl, we would like to know more about what you do in the future.

D19. What would you do if you found out your drugs had fentanyl in them? *(Read list out loud; check all that apply) [motiv1]*

Take them as I usually would *[1]*
Throw them out *[2]*
Give them away *[3]*
Sell them *[4]*
Go slower *[5]*
Use less *[6]*
Do a tester *[7]*
Use with someone else around *[8]*
Talk with the supplier or dealer *[8]*
Other *[77]*
DK/R *[99]*

D19a. *If motiv1 = "Other":* **What would you do if you found out your drugs had fentanyl in them:_____** *[motiv1_oth]*

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Interviewer prompt: We would like to know your thoughts about the effects of fentanyl or drugs that have fentanyl in them. Please indicate how much you agree or disagree with the following statements:

D23. Fentanyl or drugs that have fentanyl in them are a <u>better high</u> than drugs that do not have fentanyl in them *[percep1]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

D24. I am <u>concerned</u> about my friends using drugs that contain fentanyl *[motiv2]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

D25. I am <u>concerned</u> about my drugs having fentanyl in them *[motiv3]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

D26. I prefer using fentanyl or drugs that have fentanyl in them *[fentpref]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

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D26a. ***If "Agree" or "Strongly agree" to any of D26:*** **Why do you prefer to use drugs with fentanyl in them?** *(Read out list; check all that apply) [whyfentpref]*

Stronger or better high *[1]*
Faster onset of high *[2]*
Easier to prepare than other drugs *[3]*
Cheaper than other opioids (including heroin and prescription pills) *[4]*
Dope sick or experiencing withdrawal symptoms *[5]*
That's all my dealer was selling *[6]*
Curious about the effect of fentanyl *[7]*
It is what I am used to using *[8]*
Other: *[77]*
DK/R *[99]*

D26b. *If whyfentpref= "other":* **Why do you prefer to use drugs with fentanyl in them:_____** *[whyfentpref_oth]*

D27. I would like to be able to know if I recently took drugs with fentanyl in them *[motiv4]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

D28. I would like to be able to know if there is fentanyl in my drugs <u>before</u> I take them *[motiv5]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

D29. Have you heard of fentanyl test strips? *[testknow]*

Yes
No
DK/R

D30. Have you <u>ever</u> used a fentanyl test strip, either on your own or with people you use drugs with? *[testuseevr]*

Yes
No
DK/R

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D40. *If testuseevr= "yes":* **Have you used a fentanyl test strip <u>in the last month</u>, either on your own or with people you use drugs with?** *[testusem1]*

Yes
No
DK/R

D41. *If testusem1= "yes":* **Who performed the test?** *[testusewho]*

I did it myself
A close friend
A casual friend or acquaintance
An immediate family or household member
An extended family member
Dealer
Strangers
DK/R

D42. I*f testusem1= "yes":* **Where did the fentanyl test strips come from?** *(Read out list; check all that apply) [testgetwho]*

RAPIDS clinical trial *[1]*
Other research study *[2]*
AIDS Care Ocean State (ACOS) *[3]*
Project Weber/RENEW *[4]*
Another harm reduction organization *[5]*
Uncertain *[6]*
Other: *[77]*
DK/R *[99]*

D42a. *If testgetwho= "other":* **Where did the fentanyl test strips come from:_____** *[testgetwho_oth]*

<u>D43.</u> *If testusem1= "yes":* **<u>In the last month</u>, how many times have you tested your drugs for fentanyl?** *[testnumm1]*

_____
DK/R *[DK]*

D44. *If testnumm1>0:* **Did any of the tests come back positive? Meaning you only saw one line on the test strip?** *[testpos]*

Yes
No
DK/R

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D45. *If testpos= "Yes":* **How many tests were positive for fentanyl, meaning you only saw one line?** *[fentposno]*

_____
DK/R

D46. *If testpos= "Yes":* **Which drugs that you tested came back positive for fentanyl?** *(Read out list; check all that apply) [fentposdrg]*

Prescription opioids such as Percocet, OxyContin, Dillaudid, Vicodin *[1]*
Medications used for opioid use disorder such as Methadone, buprenorphine/Suboxone *[2]*
Benzodiazepines/Benzos such as Xanax, Ativan, Valium, Klonapin *[3]*
Prescription stimulants such as Adderall, Ritalin, Focalin, Concerta, Dexedrine *[4]*
Marijuana or hash oil, including edibles and synthetic marijuana [*5]*
Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine *[6]*
Psychedelics, such as Mushrooms, Acid, LSD, DMT *[7]*
Crystal methamphetamine (crystal meth, glass, ice, tina) *[8]*
Powder cocaine *[9]*
Crack cocaine *[10]*
Heroin *[11]*
Other *[77]*
DK/R *[99]*

D46a. *If fentposdrg = "Other":* **Which drugs that you tested came back positive for fentanyl:_____** *[fentposdrg_oth]*

D47. *If testpos= "Yes":* **What did you do when you found out you had drugs containing fentanyl?** *(Read out list; check all that apply). [skill1testpos]*

Took them as I usually would *[1]*
Threw them out *[2]*
Gave them away *[3]*
Sold them *[4]*
Went slower *[5]*
Went faster *[6]*
Used less *[7]*
Used more *[8]*
Did a tester *[9]*
Used with someone else around *[10]*
Got naloxone *[11]*
Other *[77]*
DK/R *[99]*

D47a. *If skill1testpos= "Other":* **What did you do when you found out you had drugs containing fentanyl:_____** *[skill1testpos_oth]*

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D47b. *If testpos= "Yes":* **Did you experience any of the following unwanted negative reactions from using the drug that tested positive for fentanyl?** *(Read out list; check all that apply) [fentreact]*

Lost consciousness/blacked out *[1]*
Blue or gray lips or skin *[2]*
Seizure *[3]*
Had a hard time breathing *[4]*
Elevated breathing *[5]*
Stopped breathing *[6]*
Inability to talk *[7]*
Not responsive to stimulus (like having your name called or physical contact) *[8]*
Overheating *[9]*
Irregular heart beat (fast, slow, irregular or palpitations) *[10]*
Paranoia *[11]*
Can't remember getting high *[12]*
None *[13]*
Other *[77]*
DK/R *[99]*

D47c. *If fentreact= "Other":* **Did you experience any of the following unwanted negative reactions from using the drug that tested positive for fentanyl:_____** *[fentreact_oth]*

D48. *If testusem1= "Yes":* **Did any of the tests come back negative for fentanyl, meaning you saw two lines?** *[testneg]*

Yes
No
DK/R

D49. *If testneg= "Yes":* **How many of the tests came back negative for fentanyl, meaning you saw two lines?** *[fentnegno]*

_____
DK/R

D50. *If testneg= "Yes":* **Which drugs that you tested came back negative for fentanyl?** *(Read out list; check all that apply) [fentnegdrg]*

Prescription opioids such as Percocet, OxyContin, Dillaudid, Vicodin *[1]*
Medications used for opioid use disorder such as Methadone, buprenorphine/Suboxone *[2]*
Benzodiazepines/Benzos such as Xanax, Ativan, Valium, Klonapin *[3]*
Prescription stimulants such as Adderall, Ritalin, Focalin, Concerta, Dexedrine *[4]*
Marijuana or hash oil, including edibles and synthetic marijuana *[5]*
Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine *[6]*
Psychedelics, such as Mushrooms, Acid, LSD, DMT *[7]*

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Crystal methamphetamine (crystal meth) *[8]*
Powder cocaine *[9]*
Crack cocaine *[10]*
Heroin *[11]*
Alcohol *[12]*
Other *[77]*
DK/R *[99]*

D50a. *If fentnegdrg= "Other":* **Which drugs that you tested came back negative for fentanyl:_____** *[fentnetdrg_oth]*

D51. *If testneg= "Yes":* **What did you do when you found out you had drugs that did not contain fentanyl?** *(Read out list; check all that apply). [skill1fentneg]*

Took them as I usually would *[1]*
Threw them out *[2]*
Gave them away *[3]*
Sold them *[4]*
Went slower *[5]*
Went faster *[6]*
Used less *[7]*
Used more *[8]*
Did a tester *[9]*
Used with someone else around *[10]*
Got naloxone *[11]*
Other *[77]*
DK/R *[99]*

D51a. *If skill1fentneg= "Other":* **What did you do when you found out you had drugs that did not contain fentanyl:_____** *[skill1fentneg]*

D52. *If testneg= "Yes":* **Did you have any of the following unwanted negative reactions from using the drug that tested negative for fentanyl?** (Read out list; check all that apply) *[fentreactneg]*

Lost consciousness/blacked out *[1]*
Blue or gray lips or skin *[2]*
Seizure *[3]*
Had a hard time breathing *[4]*
Elevated breathing *[5]*
Stopped breathing *[6]*
Inability to talk *[7]*
Not responsive to stimulus (like having your name called or physical contact) *[8]*
Overheating *[9]*
Irregular heart beat (fast, slow, irregular or palpitations) *[10]*

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Paranoia *[11]*
Can't remember getting high *[12]*
None *[13]*
Other *[77]*
DK/R *[99]*

D52a. *If fentreactneg= "Other":* **Did you have any of the following unwanted negative reactions from using the drug that tested negative for fentanyl:_____** *[fentreactneg_oth]*

D53. /Has fentanyl changed how you think about starting methadone or buprenorphine (Suboxone), or starting other forms of addiction treatment? *[fenttotrt]*

Yes, I accessed addiction treatment because of concerns about fentanyl
Yes, I am thinking about accessing treatment because of concerns about fentanyl (but haven't done so yet)
No
Already in some kind of addiction treatment
DK/R

D54. Has fentanyl changed how you use drugs in any of the following ways? *(Read out list; check all that apply) [fentchange]*

More likely to use with others *[1]*
More likely to inject slowly and/or taste drugs first *[2]*
More likely to use in public (e.g., outside) *[3]*
More likely to use in places where other people are around *[4]*
Less likely to use alone *[5]*
More likely to use where naloxone is available *[6]*
More likely to carry take-home naloxone *[7]*
Using less often and/or using smaller amount of drugs each time *[8]*
More likely to use drugs containing fentanyl *[9]*
More likely to use drugs unlikely to contain fentanyl (rather than drugs that may contain fentanyl) *[10]*
Other: *[77]*
Use hasn't changed *[11]*
DK/R *[99]*

D54a. *If fentchange= "More likely to use drugs unlikely to contain fentanyl:* **Specify drugs less likely to contain fentanyl:_____** *[fentchange_drg]*

D54b. *If fentchange= "Other":* **Has fentanyl changed how you use drugs in any of the following ways:_____** *[fentchange_oth]*

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SECTION X - MENTAL HEALTH

Interviewer prompt: Now we will talk about how you are feeling right now. Rate each of the following statements between 0 and 4. 0 = not at all; 1 = a little; 2 = moderately ; 3 = quite a bit; 4 = extremely. In each case, you can respond that you don't know or prefer not to answer.

	Not at all *[0]*	A little *[1]*	Moderately *[2]*	Quite a bit *[3]*	Extremely *[4]*
X1a. I feel anxious. *[sows1]*	[0]	[1]	[2]	[3]	[4]
X1b. I feel like yawning. *[sows2]*	[0]	[1]	[2]	[3]	[4]
X1c. I am perspiring. *[sows3]*	[0]	[1]	[2]	[3]	[4]
X1d. My eyes are tearing. *[sows4]*	[0]	[1]	[2]	[3]	[4]
X1e. My nose is running. *[sows5]*	[0]	[1]	[2]	[3]	[4]
X1f. I have goosebumps. *[sows6]*	[0]	[1]	[2]	[3]	[4]
X1g. I am shaking. *[sows7]*	[0]	[1]	[2]	[3]	[4]
X1h. I have hot flashes. *[sows8]*	[0]	[1]	[2]	[3]	[4]
X1j. I have cold flashes. *[sows9]*	[0]	[1]	[2]	[3]	[4]
X1k. My bones and muscles ache. *[sows10]*	[0]	[1]	[2]	[3]	[4]
X1l. I feel restless. *[sows11]*	[0]	[1]	[2]	[3]	[4]
X1m. I feel nauseous. *[sows12]*	[0]	[1]	[2]	[3]	[4]

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X1n. I feel like vomiting. *[sows13]*	[0]	[1]	[2]	[3]	[4]
X1o. My muscles twitch. *[sows14]*	[0]	[1]	[2]	[3]	[4]
X1p. I have stomach cramps. *[sows15]*	[0]	[1]	[2]	[3]	[4]
X1q. I feel like using now. *[sows16]*	[0]	[1]	[2]	[3]	[4]

Interviewer Prompt: Now I am going to ask you 7 questions about stress and anxiety. You can respond with how often you have experienced these feelings in the past 2 weeks: "not sure at all," "several days," "over half the days," or "nearly every day."

	Not sure at all *[0]*	Several days *[1]*	Over half the days *[2]*	Nearly every day *[3]*
X2a. Feeling nervous, anxious, or on edge *[gad1]*	[0]	[1]	[2]	[3]
X2b. Not being able to stop or control worrying *[gad2]*	[0]	[1]	[2]	[3]
X2c. Worrying too much about different things *[gad3]*	[0]	[1]	[2]	[3]
X2d. Trouble relaxing *[gad4]*	[0]	[1]	[2]	[3]
X2e. Being so restless that it's hard to sit still *[gad5]*	[0]	[1]	[2]	[3]
X2f. Becoming easily annoyed or irritable *[gad6]*	[0]	[1]	[2]	[3]

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X2g. Feeling afraid as if something awful might happen *[gad7]*	[0]	[1]	[2]	[3]

X2h. If you checked off any problems, how difficult have these made it for you to do your work, take care of things at home, or get along with other people? (*Read out list; check only one). [gad8]*

Not difficult at all
Somewhat difficult
Very difficult
Extremely difficult

Interviewer Prompt: ***Next, I will describe some feelings or behaviors you may have had in the past week, meaning the past 7 days.*** *Please tell me how often you have felt this way in the past week.*

Programmer note: Scoring for CESD be found in brackets in the table below. For these questions, rarely will be 3, occasionally will be 2, some of the time will be 2 and most of the time will be 0. A score for this can range between 0 and 60. A score of less than 16 means that symptoms do not have clinical significance.

	Rarely or none of the time (less than 1 day) *[0]*	Some or a little of the time (1-2 days) *[1]*	Occasionally or a moderate amount of time (3-4 days) *[2]*	Most or all of the time (5-7 days) *[3]*	DK/R *[DK]*
X3a. I was bothered by things that usually don't bother me. *[cesd1]*	[0]	[1]	[2]	[3]	
X3b. I did not feel like eating; my appetite was poor. *[cesd2]*	[0]	[1]	[2]	[3]	
X3c. I felt that I could not shake off the blues even with help from my family or friends. *[cesd3]*	[0]	[1]	[2]	[3]	

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X3e. I had trouble keeping my mind on what I was doing. *[cesd5]*	[0]	[1]	[2]	[3]	
X3f. I felt depressed. *[cesd6]*	[0]	[1]	[2]	[3]	
X3g. I felt that everything I did was an effort. *[cesd7]*	[0]	[1]	[2]	[3]	
X3i. I thought my life had been a failure. *[cesd9]*	[0]	[1]	[2]	[3]	
X3j. I felt fearful. *[cesd10]*	[0]	[1]	[2]	[3]	
X3k. My sleep was restless. *[cesd11]*	[0]	[1]	[2]	[3]	
X3m. I talked less than usual. *[cesd13]*	[0]	[1]	[2]	[3]	
X3n. I felt lonely. *[cesd14]*	[0]	[1]	[2]	[3]	
X3o. People were unfriendly. *[cesd15]*	[0]	[1]	[2]	[3]	
X3q. I had crying spells. *[cesd17]*	[0]	[1]	[2]	[3]	
X3r. I felt sad. *[cesd18]*	[0]	[1]	[2]	[3]	
X3s. I felt that people dislike me. *[cesd19]*	[0]	[1]	[2]	[3]	
X3t. I could not get "going." *[cesd20]*	[0]	[1]	[2]	[3]	

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	Rarely or none of the time (less than 1 day) *[3]*	Some or a little of the time (1-2 days) *[2]*	Occasionally or a moderate amount of time (3-4 days) *[1]*	Most or all of the time (5-7 days) *[0]*	DK/R *[DK]*
X3d. I felt I was just as good as other people. *[cesd4]*	[3]	[2]	[1]	[0]	
X3h. I felt hopeful about the future. *[cesd8]*	[3]	[2]	[1]	[0]	
X3l. I was happy. *[cesd12]*	[3]	[2]	[1]	[0]	
X3p. I enjoyed life. *[cesd16]*	[3]	[2]	[1]	[0]	

X4. In general, how satisfied are you with your life? *[*hrqol1*]*

Very satisfied	Satisfied	Dissatisfied	Very dissatisfied

X5. Would you say that in general your health is… *[hrqol2]*

Excellent	Very Good	Good	Fair	Poor	DK/R

X5. Now thinking about your physical health, which includes physical illness and injury, for how many days <u>during the past 30 days</u> was your physical health not good? *[hrqol3]*

_____ (integer, maximum 30)

X6. Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days <u>during the past 30 days</u> was your mental health not good? *[hrqol4]*

_____ (integer, maximum 30)

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X7. <u>During the past 30 days</u>, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation? *[hrqol5]*

_____ (integer, maximum 30)

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SECTION E: HEALTHCARE AND TREATMENT ENGAGEMENT

Interviewer prompt: We are now going to move on and talk about your experiences with drug and alcohol treatment programs.

E1a. How troubled or bothered have you been in the past 30 days by drug problems, like cravings, withdrawal symptoms, or wanting to stop and being unable to? *[drgprob]*

0 - Not at all	Slightly	Moderately	Considerably	4 - Extremely

E1b. How important to you now is treatment for these drug problems? *[probimp]*

0 - Not at all	Slightly	Moderately	Considerably	4 - Extremely

E1c. Have you <u>ever</u> tried to enroll in a substance use treatment program but were unable to? *[txacess]*

Yes
No
DK/R

E2. *If txacess= "yes":* **What kind of addiction treatment did you try to enroll in?** *(Read out list; check all that apply)* **.** *[txt]*

Detox *[1]*
Methadone *[2]*
Suboxone (buprenorphine) treatment *[3]*
Self-help group (like 12-step AA or NA programs) *[4]*
Outpatient drug or alcohol treatment program *[5]*
Day treatment program or partial hospitalization program *[6]*
Residential drug treatment program *[7]*
Another kind of treatment *[77]*
DK/R *[99]*

E2a. *If txt= "Another kind of treatment":* **What kind of addiction treatment did you try to enroll in:_____** *[txt_oth]*

E3. *If txacess= "yes":* **What were the main barriers to accessing addiction treatment?** *(Read out list: check all that apply)***.** *[txb]*

I couldn't afford it *[1]*
There was a waiting list *[2]*

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My health insurance would not allow me to attend the program *[3]*
I didn't have health insurance *[4]*
I didn't know of any programs *[5]*
The programs weren't youth-friendly *[6]*
I was turned down by a program *[7]*
There was no treatment program nearby *[8]*
There were no beds or appointments available *[9]*
Another reason *[77]*
DK/R *[99]*

E3a. *If txb= "yes":* **What were the main barriers to accessing addiction treatment:_____** *[txb_oth]*

E4. Have you <u>ever</u> been in any kind of alcohol or drug treatment program? *[txprog]*
Yes
No
DK/R

E5. *If txprog= "yes":* **Have you ever been kicked out of any drug or alcohol treatment program because of drug or alcohol use?** *[txkick]*
Yes
No
DK/R

E6. *If txkick= "yes":* **What program(s) were you kicked out of?** *(Read out list; check all that apply) [txkick_prog]*
Detox *[1]*
Methadone *[2]*
Suboxone (buprenorphine) treatment *[3]*
Self-help group (like 12-step AA or NA programs) *[4]*
Outpatient drug or alcohol treatment program *[5]*
Day treatment program or partial hospitalization program *[6]*
Residential drug treatment program *[7]*
Another kind of treatment *[77]*
DK/R *[99]*

E6a. *If txprog_kick = "other":* **What program(s) were you kicked out of:_____** *[txprog_kick_oth]*

E7. *If txkick= "yes":* **What substance did you use that caused you to be kicked out?** *(Read out list; check all that apply) [txkick_drg]*
Prescription opioids such as Percocet, OxyContin, Dillaudid, Vicodin *[1]*
Medications used for opioid use disorder such as Methadone, buprenorphine/Suboxone *[2]*
Benzodiazepines/Benzos such as Xanax, Ativan, Valium, Klonapin *[3]*

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Prescription stimulants such as Adderall, Ritalin, Focalin, Concerta, Dexedrine *[4]*
Marijuana or hash oil, including edibles and synthetic marijuana *[5]*
Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine *[6]*
Psychedelics, such as Mushrooms, Acid, LSD, DMT *[7]*
Crystal methamphetamine (crystal meth, glass, ice, tina) *[8]*
Powder cocaine *[9]*
Crack cocaine *[10]*
Heroin *[11]*
Other *[77]*
DK/R *[99]*

E7a. *If txkick_drg= "yes":* **What substance did you use that caused you to be kicked out:_____** *[txkick_drg_oth]*

E8. *If txprog= "yes"* **In the last month, have you been in any kind of alcohol or drug treatment program?** *[txprogm1]*

Yes
No
DK/R

E9. *If txprogm1= "yes":* **Are you currently in a drug or alcohol treatment program?** *[addictxt]*

Yes
No
DK/R

E10. *If addictxt= "yes":* **Overall, how satisfied are you with this treatment program?** *[addictxt_sat]*

Very unsatisfied	Unsatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied	DK/R

E11. *If addictxt= "yes":* **Why did you enter this treatment program?** *(Read out list; check all that apply) [addictxt_reason]*

Wanted to reduce my drug use or stop using entirely *[1]*
Other physical or mental health reasons *[2]*
Convinced by family, friends, a doctor, etc. *[3]*
Coerced or forced to by a doctor, the policy, courts, etc. *[4]*
Referred from a drug court *[5]*
Other *[77]*
DK/R *[99]*

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E11a. *If adicttxt_reason= "other":* **Why did you enter this treatment program:____** *[addictxt_reason_oth]*

E12. *If addictxt= "yes":* **Is this treatment program located in Rhode Island?** *[addictri]*

Yes
No
DK/R

E13. *If addictxt= "yes":* **What kind of addiction treatment are you currently in?** *(Read out list; check all that apply) [txtcur]*

Detoxification *[1]*
Methadone *[2]*
Buprenorphine/Suboxone/Subutex treatment *[3]*
Self-help group (like 12-step AA, NA) *[4]*
Outpatient drug or alcohol treatment program *[5]*
Day treatment program or partial hospitalization program *[6]*
Residential drug treatment program *[7]*
Another kind of treatment: *[77]*
DK/R *[99]*

E14. *If txtcur = "Methadone" or "Buprenorphine/Suboxone/Subutex treatment":* **How long have you been taking this medication for?** *[mattime]*

_____ years _____ months
DK/R *[DK]*

E15. *If txtcur = "Methadone" or "Buprenorphine/Suboxone/Subutex treatment":* **What is the dose of methadone or Buprenorphine/Suboxone/Subutex that you are currently receiving?** *[matdose]*

_____ mg (integer; if TXT_current = Methadone, allowable range 1 to 1000; If TXT_current = Buprenorphine, allowable range 1 to 40)
DK/R

E16. *If txtcur = "Methadone" or "Buprenorphine/Suboxone/Subutex treatment":* **Has the dose remained the same for the <u>past 7 days</u>?** *[txtcurstbl]*

Yes
No
DK/R

E16a. *If txtcurstble= "yes":* **<u>During the last 7 days</u>, how frequently have you used heroin/opioids, either illicit or non-medical?** *[odas1]*

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1 - More than twice every day	2 - Every day at least once or twice a day	3 - Four, five or six times in the last seven days	4 - One, two or three times in the last seven days	5 - None of the last seven days

If *[5]* → skip to *odas*3a

E16b. How intense was the effect you felt from the dose or doses of the heroin/opioid that you used in the last seven days on a scale of 1-5? A 1 would mean that the effect was extremely intense and a 5 would mean that it had no effect on you. *[odas2]*

1 - 'The effect was extremely intense'	2 -	3 -	4 -	5 - 'It had no effect at all on me'

E16c. During the last seven days, how frequently have you felt two or more of these objective heroin/opioid withdrawal symptoms? (such as cramps and muscular pains, feeling your hair standing on end, a runny nose, wanting to cry, yawning, stomach cramps or diarrhea, palpitations, sweating, and generally feeling bad…) *[odas3a]*

1 - More than twice every day	2 - Every day at least once or twice a day	3 - Three to six times in the last seven days	4 - One or two times in the last seven days	5 - None

If E16c = None *[5]* → skip to E16e

E16d. During the last seven days, how intense were the withdrawal symptoms you felt on a scale of 1-5? A 1 would mean extremely intense and a 5 would mean nothing at all. *[odas3b]*

1 - 'Extremely intense'	2 -	3 -	4 -	5 - 'Nothing at all'

E16e. During the last seven days, how frequently have you felt two or more of these subjective heroin/opioid withdrawal symptoms? (such as anxiety, restlessness, irritability, difficulty in sleeping, tiredness, shivering, muscular aches and lack of appetite) *[odas4a]*

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1 - More than twice every day	2 - Every day at least once or twice a day	3 - Three to six times in the last seven days	4 - One or two times in the last seven days	5 - None

If *[5]* NOT two or more symptoms → skip to E16g

E16f. During the last seven days, how intense were the withdrawal symptoms you felt on a scale of 1-5? A 1 would mean extremely intense and a 5 would mean nothing at all. *[odas4b]*

1 - 'Extremely intense'	2 -	3 -	4 -	5 - 'Nothing at all'

E16g. During the last seven days, how frequently have you felt felt an urgent need to use heroin/opioids? *[odas5a]*

1 - More than twice every day	2 - Every day at least once or twice a day	3 - Three to six times in the last seven days	4 - One or two times in the last seven days	5 - None

If *[5]* → skip to E16i

E16h. During the last seven days, how intensely did you feel the need to use heroin/opioids, on average on a scale of 1-5? A 1 would mean extremely intense and a 5 would mean nothing at all.? *[odas5b]*

1 - 'Extremely intense'	2 -	3 -	4 -	5 - 'Nothing at all'

E16i. During the last seven days, how frequently have you had any symptoms of overmedication of methadone? (such as feeling sleepy or sedated, difficulty in speaking, being unusually active or, alternatively, the sensation of "being drugged") *[odas6a]*

None… 5 points *[5]*
1-2 times… 4 points *[4]*
3-6 times… 3 points *[3]*
Every day, once or twice a day… 2 points *[2]*

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More than twice every day… 1 points *[1]*

E16j. During the last seven days, how intense were the overmedication symptoms you felt on a scale of 1-5? A 1 would mean extremely intense and a 5 would mean nothing at all. *[odas6b]*

1 - 'Extremely intense'	2 -	3 -	4 -	5 - 'Nothing at all'

E17. What is your current health insurance coverage? *[inssts]*

No insurance *[1]*
Insurance through my workplace *[2]*
Medicare/Medicaid or other governmental insurance like Neighborhood Health Plan*[3]*
Individual/family private coverage *[4]*
Other *[77]*
DK/R *[99]*

E17a. *If inssts= "other":* **What is your current health insurance coverage:_____** *[inssts_oth]*

E18. Have you ever been diagnosed with a mental health or cognitive disorder? *[mentdiagevr]*

Yes
No
DK/R

E19. *If mentdiagevr= "yes"* **What mental health disorder were you diagnosed with?** *(Read out list; check all that apply) [mentdiagname]*

Attention-Deficit/Hyperactivity Disorder (ADD/ADHD) *[1]*
Obsessive-compulsive disorder (OCD) *[2]*
Eating disorders (like anorexia or bulimia) *[3]*
Depressive disorder (like major depression) *[4]*
Bipolar disorder (like manic depressive disorder) *[5]*
Anxiety disorder (like panic attacks or phobias) *[6]*
Psychosis (like schizophrenia, brief psychotic episode, or paranoia) *[7*
Another diagnoses *[77]*
No, none of the above *[0]*
DK/R *[99]*

E19a. *If mendiagname= "Another diagnoses":* **What mental health disorder were you diagnosed with:_____** *[mentdiagname_oth]*

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E20. Have you ever been hospitalized because of this mental health disorder or injuries caused by the disorder? *[hospdis]*

Yes
No
DK/R

E21. Have you ever been prescribed opioids as a result of injury or acute pain? *[presinj]*

Yes
No
DK/R

Interviewer prompt: We are going to ask you two questions about chronic pain. When we say chronic pain, we mean pain on most days or every day.

E21a. In the past six months, how often did you have pain? *[pn6m]*

Never	Some days	Most days	Everyday	DK/R

E21b. Over the past six months, how often did pain limit your life or work activities? *[adl6m]*

Never	Some days	Most days	Everyday	DK/R

E22. Have you been prescribed opioids in the past month? *[presmnth]*

Yes
No
DK/R

E23. Have you ever been denied opioid medications for painful conditions? *[op_den]*

Yes
No
DK/R

E24. *If op_den= "yes":* **What was the reason for denial?** *(Read out list; check all that apply) [op_den_reason]*

No reason given *[1]*
Being homeless *[2]*
Not having health insurance *[3]*

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Physician denied because of diversion or substance use concerns *[4]*
Clinic does not prescribe narcotics *[5]*
Did not see my regular physician *[6]*
Physician said pain wasn't serious enough or other medications are sufficient *[7]*
Physician concerned about adverse effects *[8]*
Positive drug test *[9]*
Other *[77]*
DK/R *[99]*

E24a. *If op_den_reason= "other":* **What was the reason for denial:_____** *[op_den_reason_oth]*

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SECTION F – OVERDOSE

Interviewer prompt: Now we'd now like to ask you some questions about overdose.

F1. Have you ever seen someone overdose? *[skill2]*
Yes
No
DK/R

F1a. Have you ever performed rescue breathing on someone who you thought was overdosing? *[skill3]*
Yes
No
DK/R

F2. Have you ever heard of naloxone, a medication also known as Narcan? *[info7]*
Yes
No
DK/R

F3. *If info7= "yes":* **Do you know where you can buy or get Narcan/naloxone?** *[info8]*
Yes
No
DK/R *[DK]*

F4. *If info7= "yes":* **Have you ever given Narcan/naloxone to someone who you thought was overdosing?** *[skill4]*
Yes
No
DK/R

F5. *If skill4= "yes":* **Have you ever given Narcan/naloxone to someone who you thought was overdosing on fentanyl?** *[skill5]*
Yes
No
DK/R

F6. *If skill4= "yes":* **How many doses of Narcan/naloxone did you have to give the last time you reversed a fentanyl overdose?** *[dosenarcfent]*
1
2

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3
≥4
DK/R

Interviewer prompt: Please indicate how much you agree or disagree with the following statements:

F7. I am confident that I can recognize when someone is having an opioid overdose. *[motiv11]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

F8. I am confident that I would call 911 if a friend or family member were overdosing. *[motiv12]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

F9. I am confident that I would call 911 if a friend or family member were overdosing, even if drugs or drug paraphernalia were present at the scene. *[motiv13]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

F10. I am confident that I would call 911 if a friend or family member were overdosing, even if I was high on drugs. *[motiv14]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

F11. I am worried that other people might think that I am using drugs if they see me carrying naloxone (a medicine that can reverse an overdose). *[motiv15]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

F12. What do you do to avoid an accidental overdose? *(Read out list; check all that apply) [skill6]*

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Nothing *[1]*
Avoid mixing with alcohol *[2]*
Avoid mixing with other drugs *[3]*
Smell or taste my supply *[4]*
Using with someone else *[5]*
Take smaller amounts *[6]*
Go slow *[7]*
Take a tester *[8*
Use a fentanyl test strip *[9]*
Keep Narcan/naloxone nearby *[10]*
Change supplier or dealer *[11]*
Something else *[77]*
DK/R *[99]*

F12a. *If skill6= "other":* **What do you do to avoid an accidental overdose:_____** *[skill6_oth]*
F12b. Has COVID-19 changed any of the ways that you protect yourself from an overdose?
(*Read out list; check all that apply)* [*cov_skill6]*
COVID-19 has not changed how I protect myself from an overdose [1]
I have not been able to get naloxone [2]
I have not been able to get fentanyl test strips [3]
I have started using with different people[4]
I have had to use alone [5]
I have not been able to buy from my usual dealer [6]
Something else [77]
DK/R [99]

F12c. *If cov_skill6="Something else":* **How has COVID-19 impacted the ways that you protect yourself from an overdose?_____** [*cov_skill6_oth*]

Interviewer prompt: We'd now like to ask you about your own experience with accidental overdose. By accidental overdose we mean taking too much of a drug such that someone is no longer able to respond or breathe adequately. Other symptoms of an accidental overdose can include loss of consciousness, lips turning black or grey, gurgling noises, blacking out, or others. An overdose can occur with prescription or illicit drugs, or a combination of both.

F13. Have you <u>ever</u> overdosed by accident? *[skill7]*
Yes
No
DK/R

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Interviewer prompt: We'd like to ask you a little more about your experiences of overdosing by accident.

F14. *If skill7= "yes":* **Has anyone ever given a dose of naloxone/Narcan to you because they thought you had overdosed by accident?** *[narcevr]*

Yes
No
DK/R

F14a. *If skill7= "yes":* **Have you accidentally overdosed in the last month?** *[skill8]*

Yes
No
DK/R

F15. *If skill8= "yes":* **In the last month, have you experienced any of the following unwanted negative reactions from using too much of any of the drugs that you have used?** *(Read out list; check all that apply) [odsymptij]*

Lost consciousness/blacked out *[1]*
Blue or gray lips or skin *[2]*
Seizure *[3]*
Had a hard time breathing *[4]*
Elevated breathing *[5]*
Stopped breathing *[6]*
Inability to talk *[7]*
Not responsive to stimulus (like having your name called or physical contact) *[8]*
Overheating *[9]*
Irregular heart beat (fast, slow, irregular or palpitations) [*10]*
Paranoia *[11]*
Can't remember getting high *[12]*
None *[0]*
Other *[77]*
DK/R *[99]*

F15a. *If odsymptij= "other":* **In the last month, have you experienced any of the following unwanted negative reactions from using too much of any of the drugs that you have used:_____** *[odsymptij_oth]*

F16. *If skill8= "yes":* **How many times have you overdosed in the last month?** *[odnumb]*

_____ (integer, allowable range 1 to 30)
DK/R

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F17. *If skill8= "yes":* **Now we want to ask you about the most recent time you overdosed. Who was with you the last time you overdosed?** *(Read out list; check all that apply) [odw]*

A close friend *[1]*
A casual friend or acquaintance *[2]*
A sex partner *[3]*
An immediate family or household member *[4]*
An extended family member *[5]*
A dealer *[6]*
A stranger (like people on the street) *[7]*
I was alone *[8]*
DK/R *[99]*

F17a. *If skill8= "yes":* **The last time you overdosed, what drug(s) did you intend to take?** *(Read out list; check all that apply) [drgintend]*

Prescription opioids such as Percocet, OxyContin, Dillaudid, Vicodin *[1]*
Medications used for opioid use disorder such as Methadone, buprenorphine/Suboxone *[2]*
Benzodiazepines/Benzos such as Xanax, Ativan, Valium, Klonapin *[3]*
Prescription stimulants such as Adderall, Ritalin, Focalin, Concerta, Dexedrine *[4]*
Marijuana or hash oil, including edibles and synthetic marijuana *[5]*
Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine *[6]*
Psychedelics, such as Mushrooms, Acid, LSD, DMT *[7]*
Crystal methamphetamine (crystal meth, glass, ice, tina) *[8]*
Powder cocaine *[9]*
Crack cocaine *[10]*
Heroin *[11]*
Other *[77]*
DK/R *[99]*

F17aa. *If drgintend= "other":* **The last time you overdosed, what drug(s) did you intent to take:_____** *[drgintend_oth]*

F17b. *If skill8= "yes":* **The last time you overdosed, did you overdose on a drug that you thought might have contained fentanyl?** *[odfentsuspect]*

Yes
No
DK/R

F17c. *If odfentsuspect= "yes":* **The last time you overdosed on a drug that might have contained fentanyl, did you know it had fentanyl in it before you used it?** *[fentknwbfr]*

Yes
No

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DK/R *[DK]*

F17d. *If odfentsuspect= "yes":* **The last time you overdosed, what reaction did you have to the drug or drugs mentioned above?** *(Read out list; check all that apply) [drgrct]*

Lost consciousness/blacked out *[1]*
Blue or gray lips or skin *[2]*
Seizure *[3]*
Had a hard time breathing *[4]*
Elevated breathing *[5]*
Stopped breathing *[6]*
Inability to talk *[7]*
Not responsive to stimulus (like having your name called or physical contact) *[8]*
Overheating *[9]*
Irregular heart beat (fast, slow, irregular or palpitations) [*10]*
Paranoia *[11]*
Can't remember getting high *[12]*
None *[0]*
Other *[77]*
DK/R *[99]*

F17da. *If drgrct= "other":* **The last time you overdosed, what reaction did you have to the drug or drugs mentioned above:_____** *[drgrct_oth]*

F17e. Where were you the last time you overdosed? *[odplc*

Own place (room or apartment)
Partner's place
Friend's place
Dealer's place
Street (alley, doorway, etc.)
Bathroom (any public washroom)
Park
Youth drop-in center
Parking lot
Car
Inside club or bar
House party
School
Abandoned house or building
Jail or prison
Crack house/shooting gallery
Other:_____
DK/R

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F18. *If skill8= "yes":* **The last time you overdosed, did someone with you call 911?** *[odcall]*

Yes
No
DK/R

F19. *If skill8= "yes":* **The last time you overdosed, did someone administer naloxone/Narcan?** *[odnarc]*

Yes
No
DK/R

F20. *If odnarc= "yes":* **The last time you overdosed, who gave you naloxone/Narcan?** *(Read out list; check all that apply)***.** *[narcw]*

A police officer *[1]*
An ambulance official *[2]*
A health professional *[3]*
A friend *[4]*
A parent or relative *[5]*
Another person using drugs *[6]*
A stranger *[7]*
Someone else *[77]*
DK/R *[99]*

F20a. *If narcw= "other":* **The last time you overdosed, who gave you naloxone/Narcan:_____** *[narcw_oth]*

F21. *If skill8= "yes":* **The last time you overdosed, were you taken to the hospital?** *[odhosp]*

Yes
No
DK/R

F22. *If odhosp= "yes":* **The last time you overdosed and were taken to a hospital, were you offered referral to an addiction treatment program before discharge?** *[hoptxt]*

Yes
No
DK/R

F23. *If odhosp= "yes":* **The last time you overdosed and were taken to a hospital, were you given naloxone/Narcan at discharge?** *[hospnx]*

Yes
No
DK/R

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F24. *If odhosp= "yes":* **The <u>last time</u> you overdosed and were taken to a hospital, did you see a peer recovery specialist, also known as a peer recovery coach?** *[peernx]*

Yes
No
DK/R

F24a. *If skill8= "yes":* **In the <u>month before your last overdose</u>, were you in any of the following programs?** *(Read out list; check all that apply) [trtdurod]*

Detoxification *[1]*
Methadone *[2]*
Buprenorphine/Suboxone/Subutex treatment *[3]*
Self-help group (like 12-step AA, NA) *[4]*
Outpatient drug or alcohol treatment program *[5]*
Day treatment program or partial hospitalization program *[6]*
Residential drug treatment program *[7]*
Another kind of treatment *[8]*
Jail or prison *[8]*
None of the above *[10]*
DK/R *[99]*

F27. I am concerned about my friends overdosing *[motiv16]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

F28. I am concerned about overdosing *[motiv17]*
Programmer Note: PIPE response to free text before intervention, G0.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

F29. I get the support and resources I need from others to help me avoid an overdose. *[skill9]*
Programmer Note: PIPE response to free text before intervention, G0.

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

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F30. I am confident that I can ask someone to check on me after I use drugs, and call 911 if they think I am overdosing. *[motiv18]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

Egocentric Network Assessment Tool (ENAT)

Nomination question:
Interviewer prompt: Next, I have a few questions about people in your social network. People who are part of your social network are ***people you know.*** *This may include friends, family members, coworkers, sexual partners, or people you use drugs with.*

ENAT1. In the past 90 days, did someone you know experience an overdose? *[enat_nom]*

Yes
No → skip to Overdose Education
DK/R → skip to Overdose Education

ENAT1a. *If enat_nom="Yes";* **In the past 90 days, how many people did you know who experienced an overdose?** *[enat_num]*

_____

ENAT 2. Could you tell me the first name of any person you know who overdosed in the past 90 days?
Interviewer prompt: Anything you tell me is entirely confidential, but you are welcome to give me nicknames or initials if you would feel more comfortable.
(Interviewer: If the respondent lists more than three people, please ask them to name the three most recent). [enat_name]

_____ *[person1]*
_____ *[person2]*
_____ *[person3]*

Interviewer prompt: Next, I have a few questions about your relationship with [pipe person1].

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ENAT 3. How long have you known [pipe person1]? *[enat_durat]*

_____ years _____ months
DK/R [DK]

ENAT 4. What age is [pipe person1]? *(Respondent may provide estimate) [enat_age]*

_____

ENAT 5. What is [pipe person1]'s gender? *(Check only one) [enat_gend]*

Male *[1]*
Female *[2]*
Transgender Male/Trans Man/Female-to-male (FTM) *[3]*
Transgender Female/Trans Woman/Male-to-Female (MTF) *[4]*
Genderqueer, neither exclusively male nor female *[5]*
Something else *[77]*
DK/R *[99[*

ENAT5a. *If enat_gender="Something else":* **What is [pipe person1]'s gender?:_____** *[enat_gend_oth]*

ENAT 6. What is your relationship to [pipe person1]? *(Read out list, check all that apply): [enat_rel]*

A close friend *[1]*
A casual friend or acquaintance *[2]*
A sex partner *[3]*
An immediate family or household member *[4]*
An extended family member *[5]*
A Dealer *[6]*
Strangers/people I don't know *[7]*
DK/R *[99]*

ENAT 7. How close do you feel emotionally to [pipe person1]? (*Read out list; check only one*) *[enat_close]*

Not close at all *[1]*
Somewhat close *[2]*
Very close *[3]*
Extremely close *[4]*
DK/R *[99]*

ENAT 8. How much do you depend on [pipe person1] for things like money or a place to live or stay? (*Read out list; check only one*) *[enat_depend]*

Not dependent at all *[1]*
Somewhat dependent *[2]*

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Very dependent *[3]*
Extremely dependent *[4]*
DK/R *[99]*

ENAT 9. In the month before the overdose occurred, how often did you spend time with [pipe person1]? (*Read out list; check only one*) *[enat_time]*

Never *[0]*
Once or a couple times *[1]*
At least every week *[2]*
A couple of times per week *[3]*
Every day *[4]*
Multiple times per day *[4]*
DK/R *[99]*

ENAT 10. In the month before the overdose occurred, how often did you and [pipe person1] share drugs or use drugs from the same supplier? *[enat_share]*

Never *[0]*
Once or a couple times *[1]*
At least every week *[2]*
A couple of times per week *[3]*
Every day *[4]*
Multiple times per day *[4]*
DK/R *[99]*

ENAT 11. Did you witness the most recent overdose that [pipe person1] experienced? *[enat_witness]*

No *[0]*
Yes *[1]*
DK/R *[99]*

ENAT 12. The most recent time [pipe person1] overdosed, can you tell me whether the overdose was fatal or nonfatal? *[ENAT_fatal]*

Nonfatal *[1]*
Fatal *[2]*
DK/R *[99]*

Interviewer prompt: I am going to read a series of statements about how [pipe person1]'s overdosed might have impacted your own drug use.

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ENAT 13. Since [pipe person1]'s overdose, which of the following are true for you? *(Read out list; check all that apply) [enat_effect]*

I use more (frequency or amount) than I did before *[1]*
I use less (frequency or amount) than I did before *[2]*
I use alone more often *[3]*
I use alone less often *[4]*
I use when naloxone is available more often *[4]*
I use when naloxone is available less often *[5]*
I taste or check drugs first more often *[6]*
I taste or check drugs first less often *[7]*
I use more types of drugs *[8]*
I use fewer types of drugs *[9]*
I mix drugs more often *[10]*
I mix drugs less often *[11]*
No difference *[12]*
Something else *[77]*
DK/R *[99]*

ENAT *13a. If enat_effect= "77";* **Is there something else that I didn't ask you about?***:* **_____** *[enat_effect_oth]*

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BREAK FOR EDUCATION/INTERVENTION

Pipe in response from (ASSIGNED ARM) and answers from questions F12, F27 and F28.

If Arm = Control then skip to H1

If Arm = Intervention then proceed to G0.

PIPE
Interviewer prompt: We are now going to train you on how to use rapid drug tests and decrease your risk for drug overdose. You will be given 10 rapid fentanyl drug tests to use at home. Additional fentanyl test strips will be provided to you at each follow-up visit if requested.

G.0. Now I am going to show you two videos and have a short discussion about overdose prevention with you….(insert links)

INSERT OPEN ENDED TEXT BOX G.0.a

Interviewer Notes: Please summarize the participant's behavior change goals in the open ended text box. Please format them in the manner shown below.
Participant feels confident doing x, y, z
Participant would like to continue doing z
Participant rated themselves as X out of 10 in readiness to change
Participant chose this number on the readiness scale because of X
Participant rated themselves as X out of 10 in confidence to change
Participant said that X would make them more confident

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SECTION G: RAPIDS INTERVENTION (EXPERIMENTAL ARM ONLY)

G.0. PROMPT: **Now I'm going to show you a video about how to respond to an overdose and how to use naloxone. (https://vimeo.com/365544296/6685863a30) I'll also show you how to use naloxone and answer any questions you might have.**

Next, we are going to watch a video about fentanyl test strips. (https://vimeo.com/365544764/298315ea7e) I'll also show you how to use the test strips and let you practice using them.

Distribute Product and Product Flyer Insert for Arm 2.

G1. I feel confident in my ability to test my own drugs for fentanyl. *[motiv6_in]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

G2. I feel confident in my ability to read the results of the fentanyl test strips. *[motiv7_in]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

G2a.I know what to do once I get results from the fentanyl rapid tests *[resultsstrips_in]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

G3. It will be easy for me to use the fentanyl test strips in the next month. *[motiv8_in]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

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G4. I plan to use the testing strips. *[motiv9_in]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

G5. How many strips do you think you might use over the next month? *[fen_str_in]*

_____ *(0-10)*
DK/R *[DK]*

G6. Do you think your friends would be interested in using the fentanyl test strips? *[fen_friends_in]*

Yes
No
Not sure
DK/R *[DK]*

G8. Is there anything else you'd like to tell us today?
(Interviewer: Not required. Do not record identifying information here) [PPTNOTES]

_____

_____

_____

Interviewer prompt: Thank you for participating in our survey. Your answers will help us . If you have remaining questions or concerns please contact a member of our study team. (Interviewer: Provide contact information. Then click Next to enter your Interviewer Data.)

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SECTION H: STANDARD OEND (CONTROL ARM ONLY)

H.0. **Now I'm going to show you a video about how to respond to an overdose and how to use naloxone. (https://vimeo.com/365544296/6685863a30) I'll also show you how to use naloxone and answer any questions you might have.**

Programmer prompt: If D30=YES for a participant in the control arm, these additional questions will be asked at the end of the survey.

Interviewer prompt: We wanted to ask you a few questions about your experiences using fentanyl test stips because you told us that you used test strips earlier in the survey. For the first XX questions, please tell us how much you disagree or agree with the following statements on a scale of strongly disagree to strongly agree

H1. I feel confident in my ability to test my own drugs for fentanyl. *[motiv6_ctl]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

H2. I feel confident in my ability to read the results of the fentanyl test strips. *[motiv7_ctl]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

H2a.I know what to do once I get results from the fentanyl rapid tests *[resultsstrips_ctl]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

H3. It will be easy for me to use fentanyl test strips in the next month. *[motiv8_ctl]*

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Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

H4. I plan to use fentanyl test strips in the next month. *[motiv9_ctl]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

H6. Do you think your friends would be interested in using the fentanyl test strips? *[fenfriend_ctl]*

Yes
No
Not sure
DK/R *[DK]*

H8. Is there anything else you'd like to tell us today?
(Interviewer: Not required. Do not record identifying information here) [pptnotes_ctl]

_____

_____

_____

Interviewer prompt: Thank you for participating in our survey. Your answers will help us . If you have remaining questions or concerns please contact a member of our study team. (Interviewer: Provide contact information. Then click Next to enter your Interviewer Data.)

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SECTION I: INTERVIEWER DATA

I1. How would you rate the overall quality of the interview? *[QUALITY]*

High *[H]*
Medium *[M]*
Low *[L]*
Very low *[VL]*

I2. Interview notes: *(Not required. Do not record identifying information here.) [INTNOTES]*

_____

_____

_____

_____

_____

*Remember to click the **Submit** button!*

[END BASELINE ASSESSMENT]

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RAPIDS STUDY ASSESSMENT: FOLLOW UP VISITS

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SECTION 3a: FOLLOW UP VISIT - SURVEY BEGINS

Participant ID

_____ *(R0001-R1000)*

Interviewer ID

_____

Survey started (hidden)
(system-captured as mm/dd/yyyy hh:mm:ss AM/PM)

Survey ended (hidden)
(system-captured as mm/dd/yyyy hh:mm:ss AM/PM)

Did participant sign consent? [*CONSENT*]

- o Yes
- o No

To which did the participant consent?

- o Agreed to this Study Visit *(must be checked to continue)*

ARM ASSIGNMENT [PIPE FROM SCREENER, RA SEES ARM ASSIGNMENT]

- **ARM 1 (Control)**
- **ARM 2 (Experimental)**

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SECTION A: HOUSING, EMPLOYMENT & INCOME

A1. What type of place are you living in right now? *(Read all that apply, Check only one). [hous_fu]*

An apartment or house that you rent or own
A parent or family member's apartment or house
Someone else's apartment or house short-term (like couch-surfing)
College dorm
Recovery or residential treatment center
Transitional housing program
Corrections halfway house
Drop-in center or emergency shelter
Car, abandoned building, or some other indoor public place
On the street or in another outdoor public place (like a park)
Other: _____
DK/R

A1a. *If hous_fu= "other":* **What type of place are you living in right now:____** *[hous_oth_fu]*

A2. What town do you currently live in? *[town_fu]*

_____

A3. What is your current zip code? *[zip_fu]*

_____
No fixed address *[FA]*
DK/R *[DK]*

Interviewer prompt: We would now like to ask you about your experiences of homelessness. By homelessness, we mean not having a regular place to stay, and living in a shelter because of nowhere else to go, or living in a place not ordinarily used for sleeping, like an abandoned building, car, or park.

A4. Have you been homeless <u>in the last month</u>? *[hlm1_fu]*

Yes
No
DK/R

A5. *If hlm1_fu= "other":* **Are you currently homeless?** *[hlcr_fu]*

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Yes
No
DK/R

A6. Are you <u>currently</u> employed full-time or part-time doing legal work for pay. This includes work that is full-time, part-time and temporary work? [*employ_fu*]

Yes
No
DK/R

A7. *If employ_fu= "other":* **Which of the following is closest to your occupation** *(Read out list; check all that apply). [occu_fu]*

Manufacturer *[1]*
Retailer *[2]*
Wholesaler *[3]*
Service Provider *[4]*
Construction *[5]*
Mining *[6]*
Farming/Fishing/Forestry *[7]*
Government *[8]*
Other *[77]*
DK/R *[99]*

A7a. *If occu_fu= "other*: **Which of the following is closest to your occupation: _____**
[occu_txt_fu]

A8. *If employ_fu= "no":* **If you are not employed, are you…** *(Read out list; check all that apply) [unemploy_fu]*

On temporary layoff from a job *[1]*
Looking for work *[2]*
Retired *[3]*
Disabled *[4]*
A student *[5]*
A homemaker/caretaker *[6]*
Unable to work (primary reason?) *[7]*
Other *[77]*
DK/R *[99]*

A8a. *If unemploy_fu= "unable to work":* **Unable to work, primary reason:_____**
[unepmploy_una_fu]

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A8b. *If unemploy_fu= "other":* **If you are not employed, are you:_____** *[unemploy_ot_fu]*

A9. In the last month, have you received any of the following in exchange for sexual activities of any sort (like a hand job, blowjob, or sex)? *(Read out list; check all that apply) [sext_fu]*

Gifts or other goods *[1]*
Food *[2]*
Housing *[3]*
Clothes *[4]*
Drugs *[5]*
No, none of the above *[6]*
DK/R *[99]*

A10. In the last month, have you received money in exchange for sexual activities of any sort (like a hand job, blowjob, or sex)? *[sexmoney_fu]*

Yes
No
DK/R

A12. In the last month, have you been turned down for a job because of current or past drug use? *[nojob_fu]*

Yes
No
DK/R

A13. Are you currently receiving any disability benefits (such as workman's compensation or SSDI)? *[incomedis_fu]*

Yes
No
DK/R

A14. What is your average take home monthly income, including public assistance or family support (like from cash assistance, welfare, or TANF)? *[lincome__fu]*

$0
< $1 - $500
$501 - $1500
$1501 - $3000
> $3000
DK/R

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A15. Have you been arrested <u>in the last month</u>? *[m1arr_fu]*

Yes
No
DK/R

A16. *If m1arr_fu= "yes":* **Have you been incarcerated in an adult jail or prison <u>in the last month</u>?** *[m1inc_fu]*

Yes
No
DK/R

A17. *If m1arr_fu= "yes":* **Have you been on probation or parole in the <u>past month</u>?** *[m1prob]*

Yes
No → skip to B1
DK/R → skip to B1

A18. *If m1prob_fu= "yes":* **Are you currently on probation or parole?** *[curprob_fu]*

Yes
No
DK/R

A19. What is your current relationship status? *(Read out list; check only one). [relation_fu]*

You have a spouse/partner whom you live with
You have a regular partner whom you do not live with
You are dating or seeing someone
You are single
DK/R

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SECTION B: DRUG USE

Interviewer prompt: We are now going to move on to talk about your current and past drug use. As a reminder, your participation is voluntary and you have the right to refuse to answer a question. All responses are strictly confidential and will not be shared with anyone outside of the study team.

B1. How many times in the past 30 days have you snorted, smoked, swallowed, or used any of the following drugs without a prescription or not as doctor directed? Please note that we will ask about other drugs and injection drug use separately. *(Read out list and time increments) [m1pilnon_fu]*

B1a. Prescription opioids, such as Percocet, OxyContin, Dillaudid, Vicodin? _____ *[m1pilnon_po_fu]*

B1b. Medications used for opioid use disorder such as Methadone, buprenorphine/suboxone? _____ *[m1pilnon_moud_fu]*

B1c. Benzodiazepines/Benzos such as Xanax, Ativan, Valium, Klonapin? _____ *[m1pilnon_bz_fu]*

B1d. Prescription stimulants such as Adderall, Ritalin, Focalin, Concerta, Dexedrine? _____ *[m1pilnon_ps_fu]*

B2. Have you first snorted, smoked, swallowed, or used any of the following drugs without a prescription or not as doctor directed in the past 7 days or past 3 days? Please note that we will ask about other drugs and injection drug use separately. *(Read out list and time increments)*

		Past 7 days (Y/N) *[d7pilnon_fu]*	Past 3 days (Y/N) *[d3pilnon_fu]*
B2a	Prescription opioids such as Percocet, OxyContin, Dillaudid, Vicodin		
B2b	Medications used for opioid use disorder such as Methadone, buprenorphine/Suboxone		
B2c	Benzodiazepines/Benzos such as Xanax, Ativan, Valium, Klonapin		

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B2d	Prescription stimulants such as Adderall, Ritalin, Focalin, Concerta, Dexedrine		

B3. *If yes to any of B1a to B1d:* **<u>In the last month</u>, who's usually around when you're using these drugs without a prescription or not as a doctor directed?** (*Read out list; check all that apply). [pepil_fu]*

I use alone *[1]*
A close friend *[2]*
A casual friend or acquaintance *[3]*
A sex partner *[4]*
An immediate family or household member *[5]*
An extended family member *[6]*
A Dealer *[7]*
Strangers/people I don't know *[8]*
DK/R *[99]*

B3a. *If yes to any of B1a to B1d:* **<u>In the last month</u> have you used Suboxone/Subutex/Buprenorphine or methadone to manage opioid withdrawal without a prescription?** *[bupself_fu]*

Yes
No
DK/R

B4. *If yes to any of B1a to B1d:* **<u>In the last month</u>, how did you get Suboxone/Subutex/Buprenorphine or methadone without a prescription?** *(Read out list, check all that apply) [bupbuy_fu]*

Purchased from a dealer or on the street *[1]*
A close friend *[2]*
A casual friend of acquaintance *[3]*
A sex partner *[4]*
An immediate family or household member *[5]*
An extended family member *[6]*
Purchased from the internet or "dark web" *[7]*
Other *[77]*
DK/R *[99]*

B5a. *If bupbuy_fu= "yes":* **In last month, how did you get Suboxone/Subutex/Buprenorphine or methadone without a prescription:_____** *[bupbuy_oth_fu]*

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B5. *If bupbuy_fu= "yes":* **In the last month, how have you used Suboxone/Subutex/Buprenorphine without a prescription** *(Read out list, check all that apply) [buptyp_fu]*

A film or tablet that dissolves under your tongue *[1]*
Skin patch *[2]*
Pills (orally) *[3]*
Snorting *[4]*
Smoking *[5]*
Injecting *[6]*
Other *[77]*
DK/R *[99]*

B5a. *If buptyp_fu = "yes":* **In the last month, how have you used Suboxone/Subutex/Buprenorphine without a prescription:_____** *[buptyp_oth_fu]*

B6. How many times in the past 30 days have you snorted, smoked, swallowed, or used any of the following drugs? Please note that we will ask about other drugs and injection drug use separately. *(Read out list and time increments) [m1drgnon_fu]*

B6a. Marijuana or hash oil, including edibles and synthetic marijuana:_____ *[m1drgnon_m_fu]*

B6b. Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine:_____ *[m1drgnon_cd_fu]*

B6c. Psychedelics, such as Mushrooms, Acid, LSD, DMT:_____ *[m1drgnon_p_fu]*

B6d. Crystal methamphetamine (crystal meth, glass, tina, crank, ice):_____ *[m1drgnon_cm_fu]*

B6e. Powder cocaine:_____ *[m1drgnon_pc_fu]*

B6f. Crack cocaine:_____ *[m1drgnon_cc_fu]*

B6g. Heroin:_____ *[m1drgnon_he_fu]*

B6h. Alcohol:_____ *[m1drgnon_alc_fu]*

B6i. Alcohol to intoxication:_____ *[m1drgnon_alix_fu]*

B6j. Other:_____ *[m1drgnon_oth_age_fu]*

B6k: Other drug mentioned:_____ *[m1drgnon_oth_drg_fu]*

B7. Have you snorted, smoked, swallowed, or used any of the following drugs without a prescription or not as doctor directed in the past 7 days or past 3 days? Please note that we will ask about other drugs and injection drug use separately. *(Read out list and time increments)*

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		Past 7 days (Y/N) *[d7drgnon_fu]*	Past 3 days (Y/N) *[d3drgnon_fu]*
B7a	Marijuana or hash oil, including edibles and synthetic marijuana		
B7b	Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine		
B7c	Psychedelics, such as Mushrooms, Acid, LSD, DMT		
B7d	Crystal methamphetamine (crystal meth, glass, tina, crank, ice)		
B7e	Powder cocaine		
B7f	Crack cocaine		
B7g	Heroin		
B7h	Alcohol		
B7i	Alcohol to intoxication		
B7j	Other:		

B8. ***If yes to any of B6a to B6j:*** **<u>In the last month</u>, who's usually around when you're using these drugs?** *(Read out list; check all that apply). [pepdrg_non]*

I use alone *[1]*
A close friend *[2]*
A casual friend or acquaintance *[3]*
A sex partner *[4]*
An immediate family or household member *[5]*
An extended family member *[6]*
A Dealer *[7]*
Strangers/people I don't know *[8]*

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DK/R *[99]*

B8a. Of all the drugs that you have snorted, smoked, swallowed or used in the last month, which do you use most often? *[mostnononj_fu]:_____*

B9. Of all the drugs that you have snorted, smoked, swallowed, or used in the last month, which is the one you prefer to use most? *[prefnoninj_fu]:_____*

Interviewer prompt: Now we would like to ask you some questions about injecting drugs. Your responses will be kept completely confidential and will never be shared with anyone outside of the study team.

B10. <u>In the last month</u>, have you seen anyone inject drugs? *[lijsee_fu]*
Yes
No
DK/R

B11. *If ijsee_fu= "yes":* **Who have you seen inject drugs?** *(Read out list; check all that apply) [ijw_fu]*
A close friend *[1]*
A casual friend or acquaintance *[2]*
A sex partner *[3]*
An immediate family or household member *[4]*
An extended family member *[5]*
Dealer *[6]*
Strangers (like people on the street) *[7]*
DK/R *[99]*

B12. Do you have a sex partner who currently injects drugs? *[ijsexp_fu]*
Yes
No
DK/R

B13. Do you have close friends who currently inject drugs? *[ijfriend_fu]*
Yes
No
DK/R

B14. <u>In the last month</u>, have you used a needle to chip, fix, muscle, or inject drugs even once? *[ijm1_fu]*

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Yes
No
DK/R

B15. *If ijmi_fu= "yes":* **How many times in the past 30 days have you injected any of the following prescription drugs.** *(Read out list and time increments) [m1pilij_fu]*

B15a. Prescription opioids, such as Percocet, OxyContin, Dillaudid, Vicodin? _____ *[m1pilnij_poj_fu]*

B15b. Medications used for opioid use disorder such as Methadone, buprenorphine/suboxone? _____ *[m1pilij_moudj_fu]*

B15c. Benzodiazepines/Benzos such as Xanax, Ativan, Valium, Klonapin? _____ *[m1pilij_bzj_fu]*

B15d. Prescription stimulants such as Adderall, Ritalin, Focalin, Concerta, Dexedrine? _____ *[m1pilij_psj_fu]*

B16. *If ijmi_fu= "yes":* **Have you injected any of the following prescription drugs in the past 7 days or past 3 days?** *(Read out list and time increments)*

		Past 7 days (Y/N) *[d7pilij_fu]*	Past 3 days (Y/N) *[d3pilij_fu]*
B16a	Prescription opioids such as Percocet, OxyContin, Dillaudid, Vicodin		
B16b	Medications used for opioid use disorder such as Methadone, buprenorphine/Suboxone		
B16c	Benzodiazepines/Benzos such as Xanax, Ativan, Valium, Klonapin		
B16d	Prescription stimulants such as Adderall, Ritalin, Focalin, Concerta, Dexedrine		

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B17. How many times in the past 30 days have you injected any of the following drugs? We will not be asking about fentanyl use right now. We will be asking about that separately later on. *(Read out list and time increments) [m1drgij_fu]*

B17a. Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine:_____ *[m1drgij_cd_fu]*

B17b. Psychedelics, such as Mushrooms, Acid, LSD, DMT:_____ *[m1drgij_p_fu]*

B17c. Crystal methamphetamine (crystal meth, glass, tina, crank, ice):_____ *[m1drgij_cm_fu]*

B17d. Powder cocaine:_____ *[m1drgij_pc_fu]*

B17e. Crack cocaine:_____ *[m1drgij_cc_fu]*

B17f. Heroin:_____ *[m1drgij_he_fu]*

B17g. Alcohol:_____ *[m1drgij_alc_fu]*

B17h. Other:_____ *[m1drgij_oth_age_fu]*

B17i: Other drug mentioned:_____ *[m1drgij_oth_drg_fu]*

B18. Have you injected any of the following drugs in the <u>past 7 days</u> or <u>past 3 days</u>? We will not be asking about fentanyl use right now. We will be asking about that separately later on. *(Read out list and time increments)*

		Past 7 days (Y/N) *[d7drgij_fu]*	Past 3 days (Y/N) *[d3drgij_fu]*
B18a	Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine		
B18b	Psychedelics, such as Mushrooms, Acid, LSD, DMT		
B18c	Crystal methamphetamine (crystal meth, glass, tina, crank, ice)		
B18d	Powder cocaine		
B18e	Crack cocaine		
B18d	Heroin		

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B18e	Alcohol		
B18f	Other:		

B19. Of all the drugs you have injected in the last month, which is the one that you use the most? (*Read out list; Check only one*) *[lijmost_fu]:*_____

B19a. Of all the drugs you have injected in the last month, which is the one you prefer to use the most? (*Read out list; Check only one*) *[ijpref_fu]:*_____

B19c. *If ijm1_fu= "yes":* **In the last month, how often have you shared syringes?** *[syrsharem1_fu]*

Never
Once or a couple times
At least every week
Every day
Multiple times per day
DK/R

B20. *If syrsharem1_fu<> (doesn't equal) "never" or "DK/R"* **Who have you shared a syringe with?** *(Read out list; check all that apply) [syrsharewho]*

A close friend *[1]*
A casual friend or acquaintance *[2]*
A sex partner *[3]*
An immediate family or household member *[PAR]*
An extended family member *[4]*
Dealer *[5]*
Strangers (people I don't know) *[6]*
DK/R *[9]*

B23. *If ijm1_fu= "yes":* **<u>In the last month</u>, how often did you need someone to help you inject** *[helpijm1_fu]*

Never
Once or a couple times
At least every week
Everyday
Multiple times per day

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DK/R

B24. *If helpijm1_fu <> "Never" or "DK/R":* **<u>In the last month</u>, who helped you inject?** *(Read out list; check all that apply) [helpijm1_who_fu]*

A close friend *[1]*
A casual friend or acquaintance *[2]*
A sex partner *[3]*
An immediate family or household member *[4]*
An extended family member *[5]*
Dealer *[6]*
Strangers (people I don't know) *[7]*
DK/R *[99]*

B25. <u>In the last month</u>, did you go on a run or a binge, as in used a larger amount of drugs as usual over a short amount of time? *[bngm1_fu]*

Yes
No
DK/R

Interviewer prompt: We are now going to ask about drug dealing. By dealing, we mean giving drugs to someone in exchange for money, food, shelter, or other goods. Please remember that all responses are strictly confidential and will not be shared with anyone outside of the study team.

B26. <u>In the last month</u>, have you dealt drugs? *[dealt_fu]*

Yes
No
DK/R

B27. *If dealt_fu= "yes":* **What is the main reason you've dealt drugs?** *(Read out list; check only one) [dealw_fu]*

Income for drugs
Income for other purposes
To clear debts
For food or shelter
Another reason
DK/R

B27a. *If dealw="another reason":* **What is the main reason you've dealt drugs:_____** *[dealw_oth_fu]*

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B28. *If dealt_fu= "yes":* **<u>In the last month</u>, have you dealt drugs that you suspected or knew had fentanyl in them?** *[fentdeal_fu]*

Yes
No
DK/R

B29. *If dealt_fu= "yes":* **Are you concerned about fentanyl contaminating your supply?** [*fentdeal_concern_fu*]

Very concerned
A little concerned
Neutral
Not concerned
DK/R

B30. *If dealt_fu= "yes":* **If given the choice, would you prefer not to deal drugs that had fentanyl in them?** *[fentindrg_fu]*

Very concerned
A little concerned
Neutral
Not concerned
DK/R

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SECTION C: FENTANYL

Interviewer prompt: Now we are going to ask you questions about fentanyl. Please answer True, False, or Don't know/Refuse for the next 6 questions.

C1. Fentanyl is an opioid *[info1_fu]*
True
False
DK/R

C2. Fentanyl is not as strong as heroin *[info2_fu]*
True
False
DK/R

C3. Fentanyl acts more quickly than heroin *[info3_fu]*
True
False
DK/R

C4. Drugs that are mixed with fentanyl look different than drugs that are not mixed with fentanyl *[info4_fu]*
True
False
DK/R

C5. Someone is more likely to overdose when using drugs that contain fentanyl than when using drugs that do not contain with fentanyl *[info5_fu]*
True
False
DK/R

C6. In Rhode Island, fentanyl now causes more overdoses than heroin *[info6_fu]*
True
False
DK/R

C7. <u>In the last month</u>, have you been <u>prescribed</u> fentanyl by a doctor? *[fentrxm1_fu]*
Yes
No
DK/R

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C8. *If fentrxm1_fu= "yes":* **In what forms have you been prescribed fentanyl?** *(Read out list; check all that apply) [fentform_fu]*

Skin patch *[1]*
Pills *[2]*
Nasal spray *[3]*
Lozenge/lollipop *[4]*
A film that dissolves under your tongue *[5]*
A spray that goes under your tongue *[6]*
Other: *[7]*
DK/R *[99]*

C8a. *If fentform_fu= "other":* **In what forms have you been prescribed fentanyl: _____** *[fentform_oth_fu]*

C9. *If fentrxm1_fu= "yes":* **In the last month, have you used prescription fentanyl in a way that was not prescribed by a doctor (without a prescription, or different route or different dose than as prescribed by a doctor)?** *[fentnorx_fu]*

Yes
No
DK/R

C10. *If fentnorx_fu= "yes":* **In the last month, how often have you used prescription fentanyl in a way that was not prescribed by a doctor?** *[fentdiv6_fu]*

Never
Once or a couple of times
About once a month
At least every week
Every day
DK/R

C11. *If fentnorx_fu= "yes":* **In the last month, what forms of prescription fentanyl have you used in a way that was not prescribed by a doctor?** *(Read out list; check all that apply) [fentdivform_fu]*

Skin patch *[1]*
Pills (orally) *[2]*
Nasal spray *[3]*
Injecting *[4]*
Snorting *[5]*
Smoking *[6]*
Lozenge/lollipop *[7]*
A film that dissolves under your tongue *[8]*

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Other: *[77]*
DK/R *[99]*

C11a. *If fentdivform_fu= "other":* **In the last month, what forms of prescription fentanyl have you used in a way that was not prescribed by a doctor: _____** *[fentdivform_oth_fu]*

C12. *If fentnorx_fu= "yes":* **In the last month, how did you get fentanyl without a prescription?** *(Read out list; check all that apply) [fentbuy_fu]*

Purchased from a dealer or on the street *[1]*
A close friend *[2]*
A casual friend of acquaintance *[3]*
A sex partner *[4]*
An immediate family or household member *[5]*
An extended family member *[6]*
Purchased from the internet or "dark web" *[7]*
Other: *[77]*
DK/R *[99]*

C12a. *If fentbuy_fu= "other":* **In the last month, who did you get fentanyl without a prescription:_____** *[fentbuy_oth_fu]*

Interviewer prompt: Now we are going to be talking about drugs that contained fentanyl. For example, you thought you were buying heroin, but it was contained fentanyl.

C13. In the last month, how often have you used fentanyl or drugs you were confident contained fentanyl? *[fentfreq_fu]*

Never
Once or a couple of times
About once a month
At least every week
Every day
DK/R

C14. *If fentfreq_fu <> "never" or "DK/R":* **What drugs have you used that you were confident contained fentanyl in the past...** *(Read out list; check all that apply) [fentdrgconf_fu]*

		Past month (Y/N)	Past 7 days (Y/N)	Past 3 days (Y/N)

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C14a	Marijuana or hash oil, including edibles and synthetic marijuana			
C14b	Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine OR Molly/MDMA/Ecstasy *[MO]*			
C14c	Psychedelics, such as Mushrooms, Acid, LSD, DMT OR Mushrooms *[MU]*			
C14d	Crystal methamphetamine (crystal meth, tina, crank, ice)			
C14e	Powder cocaine			
C14f	Crack cocaine			
C14h	Heroin			
C14j	Prescription Opioid Pills (Vicodin, Percocet, etc.)			
C14k	Prescription Benzodiazepines (Xanax, Klonopin, etc.)			
C14l	Prescription Stimulants (Adderall, Ritalin, etc.)			
C14 m	Other:			
C14n	DK/R			

C15. *If fentfreq_fu <> "never" or "DK/R":* **The <u>last time</u> you used a drug you were confident contained fentanyl, did you know that the drug that contained fentanyl before you used it?** *[fentconf_fu]*

Yes
No

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DK/R

C16. *If fentfreq_fu <> "never" or "DK/R":* **The last time you used a drug you were confident contained fentanyl, why were you confident that it contained fentanyl?** *(Read out list; check all that apply) [fentwhy_fu]*

A dealer told me *[1]*
A sex partner told me *[2]*
A friend told me *[3]*
I overdosed *[4]*
A sex partner overdosed *[5]*
A friend overdosed *[6]*
I had a bad reaction *[7]*
Quicker onset of high *[8]*
Different high *[9]*
Differences in appearance, smell or taste *[10]*
Other: *[77]*
DK/R *[99]*

C16a. *If fentwhy_fu= "Other":* **The last time you used a drug you were confident contained fentanyl, why were you confident that it contained fentanyl:_____** *[fentwhy_oth_fu]*

C17. The last time you used a drug that you were confident contained fentanyl, how did you get it? *[fentobt_fu]*

Purchased from a dealer or on the street
A close friend
A casual friend of acquaintance
A sex partner
An immediate family or household member
An extended family member
Purchased from the internet or "dark web"
Other
No
DK/R

C17b. *If fentobt_fu = "other":* **The last time you used a drug that you were confident contained fentanyl, how did you get it:_____** *[fentobt_why_fu]*

C18. The last time you used a drug you were confident contained fentanyl, what did you do when you found out you? *(Read out list; check all that apply) [skill1_fu]*

Took them as I usually would *[1]*
Threw them out *[2]*

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Gave them away *[3]*
Sold them *[4]*
Went slower *[5]*
Used less *[6]*
Did a tester *[7]*
Used with someone else around *[8]*
Other: *[77]*
DK/R *[99]*

C18a. *If skill1_fu= "other":* **The last time you used a drug you were confident contained fentanyl, what did you do when you found out:_____** *[skill1_oth_fu]*

Interviewer prompt: Now that we have asked you what you've done in the past when you had drugs that contained fentanyl, we would like to know more about what you do in the future.

C19. What would you do if you found out your drugs had fentanyl in them? *(Read out list; check all that apply) [motiv1_fu]*

Take them as I usually would *[1]*
Throw them out *[2]*
Give them away *[3]*
Sell them *[4]*
Go slower *[5]*
Use less *[6]*
Do a tester *[7]*
Use with someone else around *[8]*
Talk with the supplier or dealer *[8]*
Other *[77]*
DK/R *[99]*

D19a. *If motiv1_fu = "Other":* **What would you do if you found out your drugs had fentanyl in them:_____** *[motiv1_oth_fu]*

Interviewer prompt: We would like to know your thoughts about the effects of fentanyl or drugs that have fentanyl in them. Please indicate how much you agree or disagree with the following statements:

C20. Fentanyl or drugs that have fentanyl in them are a better high than drugs that do not have fentanyl in them *[precep1_fu]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

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C21. I am <u>concerned</u> about my friends using drugs that contain fentanyl *[motiv2_fu]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

C22. I am <u>concerned</u> about my drugs having fentanyl in them *[motiv3_fu]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

C23. I prefer using fentanyl or drugs that have fentanyl in them *[fentpref]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

C24. ***If "Agree" or "Strongly agree" to any of D26:*** **Why do you prefer to use drugs with fentanyl in them?** *(Read out list; check all that apply) [whyfentprep_fu]*

Stronger or better high *[1]*
Faster onset of high *[2]*
Easier to prepare than other drugs *[3]*
Cheaper than other opioids (including heroin and prescription pills) *[4]*
Dope sick or experiencing withdrawal symptoms *[5]*
That's all my dealer was selling *[6]*
Curious about the effect of fentanyl *[7]*
It is what I am used to using *[8]*
Other: *[77]*
DK/R *[99]*

C24a. *If whyfentpref_fu= "other":* **Why do you prefer to use drugs with fentanyl in them:_____** *[whyfentpref_oth]*

C27. Have you used a fentanyl test strip in the last month, either on your own or with people you use drugs with? *[testusem1_fu]*

Yes

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No
DK/R

C28. *If testusem1_fu= "yes":* **Who performed the test?** *[teseusewhom1_fu]*
I did it myself
A close friend
A casual friend or acquaintance
An immediate family or household member
An extended family member
Dealer
Strangers
DK/R

C29. Where did the fentanyl test strips come from? *(Read out list; check all that apply) [testgetwho_fu]*
RAPIDS clinical trial *[1]*
Other research study *[2]*
AIDS Care Ocean State (ACOS) *[3]*
Project Weber/RENEW *[4]*
Another harm reduction organization *[5]*
Uncertain *[6]*
Other: *[77]*
DK/R *[99]*

C29a. *If testgetwho_fu= "other":* **Where did the fentanyl test strips come from:_____** *[testgetwho_oth_fu]*

C30. *If testusem1_fy= "yes":* **In the last month, how many times have you tested your drugs for fentanyl?** *[testnumm1_fu]*

_____
DK/R

C31. *If testusem1_fu>0:* **Did any of the tests come back positive? Meaning you only saw one line on the test strip?** *[testpos_fu]*
Yes
No
DK/R

C32. *If testpos_fu= "yes":* **How many tests were positive for fentanyl, meaning you only saw one line?** *[fentposno_fu]*

_____

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DK/R

C33. *If testpos_fu= "yes":* **Which drugs that you tested came back positive for fentanyl?** *(Read out list; check all that apply) [fentposdrg_fu]*

Prescription opioids such as Percocet, OxyContin, Dillaudid, Vicodin *[1]*
Medications used for opioid use disorder such as Methadone, buprenorphine/Suboxone *[2]*
Benzodiazepines/Benzos such as Xanax, Ativan, Valium, Klonapin *[3]*
Prescription stimulants such as Adderall, Ritalin, Focalin, Concerta, Dexedrine *[4]*
Marijuana or hash oil, including edibles and synthetic marijuana [*5]*
Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine *[6]*
Psychedelics, such as Mushrooms, Acid, LSD, DMT *[7]*
Crystal methamphetamine (crystal meth, glass, ice, tina) *[8]*
Powder cocaine *[9]*
Crack cocaine *[10]*
Heroin *[11]*
Other *[77]*
DK/R *[99]*

C33a. *If fentposdrg_fu = "Other":* **Which drugs that you tested came back positive for fentanyl:_____** *[fentposdrg_oth_fu]*

C34. *If testpos_fu= "yes":* **What did you do when you found out you had drugs containing fentanyl?** *(Read out list; check all that apply). [skill1testpos_fu]*

Took them as I usually would *[1]*
Threw them out *[2]*
Gave them away *[3]*
Sold them *[4]*
Went slower *[5]*
Went faster *[6]*
Used less *[7]*
Used more *[8]*
Did a tester *[9]*
Used with someone else around *[10]*
Got naloxone *[11]*
Other *[77]*
DK/R *[99]*

C34a. *If skill1testpos_fu= "Other":* **What did you do when you found out you had drugs containing fentanyl:_____** *[skill1testpos_oth_fu]*

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C35.*If testpos_fu= "Yes":* **Did you experience any of the following unwanted negative reactions from using the drug that tested positive for fentanyl?** *(Read out list; check all that apply) [fentreact_fu]*

Lost consciousness/blacked out *[1]*
Blue or gray lips or skin *[2]*
Seizure *[3]*
Had a hard time breathing *[4]*
Elevated breathing *[5]*
Stopped breathing *[6]*
Inability to talk *[7]*
Not responsive to stimulus (like having your name called or physical contact) *[8]*
Overheating *[9]*
Irregular heart beat (fast, slow, irregular or palpitations) *[10]*
Paranoia *[11]*
Can't remember getting high *[12]*
None *[13]*
Other *[77]*
DK/R *[99]*

C25. *If fentreact_fu= "Other":* **Did you experience any of the following unwanted negative reactions from using the drug that tested positive for fentanyl:_____** *[fentreact_oth_fu]*

C36. Did any of the tests come back negative for fentanyl, meaning you saw two lines? *[testneg_fu]*

Yes
No
DK/R

C37. How many of the tests came back negative for fentanyl, meaning you saw two lines? *[fentnegno_fu]*

_____
DK/R

C38. Which drugs that you tested came back negative for fentanyl? *(Read out list; check all that apply) [fentnegdrg_fu]*

Prescription opioids such as Percocet, OxyContin, Dillaudid, Vicodin *[1]*
Medications used for opioid use disorder such as Methadone, buprenorphine/Suboxone *[2]*
Benzodiazepines/Benzos such as Xanax, Ativan, Valium, Klonapin *[3]*
Prescription stimulants such as Adderall, Ritalin, Focalin, Concerta, Dexedrine *[4]*
Marijuana or hash oil, including edibles and synthetic marijuana *[5]*
Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine *[6]*

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Psychedelics, such as Mushrooms, Acid, LSD, DMT *[7]*
Crystal methamphetamine (crystal meth) *[8]*
Powder cocaine *[9]*
Crack cocaine *[10]*
Heroin *[11]*
Alcohol *[12]*
Other *[77]*
DK/R *[99]*

C38a. *If fentnegdrg_fu= "Other":* **Which drugs that you tested came back negative for fentanyl:_____** *[fentnetdrg_oth_fu]*

C39. *If testneg_fu= "Yes":* **What did you do when you found out you had drugs that did not contain fentanyl?** *(Read out list; check all that apply). [skill1fentneg_fu]*

Took them as I usually would *[1]*
Threw them out *[2]*
Gave them away *[3]*
Sold them *[4]*
Went slower *[5]*
Went faster *[6]*
Used less *[7]*
Used more *[8]*
Did a tester *[9]*
Used with someone else around *[10]*
Got naloxone *[11]*
Other *[77]*
DK/R *[99]*

C39a. *If skill1fentneg_fu= "Other":* **What did you do when you found out you had drugs that did not contain fentanyl:_____** *[skill1fentneg_fu]*

C40. *If testneg_fu= "yes":* **Did you experience any of the following unwanted negative reactions from using the drug that tested negative for fentanyl?** (Read out list; check all that apply) *[fentreactneg_fu]*

Lost consciousness/blacked out *[1]*
Blue or gray lips or skin *[2]*
Seizure *[3]*
Had a hard time breathing *[4]*
Elevated breathing *[5]*
Stopped breathing *[6]*
Inability to talk *[7]*

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Not responsive to stimulus (like having your name called or physical contact) *[8]*
Overheating *[9]*
Irregular heart beat (fast, slow, irregular or palpitations) *[10]*
Paranoia *[11]*
Can't remember getting high *[12]*
None *[13]*
Other *[77]*
DK/R *[99]*

C40a. *If fentreactneg_fu= "Other":* **Did you have any of the following unwanted negative reactions from using the drug that tested negative for fentanyl:_____** *[fentreactneg_oth_fu]*

C43. Has fentanyl changed how you think about starting methadone or buprenorphine (Suboxone), or starting other forms of addiction treatment? *[fentottrt_neg]*

Yes, I accessed addiction treatment because of concerns about fentanyl
Yes, I am thinking about accessing treatment because of concerns about fentanyl (but haven't done so yet)
No
Already in some kind of addiction treatment
DK/R

C44. Has fentanyl changed how you use drugs in any of the following ways? *(Read out list; check all that apply) [fentchange_fu]*

More likely to use with others *[1]*
More likely to inject slowly and/or taste drugs first *[2]*
More likely to use in public (e.g., outside) *[3]*
More likely to use in places where other people are around *[4]*
Less likely to use alone *[5]*
More likely to use where naloxone is available *[6]*
More likely to carry take-home naloxone *[7]*
Using less often and/or using smaller amount of drugs each time *[8]*
More likely to use drugs containing fentanyl *[9]*
More likely to use drugs unlikely to contain fentanyl (rather than drugs that may contain fentanyl) *[10]*
Other: *[77]*
Use hasn't changed *[11]*
DK/R *[99]*

C44a. *If fentchange_fu= "More likely to use drugs unlikely to contain fentanyl:* **Specify drugs less likely to contain fentanyl:_____** *[fentchange_drg_fu]*

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C44b. *If fentchange_fu= "Other":* **Has fentanyl changed how you use drugs in any of the following ways:_____** *[fentchange_oth_fu]*

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SECTION D - MENTAL HEALTH

Interviewer prompt: Now we will talk about how you are feeling right now. Rate each of the following statements between 0 and 4. 0 = not at all; 1 = a little; 2 = moderately ; 3 = quite a bit; 4 = extremely. In each case, you can respond that you don't know or prefer not to answer.

	Not at all *[0]*	A little *[1]*	Moderately *[2]*	Quite a bit *[3]*	Extremely *[4]*
D1a. I feel anxious. *[sows1_fu]*	[0]	[1]	[2]	[3]	[4]
D1b. I feel like yawning. *[sows2_fu]*	[0]	[1]	[2]	[3]	[4]
D1c. I am perspiring. *[sows3_fu]*	[0]	[1]	[2]	[3]	[4]
D1d. My eyes are tearing. *[sows4_fu]*	[0]	[1]	[2]	[3]	[4]
D1e. My nose is running. *[sows5_fu]*	[0]	[1]	[2]	[3]	[4]
D1f. I have goosebumps. *[sows6_fu]*	[0]	[1]	[2]	[3]	[4]
D1g. I am shaking. *[sows7_fu]*	[0]	[1]	[2]	[3]	[4]
D1h. I have hot flashes. *[sows8_fu]*	[0]	[1]	[2]	[3]	[4]
D1j. I have cold flashes. *[sows9_fu]*	[0]	[1]	[2]	[3]	[4]
D1k. My bones and muscles ache. *[sows10_fu]*	[0]	[1]	[2]	[3]	[4]
D1l. I feel restless. *[sows11_fu]*	[0]	[1]	[2]	[3]	[4]
D1m. I feel nauseous. *[sows12_fu]*	[0]	[1]	[2]	[3]	[4]

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D1n. I feel like vomiting. *[sows13_fu]*	[0]	[1]	[2]	[3]	[4]
D1o. My muscles twitch. *[sows14_fu]*	[0]	[1]	[2]	[3]	[4]
D1p. I have stomach cramps. *[sows15_fu]*	[0]	[1]	[2]	[3]	[4]
D1q. I feel like using now. *[sows16_fu]*	[0]	[1]	[2]	[3]	[4]

https://www.integration.samhsa.gov/clinical-practice/gad708.19.08cartwright.pdf

Interviewer Prompt: Now I am going to ask you 7 questions about stress and anxiety. You can respond with how often you have experienced these feelings in the past 2 weeks: "not sure at all," "several days," "over half the days," or "nearly every day."

	Not sure at all *[0]*	Several days *[1]*	Over half the days *[2]*	Nearly every day *[3]*
D2a. Feeling nervous, anxious, or on edge *[gad1_fu]*	[0]	[1]	[2]	[3]
D2b. Not being able to stop or control worrying *[gad2_fu]*	[0]	[1]	[2]	[3]
D2c. Worrying too much about different things *[gad3_fu]*	[0]	[1]	[2]	[3]
D2d. Trouble relaxing *[gad4_fu]*	[0]	[1]	[2]	[3]
D2e. Being so restless that it's hard to sit still *[gad5_fu]*	[0]	[1]	[2]	[3]

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D2f. Becoming easily annoyed or irritable *[gad6_fu]*	[0]	[1]	[2]	[3]
D2g. Feeling afraid as if something awful might happen *[gad7_fu]*	[0]	[1]	[2]	[3]

D2h. If you checked off any problems, how difficult have these made it for you to do your work, take care of things at home, or get along with other people? (*Read out list; check only one). [gad8_fu]*

Not difficult at all
Somewhat difficult
Very difficult
Extremely difficult

Interviewer Prompt: Next, I will describe some feelings or behaviors you may have had in the past week. Please tell me how often you have felt this way in the past week.

Programmer note: Scoring for CESD be found in brackets in the table below. For these questions, rarely will be 3, occasionally will be 2, some of the time will be 2 and most of the time will be 0. A score for this can range between 0 and 60. A score of less than 16 means that symptoms do not have clinical significance.

	Rarely or none of the time (less than 1 day) *[0]*	Some or a little of the time (1-2 days) *[1]*	Occasionally or a moderate amount of time (3-4 days) *[2]*	Most or all of the time (5-7 days) *[3]*	DK/R *[DK]*
D3a. I was bothered by things that usually don't bother me. *[cesd1_fu]*	[0]	[1]	[2]	[3]	
D3b. I did not feel like eating; my appetite was poor. *[cesd2_fu]*	[0]	[1]	[2]	[3]	

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D3c. I felt that I could not shake off the blues even with help from my family or friends. *[cesd3_fu]*	[0]	[1]	[2]	[3]	
D3e. I had trouble keeping my mind on what I was doing. *[cesd5_fu]*	[0]	[1]	[2]	[3]	
D3f. I felt depressed. *[cesd6_fu]*	[0]	[1]	[2]	[3]	
D3g. I felt that everything I did was an effort. *[cesd7_fu]*	[0]	[1]	[2]	[3]	
D3i. I thought my life had been a failure. *[cesd9_fu]*	[0]	[1]	[2]	[3]	
D3j. I felt fearful. *[cesd10_fu]*	[0]	[1]	[2]	[3]	
D3k. My sleep was restless. *[cesd11_fu]*	[0]	[1]	[2]	[3]	
D3m. I talked less than usual. *[cesd13_fu]*	[0]	[1]	[2]	[3]	
D3n. I felt lonely. *[cesd14_fu]*	[0]	[1]	[2]	[3]	
D3o. People were unfriendly. *[cesd15_fu]*	[0]	[1]	[2]	[3]	
D3q. I had crying spells. *[cesd17_fu]*	[0]	[1]	[2]	[3]	
D3r. I felt sad. *[cesd18_fu]*	[0]	[1]	[2]	[3]	
D3s. I felt that people dislike me. *[cesd19_fu]*	[0]	[1]	[2]	[3]	

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D3t. I could not get "going." *[cesd20_fu]*	[0]	[1]	[2]	[3]	

	Rarely or none of the time (less than 1 day) *[3]*	Some or a little of the time (1-2 days) *[2]*	Occasionally or a moderate amount of time (3-4 days) *[1]*	Most or all of the time (5-7 days) *[0]*	DK/R *[DK]*
D3d. I felt I was just as good as other people. *[cesd4_fu]*	[3]	[2]	[1]	[0]	
D3h. I felt hopeful about the future. *[cesd8_fu]*	[3]	[2]	[1]	[0]	
D3l. I was happy. *[cesd12_fu]*	[3]	[2]	[1]	[0]	
D3p. I enjoyed life. *[cesd16_fu]*	[3]	[2]	[1]	[0]	

D4. In general, how satisfied are you with your life? *[hrqol1_fu]*

Very satisfied	Satisfied	Dissatisfied	Very dissatisfied

D5. Would you say that in general your health is… *[hrqol2_fu]*

Excellent	Very Good	Good	Fair	Poor	DK/R

D5. Now thinking about your physical health, which includes physical illness and injury, for how many days during the past 30 days was your physical health not good? *[hrqol3_fu]*

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_____ (integer, maximum 30)

D6. Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good? *[hrqol4_fu]*

_____ (integer, maximum 30)

D7. During the past 30 days, for about how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation? *[hrqol5_fu]*

_____ (integer, maximum 30)

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SECTION E: HEALTHCARE AND TREATMENT ENGAGEMENT

Interviewer prompt: We are now going to move on and talk about your experiences with drug and alcohol treatment programs.

E1a. How troubled or bothered have you been in the past 30 days by drug problems, like cravings, withdrawal symptoms, or wanting to stop and being unable to? *[drgprob_fu]*

0 - Not at all	Slightly	Moderately	Considerably	4 - Extremely

E1b. How important to you now is treatment for these drug problems? *[probimp_fu]*

0 - Not at all	Slightly	Moderately	Considerably	4 - Extremely

E1c. Have you tried to enroll in a substance use treatment program but were unable to <u>in the last month</u>? *[txcaccess_fu]*

Yes
No
DK/R

E2. *If txacess_fu= "yes";* **What kind of addiction treatment did you try to enroll in?** *(Read out list; check all that apply)* **.** *[txt_fu]*

Detox *[1]*
Methadone *[2]*
Suboxone (buprenorphine) treatment *[3]*
Self-help group (like 12-step AA or NA programs) *[4]*
Outpatient drug or alcohol treatment program *[5]*
Day treatment program or partial hospitalization program *[6]*
Residential drug treatment program *[7]*
Another kind of treatment *[77]*
DK/R *[99]*

E2a. *If txt_fu= "Another kind of treatment";* **What kind of addiction treatment did you try to enroll in:_____** *[txt_fu]*

E3. What were the main barriers to accessing addiction treatment? *(Read out list: check all that apply)***.** *[txb_fu]*

I couldn't afford it *[1]*
There was a waiting list *[2]*

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My health insurance would not allow me to attend the program *[3]*
I didn't have health insurance *[4]*
I didn't know of any programs *[5]*
The programs weren't youth-friendly *[6]*
I was turned down by a program *[7]*
There was no treatment program nearby *[8]*
There were no beds or appointments available *[9]*
Another reason *[77]*
DK/R *[99]*

E3a. *If txb= "yes":* **What were the main barriers to accessing addiction treatment:_____** *[txb_oth_fu]*

E5. Have you been kicked out of any drug or alcohol treatment program because of drug or alcohol use <u>in the last month</u>? *[tx_kick_fu]*

Yes
No
DK/R

E6. *If txkick_fu= "yes":* **What program(s) were you kicked out of?** *(Read out list; check all that apply) [txkick_prog_fu]*

Detox *[1]*
Methadone *[2]*
Suboxone (buprenorphine) treatment *[3]*
Self-help group (like 12-step AA or NA programs) *[4]*
Outpatient drug or alcohol treatment program *[5]*
Day treatment program or partial hospitalization program *[6]*
Residential drug treatment program *[7]*
Another kind of treatment *[77]*
DK/R *[99]*

E6a. *If txprog_kick_fu = "other":* **What program(s) were you kicked out of:_____** *[txprog_kick_oth_fu]*

E7. What substance did you use that caused you to be kicked out? *(Read out list; check all that apply) [txkick_drg_fu]*

Prescription opioids such as Percocet, OxyContin, Dillaudid, Vicodin *[1]*
Medications used for opioid use disorder such as Methadone, buprenorphine/Suboxone *[2]*
Benzodiazepines/Benzos such as Xanax, Ativan, Valium, Klonapin *[3]*
Prescription stimulants such as Adderall, Ritalin, Focalin, Concerta, Dexedrine *[4]*
Marijuana or hash oil, including edibles and synthetic marijuana *[5]*
Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine *[6]*

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Psychedelics, such as Mushrooms, Acid, LSD, DMT *[7]*
Crystal methamphetamine (crystal meth, glass, ice, tina) *[8]*
Powder cocaine *[9]*
Crack cocaine *[10]*
Heroin *[11]*
Other *[77]*
DK/R *[99]*

E7a. *If txkick_drg_fu= "yes":* **What substance did you use that caused you to be kicked out:_____** *[txkick_drg_oth_fu]*

E8. *If txprog_fu= "yes";* **In the last month, have you been in any kind of alcohol or drug treatment program?** *[txprogm1_fu]*
Yes
No
DK/R

E9. *If txprogm1= "yes":* **Are you currently in a drug or alcohol treatment program?** *[addictxt_fu]*
Yes
No
DK/R

E10. Overall, how satisfied are you with this treatment program? *[addictxt_sat_fu]*

Very unsatisfied	Unsatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied	DK/R

E11. *If addictxt_fu= "yes":* **Why did you enter this treatment program?** *(Read out list; check all that apply) [addictxt_reason_fu]*
Wanted to reduce my drug use or stop using entirely *[1]*
Other physical or mental health reasons *[2]*
Convinced by family, friends, a doctor, etc. *[3]*
Coerced or forced to by a doctor, the policy, courts, etc. *[4]*
Referred from a drug court *[5]*
Other *[77]*
DK/R *[99]*

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E11a. *If adicttxt_reason_fu= "other":* **Why did you enter this treatment program:_____** *[addictxt_reason_oth_fu]*

E12. *If addictxt_fu= "yes":* **Is this treatment program located in Rhode Island?** *[addictri_fu]*

Yes
No
DK/R

E13. *If addictxt_fu= "yes":* **What kind of addiction treatment are you currently in?** *(Read out list; check all that apply) [txtcur_fu]*

Detoxification *[1]*
Methadone *[2]*
Buprenorphine/Suboxone/Subutex treatment *[3]*
Self-help group (like 12-step AA, NA) *[4]*
Outpatient drug or alcohol treatment program *[5]*
Day treatment program or partial hospitalization program *[6]*
Residential drug treatment program *[7]*
Another kind of treatment: *[77]*
DK/R *[99]*

E14. *If txtcur_fu = "Methadone" or "Buprenorphine/Suboxone/Subutex treatment":* **How long have you been taking this medication for?** *[mattime_fu]*

_____ years _____ months
DK/R *[DK]*

E15. *If txtcur_fu = "Methadone" or "Buprenorphine/Suboxone/Subutex treatment":* **What is the dose of methadone or Buprenorphine/Suboxone/Subutex that you are currently receiving?** *[matdose_fu]*

_____ mg (integer; if TXT_current = Methadone, allowable range 1 to 1000; If TXT_current = Buprenorphine, allowable range 1 to 40)
DK/R

E16. *If txtcur_fu = "Methadone" or "Buprenorphine/Suboxone/Subutex treatment":* **Has the dose remained the same for the <u>past 7 days</u>?** *[txtcurstbl_fu]*

Yes
No
DK/R

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E16a. *If txtcurstble_fu= "yes":* **<u>During the last 7 days</u>, how frequently have you used heroin/opioids, either illicit or non-medical?** *[odas1_fu]*

1 - More than twice every day	2 - Every day at least once or twice a day	3 - Four, five or six times in the last seven days	4 - One, two or three times in the last seven days	5 - None of the last seven days

If *[5]* → skip to *odas*3a*_fu*

E16b. How intense was the effect you felt from the dose or doses of the heroin/opioid that you used in the last seven days on a scale of 1-5? A 1 would mean that the effect was extremely intense and a 5 would mean that it had no effect on you. *[odas2_fu]*

1 - 'The effect was extremely intense'	2 -	3 -	4 -	5 - 'It had no effect at all on me'

E16c. During the last seven days, how frequently have you felt two or more of these objective heroin/opioid withdrawal symptoms? (such as cramps and muscular pains, feeling your hair standing on end, a runny nose, wanting to cry, yawning, stomach cramps or diarrhea, palpitations, sweating, and generally feeling bad…) *[odas3a_fu]*

1 - More than twice every day	2 - Every day at least once or twice a day	3 - Three to six times in the last seven days	4 - One or two times in the last seven days	5 - None

If E16c = None *[5]* → skip to E16e

E16d. During the last seven days, how intense were the withdrawal symptoms you felt on a scale of 1-5? A 1 would mean extremely intense and a 5 would mean nothing at all. *[odas3b_fu]*

1 - 'Extremely intense'	2 -	3 -	4 -	5 - 'Nothing at all'

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E16e. During the last seven days, how frequently have you felt two or more of these subjective heroin/opioid withdrawal symptoms? (such as anxiety, restlessness, irritability, difficulty in sleeping, tiredness, shivering, muscular aches and lack of appetite) *[odas4a_fu]*

1 - More than twice every day	2 - Every day at least once or twice a day	3 - Three to six times in the last seven days	4 - One or two times in the last seven days	5 - None

If *[5]* NOT two or more symptoms → skip to E16g

E16f. During the last seven days, how intense were the withdrawal symptoms you felt on a scale of 1-5? A 1 would mean extremely intense and a 5 would mean nothing at all.*[odas4b_fu]*

1 - 'Extremely intense'	2 -	3 -	4 -	5 - 'Nothing at all'

E16g. During the last seven days, how frequently have you felt felt an urgent need to use heroin/opioids? *[odas5a_fu]*

1 - More than twice every day	2 - Every day at least once or twice a day	3 - Three to six times in the last seven days	4 - One or two times in the last seven days	5 - None

If *[5]* → skip to E16i

E16h. During the last seven days, how intensely did you feel the need to use heroin/opioids, on average on a scale of 1-5? A 1 would mean extremely intense and a 5 would mean nothing at all.? *[odas5b_fu]*

1 - 'Extremely intense'	2 -	3 -	4 -	5 - 'Nothing at all'

E16i. During the last seven days, how frequently have you had any symptoms of overmedication of methadone? (such as feeling sleepy or sedated, difficulty in speaking, being unusually active or, alternatively, the sensation of "being drugged") *[odas6a_fu]*

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None… 5 points *[5]*
1-2 times… 4 points *[4]*
3-6 times… 3 points *[3]*
Every day, once or twice a day… 2 points *[2]*
More than twice every day… 1 points *[1]*

E16j. During the last seven days, how intense were the overmedication symptoms you felt on a scale of 1-5? A 1 would mean extremely intense and a 5 would mean nothing at all. *[odas6b_fu]*

1 - 'Extremely intense'	2 -	3 -	4 -	5 - 'Nothing at all'

E17. What is your current health insurance coverage? *[inssts_fu]*
No insurance *[1]*
Insurance through my workplace *[2]*
Medicare/Medicaid or other governmental insurance like Neighborhood Health Plan*[3]*
Individual/family private coverage *[4]*
Other *[77]*
DK/R *[99]*

E17a. *If inssts_ = "other":* **What is your current health insurance coverage:_____** *[inssts_oth_]*

E18. Have you been diagnosed with a mental health or cognitive disorder in the last month? *[mentdiagevr_fu]*
Yes
No
DK/R

E19. *If mentdiagevr= "yes"* **What mental health disorder were you diagnosed with?** *(Read out list; check all that apply) [mentdiagname_fu]*
Attention-Deficit/Hyperactivity Disorder (ADD/ADHD) *[1]*
Obsessive-compulsive disorder (OCD) *[2]*
Eating disorders (like anorexia or bulimia) *[3]*
Depressive disorder (like major depression) *[4]*
Bipolar disorder (like manic depressive disorder) *[5]*
Anxiety disorder (like panic attacks or phobias) *[6]*
Psychosis (like schizophrenia, brief psychotic episode, or paranoia) *[7*
Another diagnoses *[77]*

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No, none of the above *[0]*
DK/R *[99]*

E19a. *If mendiagname_fu= "Another diagnoses":* **What mental health disorder were you diagnosed with:_____** *[mentdiagname_oth_fu]*

E20. Have you ever been hospitalized because of this mental health disorder or injuries caused by the disorder? *[hospdis_fu]*
Yes
No
DK/R

E21. Have you ever been prescribed opioids as a result of injury or acute pain? *[presinj_fu]*
Yes
No
DK/R

Interviewer prompt: We are going to ask you two questions about chronic pain. When we say chronic pain, we mean pain on most days or every day.

E21a. <u>In the past six months</u>, how often did you have pain? *[pn6m_fu]*

Never	Some days	Most days	Everyday	DK/R

E21b. <u>Over the past six months</u>, how often did pain limit your life or work activities? *[ald6m_fu]*

Never	Some days	Most days	Everyday	DK/R

E22. Have you been prescribed opioids in the <u>past month</u>? *[presmnth_fu]*
Yes
No
DK/R

E23. Have you been denied opioid medications for painful conditions in the <u>last month</u>? *[op_den_fu]*
Yes
No

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DK/R

E24. What was the reason for denial? *(Read out list; check all that apply) [op_den_reason_fu]*

No reason given *[1]*
Being homeless *[2]*
Not having health insurance *[3]*
Physician denied because of diversion or substance use concerns *[4]*
Clinic does not prescribe narcotics *[5]*
Did not see my regular physician *[6]*
Physician said pain wasn't serious enough or other medications are sufficient *[7]*
Physician concerned about adverse effects *[8]*
Positive drug test *[9]*
Other *[77]*
DK/R *[99]*

E24a. *If op_den_reason_fu= "other":* **What was the reason for denial:_____**
[op_den_reason_oth_fu]

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SECTION F – OVERDOSE

Interviewer prompt: Now we'd now like to ask you some questions about overdose.

F1. In the last month, have you seen someone overdose? *[skill2_fu]*
Yes
No
DK/R

F1a. In the last month, have you performed rescue breathing on someone who you thought was overdosing? *[skill3_fu]*
Yes
No
DK/R

F4. In the last month, have you given Narcan/naloxone to someone who you thought was overdosing? *[skill4_fu]*
Yes
No
DK/R

F5. *If skill4_fu= "yes";* **In the last month, have you given Narcan/naloxone to someone who you thought was overdosing on fentanyl?** *[sill5_fu]*
Yes
No
DK/R

F6. *If skill5_fu= "yes";* **How many doses of Narcan/naloxone did you have to give the last time you reversed a fentanyl overdose?** *[dosenarcfent_fu]*
1
2
3
≥4
DK/R

Interviewer prompt: Please indicate how much you agree or disagree with the following statements:

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F7. I am confident that I can recognize when someone is having an opioid overdose. *[motiv11_fu]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

F8. I am confident that I would call 911 if a friend or family member were overdosing. *[motiv12_fu]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

F9. I am confident that I would call 911 if a friend or family member were overdosing, even if drugs or drug paraphernalia were present at the scene. *[motiv13_fu]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

F10. I am confident that I would call 911 if a friend or family member were overdosing, even if I was high on drugs. *[motiv14_fu]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

F11. I am worried that other people might think that I am using drugs if they see me carrying naloxone (a medicine that can reverse an overdose). *[motiv15_fu]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

F12. What do you do to avoid an accidental overdose? *(Read out list; check all that apply)* *[skill6_fu]*

Nothing *[1]*
Avoid mixing with alcohol *[2]*
Avoid mixing with other drugs *[3]*
Smell or taste my supply *[4]*

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Using with someone else *[5]*
Take smaller amounts *[6]*
Go slow *[7]*
Take a tester *[8*
Use a fentanyl test strip *[9]*
Keep Narcan/naloxone nearby *[10]*
Change supplier or dealer *[11]*
Something else *[77]*
DK/R *[99]*

F12a. *If skill6_fu= "other":* **What do you do to avoid an accidental overdose:_____** *[skill6_oth_fu]*

Interviewer prompt: We'd know like to ask you about your own experience with accidental overdose. By accidental overdose we mean taking too much of a drug such that someone is no longer able to respond or breathe adequately. Other symptoms of an accidental overdose can include loss of consciousness, lips turning black or grey, gurgling noises, blacking out, or others. An overdose can occur with prescription or illicit drugs, or a combination of both.

F13. Since your last visit, have you accidentally overdosed? *[odsincevist]*
Yes
No
DK/R

F14. Was this in the last month? *[skill8_fu]*
Yes
No
DK/R

F15. *If skill8_fu= "yes";* **In the last month, have you experienced any of the following unwanted negative reactions from using too much of any of the drugs that you have used?** *(Read out list; check all that apply) [odsymptij_fu]*
Lost consciousness/blacked out *[1]*
Blue or gray lips or skin *[2]*
Seizure *[3]*
Had a hard time breathing *[4]*
Elevated breathing *[5]*
Stopped breathing *[6]*
Inability to talk *[7]*
Not responsive to stimulus (like having your name called or physical contact) *[8]*
Overheating *[9]*
Irregular heart beat (fast, slow, irregular or palpitations) [*10]*

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Paranoia *[11]*
Can't remember getting high *[12]*
None *[0]*
Other *[77]*
DK/R *[99]*

F15a. *If odsymptij_fu= "other":* **In the last month, have you experienced any of the following unwanted negative reactions from using too much of any of the drugs that you have used:_____** *[odsymptij_oth_fu]*

F16. *If skill8_fu= "yes":* **How many times have you overdosed in the last month?** *[odnumb_fu]*
_____ (integer, allowable range 1 to 30)
DK/R

F17. *If skill8_fu= "yes";* **Now we want to ask you about the most recent time you overdosed. Who was with you the last time you overdosed?** *(Read out list; check all that apply)[odw_fu]*
A close friend *[1]*
A casual friend or acquaintance *[2]*
A sex partner *[3]*
An immediate family or household member *[4]*
An extended family member *[5]*
A dealer *[6]*
A stranger (like people on the street) *[7]*
I was alone *[8]*
DK/R *[99]*

F17a. *If skill8_fu= "yes":* **The last time you overdosed, what drug(s) did you intend to take?** *(Read out list; check all that apply) [drgintend_fu]*
Prescription opioids such as Percocet, OxyContin, Dillaudid, Vicodin *[1]*
Medications used for opioid use disorder such as Methadone, buprenorphine/Suboxone *[2]*
Benzodiazepines/Benzos such as Xanax, Ativan, Valium, Klonapin *[3]*
Prescription stimulants such as Adderall, Ritalin, Focalin, Concerta, Dexedrine *[4]*
Marijuana or hash oil, including edibles and synthetic marijuana *[5]*
Club drugs such as Molly, MDMA, Ecstasy, GHB, Ketamine *[6]*
Psychedelics, such as Mushrooms, Acid, LSD, DMT *[7]*
Crystal methamphetamine (crystal meth, glass, ice, tina) *[8]*
Powder cocaine *[9]*
Crack cocaine *[10]*
Heroin *[11]*

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Other *[77]*
DK/R *[99]*

F17aa. *If drgintend_fu= "other":* **The last time you overdosed, what drug(s) did you intent to take:_____** *[drgintend_oth_fu]*

F17b. *If skill8_fu= "yes":* **The last time you overdosed, did you overdose on a drug that you thought might have contained fentanyl?** *[odfentsuspect_fu]*
Yes
No
DK/R

F17c. *If odfentsuspect_fu= "yes":* **The last time you overdosed on a drug that might have contained fentanyl, did you know it had fentanyl in it before you used it?** *[fentknwbfr_fu]*
Yes
No
DK/R *[DK]*

F17d. *If odfentsuspect_fu= "yes":* **The last time you overdosed, what reaction did you have to the drug or drugs mentioned above?** *(Read out list; check all that apply) [drgrct_fu]*
Lost consciousness/blacked out *[1]*
Blue or gray lips or skin *[2]*
Seizure *[3]*
Had a hard time breathing *[4]*
Elevated breathing *[5]*
Stopped breathing *[6]*
Inability to talk *[7]*
Not responsive to stimulus (like having your name called or physical contact) *[8]*
Overheating *[9]*
Irregular heart beat (fast, slow, irregular or palpitations) [*10]*
Paranoia *[11]*
Can't remember getting high *[12]*
None *[0]*
Other *[77]*
DK/R *[99]*

F17da. *If drgrct_fu= "other":* **The last time you overdosed, what reaction did you have to the drug or drugs mentioned above:_____** *[drgrct_oth_fu]*

F17e. Where were you the last time you overdosed? *[odplc_fu]*
Own place (room or apartment)
Partner's place

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Friend's place
Dealer's place
Street (alley, doorway, etc.)
Bathroom (any public washroom)
Park
Youth drop-in center
Parking lot
Car
Inside club or bar
House party
School
Abandoned house or building
Jail or prison
Crack house/shooting gallery
Other:_____
DK/R

F19. *If skill8_fu= "yes":* **The <u>last time</u> you overdosed, did someone with you call 911?** *[odcall_fu]*
Yes
No
DK/R

F19. *If skill8_fu= "yes":* **The <u>last time</u> you overdosed, did someone administer naloxone/Narcan?** *[odnarc_fu]*
Yes
No
DK/R

F20. *If odnarc_fu= "yes":* **The <u>last time</u> you overdosed, who gave you naloxone/Narcan?** *(Read out list; check all that apply)***.** *[narcw_fu]*
A police officer *[1]*
An ambulance official *[2]*
A health professional *[3]*
A friend *[4]*
A parent or relative *[5]*
Another person using drugs *[6]*
A stranger *[7]*
Someone else *[77]*
DK/R *[99]*

F20a. *If narcw_fu= "other":* **The <u>last time</u> you overdosed, who gave you naloxone/Narcan:_____** *[narcw_oth_fu]*

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F21. *If skill8_fu= "yes":* **The <u>last time</u> you overdosed, were you taken to the hospital?** *[odhosp_fu]*

Yes
No
DK/R

F22. *If odhosp_fu= "yes":* **The <u>last time</u> you overdosed and were taken to a hospital, were you offered referral to an addiction treatment program before discharge?** *[hoptxt_fu]*

Yes
No
DK/R

F23. *If odhosp_fu= "yes":* **The <u>last time</u> you overdosed and were taken to a hospital, were you given naloxone/Narcan at discharge?** *[hospnx_fu]*

Yes
No
DK/R

F24. *If odhosp_fu= "yes":* **The <u>last time</u> you overdosed and were taken to a hospital, did you see a peer recovery specialist, also known as a peer recovery coach?** *[peernx_fu]*

Yes
No
DK/R

F24a. *If skill8= "yes":* **In the <u>month before your last overdose</u>, were you in any of the following programs?** *(Read out list; check all that apply) [trtdurod_fu]*

Detoxification *[1]*
Methadone *[2]*
Buprenorphine/Suboxone/Subutex treatment *[3]*
Self-help group (like 12-step AA, NA) *[4]*
Outpatient drug or alcohol treatment program *[5]*
Day treatment program or partial hospitalization program *[6]*
Residential drug treatment program *[7]*
Another kind of treatment *[8]*
Jail or prison *[8]*
None of the above *[10]*
DK/R *[99]*

F27. I am concerned about my friends overdosing *[motiv16_fu]*

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Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

F28. I am concerned about overdosing *[motiv17_fu]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

F29. I get the support and resources I need from others to help me avoid an overdose. *[skill9_fu]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

F30. I am confident that I can ask someone to check on me after I use drugs, and call 911 if they think I am overdosing. *[motiv18_fu]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

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SECTION G: RAPIDS INTERVENTION (EXPERIMENTAL ARM ONLY)

Break for intervention booster session:
Pipe in response from F12, F28, and F29.

PIPE

G.0. Now I would like to talk to you about how you are doing with the change goals that we talked about the last time you were here.

INSERT OPEN ENDED TEXT BOX G.0.a

Interviewer Notes: Please summarize the participant's behavior change goals in the open ended text box. Please format them in the manner shown below.
Participant feels confident doing x, y, z
Participant would like to continue doing z
Participant rated themselves as X out of 10 in readiness to change
Participant chose this number on the readiness scale because of X
Participant rated themselves as X out of 10 in confidence to change
Participant said that X would make them more confident

Interviewer prompt: We would now like to ask you about your experiencing testing your drugs with the test strips we've given you. At the end of the interview, we can give you additional test strips for personal use. .

G1. I feel confident in my ability to test my own drugs for fentanyl. *[motiv6_in_fu]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

G2. I feel confident in my ability to read the results of the fentanyl test strips. *[motiv7_in_fu]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

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G2a.I know what to do once I get results from the fentanyl rapid tests *[resultsstrips_in_fu]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

G3. It will be easy for me to use the fentanyl test strips in the next month. *[motiv8_in_fu]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

G4. I plan to continue to use the testing strips. *[motiv9_in_fu]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

G5. Have you used a fentanyl test strip in the last month, either on your own or with people you use drugs with?? *[usetest_in_fu]*

Yes
No → skip to G8
DK/R → skip to G8

G6. *In usetest_in_fu= "yes";* **Of the 10 tests we gave you, how many tests did you use?** *[fen_str_in_fu]*

_____
DK/R

G7. Who performed the test? *(Read out list; check all that apply)* [*test_use_who_in_fu*]

I did it myself *[1]*
A close friend *[2]*
A casual friend or acquaintance *[3]*
A sex partner *[4]*
An immediate family or household member *[5]*
An extended family member *[6]*
A dealer *[7]*

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A stranger (like people on the street) *[8]*
Other *[77]*
DK/R *[99]*

G7a. *If test_use_who_in_fu= "other":* **Who performed the test:_____** *[test_use_who_in_oth_fu]*

G8.*In usetest_in_fu= "yes";* **In the last month, did you give any of the fentanyl test strips to someone else?** *[givetest_in_fu]*
Yes
No
DK/R

G9. *If givetest_in_fu= "yes";* **Who did you give the fentanyl test strips to?** *(Read out list; check all that apply) [give_test_who_in_fu]*
A close friend *[1]*
A casual friend or acquaintance *[2]*
A sex partner *[3]*
An immediate family or household member *[4]*
An extended family member *[5]*
A dealer *[6]*
A stranger (like people on the street) *[7]*
Other *[77]*
DK/R *[99]*

G9a. *If give_test_who_in_fu= "other";* **Who did you give the fentanyl test strips to:____** *[give_test_who_in_oth_fu]*

G10. In the last month, did you use want to use a fentanyl test strip, but were unable to? *[testunbl_in_fu]*
Yes
No
DK/R

G11. *If testunbl_in_fu= "yes";* **What got in the way of using the rapid fentanyl test strips** *(read out list, check all that apply) [testunable_why_in_fu]*
I did not have them on me *[1]*
I did not want to use any of my drug *[2]*
I did not have access to a private location to use them in *[3]*
I did not have the time to use them *[4]*
They were confiscated by a police officer *[5]*
They were taken by a friend, family member, or acquaintance [*6]*
I lost them *[7]*

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I was told not to use them by somebody that I inject with *[8]*
The person who prepares drugs for me doesn't like/use test strips *[9]*
The person who prepares drugs for me did not have any at the time *[10]*
I didn't know how to use them properly *[11]*
The ones I had were messed up or damaged *[11]*
They were not convenient to use *[12]*
I felt embarrassed/stigma *[13]*
Other *[77]*
DK/R *[99]*

G11a. *If testunable_why_in_fu= "other";* **What got in the way of using the rapid fentanyl test strips:_____** *[testunable_why_in_oth_fu]*

G12. <u>In the last month</u>, did you get any fentanyl test strips in addition to the 10 that we gave you? *[test_get_in_fu]*
Yes
No
DK/R

G13. *If test_get_in_fu= "yes";* **Where did the fentanyl test strips come from?** *(Read out list; Check all that apply)* [test_get_who__in_fu]
RAPIDS clinical trial *[1]*
Other research study *[2]*
AIDS Care Ocean State (ACOS) *[3]*
Project Weber/RENEW *[4]*
Another harm reduction organization *[5]*
Uncertain *[6]*
Other: *[77]*
DK/R *[99]*

G13a. *If test_get_who_fu= "Other";* **Where did the fentanyl test strips come from:_____** *[test_get_who_in_oth]*

G14. How many strips do you think you might use over the next month? *[fenstr_in_fu]*
_____ *(0-10)*
DK/R

G15. How much money are you willing to spend on a fentanyl test strip? *[sepndtest_in_fu]*

_____
DK/R

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G16. Where would you be most comfortable getting more fentanyl tests? *(Read out list; check all that apply) [gettest_in_fu]*

A pharmacy *[1]*
An online store *[2]*
A needle exchange Program *[3]*
A community-based organization *[4]*
A community health clinic *[5]*
A health department office *[6]*
Other *[77]*
DK/R *[99]*

G17. Do you think your friends would be interested in using the fentanyl test strips? *[fen_friends_in_fu]*

Yes
No
Not sure
DK/R

G18. Is there anything else you'd like to tell us today?
(Interviewer: Not required. Do not record identifying information here) [pptnotes_in_fu]

_____

_____

_____

Interviewer prompt: Thank you for participating in our survey. Your answers will help us . If you have remaining questions or concerns please contact a member of our study team. (Interviewer: Provide contact information. Then click Next to enter your Interviewer Data.)

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SECTION H: STANDARD OEND (CONTROL ARM ONLY)

Programmer prompt: ONLY IF C27 = YES , these questions will be asked at the end of the survey.

Interviewer prompt: We wanted to ask you a few questions about your experiences using fentanyl test stips because you told us that you used test strips earlier in the survey. For the first four questions, please tell us how much you disagree or agree with the following statements on a scale of strongly disagree to strongly agree.

H1. I feel confident in my ability to test my own drugs for fentanyl. *[motiv6_ctl_fu]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

H2. I feel confident in my ability to read the results of the fentanyl test strips. *[motiv7_ctl_fu]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

H2a.I know what to do once I get results from the fentanyl rapid tests *[resultsstrips_ctl_fu]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

H3. It will be easy for me to use the fentanyl test strips in the next month. *[motiv8_ctl_fu]*

Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

H4. I plan to continue to use the testing strips. *[motiv9_ctl_fu]*

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Strongly disagree	Disagree	Neutral	Agree	Strongly agree	DK/R

H5. Have you used a fentanyl test strip in the last month, either on your own or with people you use drugs with? *[usetest_ctl_fu]*

Yes
No → skip to H8
DK/R → skip to G8

H6. Who performed the test? *(Read out list; check all that apply)* [testusewho_ctl_fu]

I did it myself *[1]*
A close friend *[2]*
A casual friend or acquaintance *[3]*
A sex partner *[4]*
An immediate family or household member *[5]*
An extended family member *[6]*
A dealer *[7]*
A stranger (like people on the street) *[8]*
Other *[77]*
DK/R *[99]*

H6a. *If testusewho_ctl_fu= "other";* **Who performed the test:_____** *[testusewho_ctl_oth_fu]*

H7. Where did the fentanyl test strips come from?? *(Read out list; Check all that apply)* [test_get_who_ctl_fu]

RAPIDS clinical trial *[1]*
Other research study *[2]*
AIDS Care Ocean State (ACOS) *[3]*
Project Weber/RENEW *[4]*
Another harm reduction organization *[5]*
Uncertain *[6]*
Other: *[77]*
DK/R *[99]*

H7a. *If test_get_who_ctl_fu= "Other";* **Where did the fentanyl test strips come from:_____** *[test_get_who_ctl_oth]*

H8. <u>In the last month</u>, did you give any of the fentanyl test strips to someone else? *[GIVETEST]*

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Yes
No → skip to H10
DK/R → skip to H10

H9. Who did you give the fentanyl test strips to? *(Read out list; check all that apply) [give_test_who_ctl_fu]*

A close friend *[1]*
A casual friend or acquaintance *[2]*
A sex partner *[3]*
An immediate family or household member *[4]*
An extended family member *[5]*
A dealer *[6]*
A stranger (like people on the street) *[7]*
Other *[77]*
DK/R *[99]*

H9a. *If give_test_who_ctl_fu= "other";* **Who did you give the fentanyl test strips to:____** *[give_test_who_ctl_oth_fu]*

H10. <u>In the last month</u>, did you use want to use a fentanyl test strip, but were unable to? *[testunbl_ctl_fu]*

Yes
No → skip to G12
DK/R → skip to G12

H11. *If testunbl_ctl_fu= "yes";* **What got in the way of using the rapid fentanyl test strips** *(read out list, check all that apply) [testunable_why_ctl_fu]*

I did not have them on me *[1]*
I did not want to use any of my drug *[2]*
I did not have access to a private location to use them in *[3]*
I did not have the time to use them *[4]*
They were confiscated by a police officer *[5]*
They were taken by a friend, family member, or acquaintance [*6]*
I lost them *[7]*
I was told not to use them by somebody that I inject with *[8]*
The person who prepares drugs for me doesn't like/use test strips *[9]*
The person who prepares drugs for me did not have any at the time *[10]*
I didn't know how to use them properly *[11]*
The ones I had were messed up or damaged *[11]*
They were not convenient to use *[12]*
I felt embarrassed/stigma *[13]*

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Other *[77]*
DK/R *[99]*

H11a. *If testunable_why_in_fu= "other";* **What got in the way of using the rapid fentanyl test strips:_____** *[testunable_why_ctl_oth_fu]*

H14. How much money are you willing to spend on a fentanyl test strip? *[spendtest_ctl_fu]*

_____
DK/R

H15. Where would you be most comfortable getting more fentanyl tests? *(Read out list; check all that apply) [gettest_ctl_fu]*

A pharmacy *[1]*
An online store *[2]*
A needle exchange Program *[3]*
A community-based organization *[4]*
A community health clinic *[5]*
A health department office *[6]*
Other *[77]*
DK/R *[99]*

H15a. *If gettest_ctl_fu= "other";* **Where would you be most comfortable getting more fentanyl tests:_____** *[gestest_ctl_oth_fu]*

H16. Do you think your friends would be interested in using the fentanyl test strips? *[fen_friends_ctl_fu]*

Yes
No
Not sure
DK/R

H17. Is there anything else you'd like to tell us today?
(Interviewer: Not required. Do not record identifying information here) [pptnotes_ctl_fu]

_____

_____

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Interviewer prompt: Thank you for participating in our survey. Your answers will help us . If you have remaining questions or concerns please contact a member of our study team. (Interviewer: Provide contact information. Then click Next to enter your Interviewer Data.)

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SECTION I: INTERVIEWER DATA

I1. How would you rate the overall quality of the interview? *[quality_fu]*

High
Medium
Low
Very low

I2. Interview notes: *(Not required. Do not record identifying information here.) [intnotes_fu]*

_____

_____

_____

_____

_____

*Remember to click the **Submit** button!*

[END FOLLOW-UP ASSESSMENT]

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BLOOMBERG SCHOOL
of PUBLIC HEALTH

TECHNOLOGY	DETECTION LIMIT	SENSITIVITY		SPECIFICITY	
		Rhode Island Lab	Baltimore Lab	Rhode Island Lab	Baltimore Lab
BTNX Fentanyl Testing Strips (immunoassay)	0.13 micrograms/ml	96%	100%	90%	98%
TruNarc (Raman Spectroscopy)	25 micrograms/ml	4% (61% with SERS kit)	4% (39% with SERS kit)	100% (92% with SERS kit)	98% (92% with SERS kit)
Bruker Alpha (FTIR Spectroscopy)	3-4% weight, which is comparable to TruNarc	83%		90%	

Results

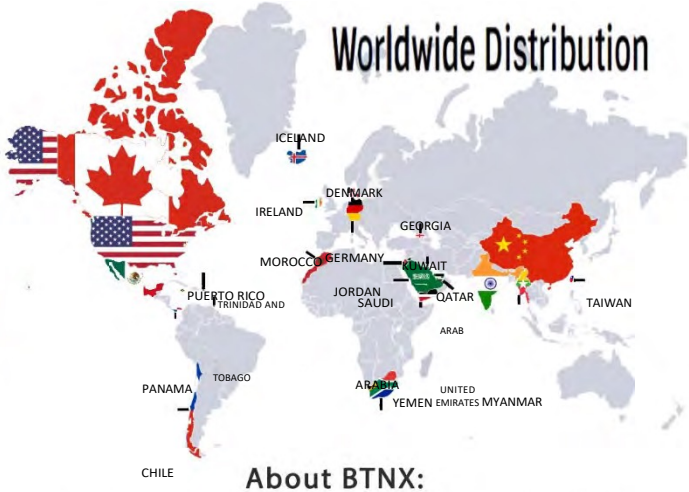
Johns Hopkins research shows that BTNX has the lowest detection limit as well as the highest accuracy of all 3 tests that were used in the research.

Link to Full Research: https://bit.ly/2HxmdnS

BTNX FENTANYL ANALOGUE LIST

BTNX INC.

Cross Reactivity List	
CARFENTANIL	BUTYRYL FENTANYL
P-FLUORO FENTANYL	ACETYL FENTANYL
FENTANYL	FURANYL FENTANYL
VALERYL FENTANYL	OCFENTANIL
3-METHYL FENTANYL	2-FLUOROFENTANIL
SUFENTANIL	NORFENTANYL



About BTNX:

BTNX Inc. is a biotechnology company and a world leader in rapid, point-of-care diagnostics. We specialize in innovation, research, development and manufacturing of advanced in-vitro diagnostic (IVD) tests for laboratories, clinics, hospitals and physicians' offices.

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BTNX INC.

Fentanyl Strips

FOR HARM REDUCTION USE

As tested by Johns Hopkins Bloomberg School of Public Health

Brown University IRB Amendment Approval: 11/09/2021
Brown University IRB Amendment Approval: 12/13/2021

Rapid Response

CONTACT US

Email: info@btnx.com

Toll Free: 1 - 888 - 339 - 9964 (US & Canada)

Website: www. btnx. com

Join Us on Facebook:
https://bit.ly/2HC7uHn

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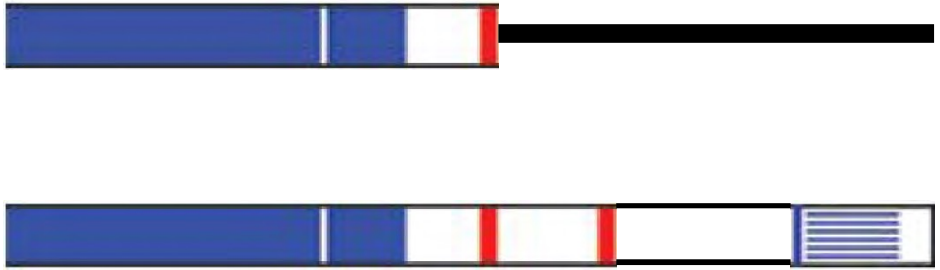

Positive for fentanyl

Use caut·on &

No drug use is 100o/o safe.

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Use with someone else around and always have naloxone

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How to use a fentanyl test strip to help prevent overdose

A deadly opioid called **fentanyl** is being added to drugs like **heroin cocaine, and ills.**

Fentanyl test strips can tell you whether or not you have fentanyl in your drugs. You can follow these steps to use a fentanyl test strip to prevent overdose.

Step 1 -Add water

Testing residue

Add 10 drops of sterile water to your cooker after you have drawn your shot and stir well.

Testing pills or powder

Add water to an empty bag with residue in it and mix well. If you have pills, break a piece off and stir it into water.

Step 2 -Test

Hold the blue end of your test strip and dip it into the water for 15 seconds. Be sure you only dip up to the wavy lines.

Step 3 - Wait

Wait two minutes until you can see lines show up in the middle.

Step 4 - Results

1 line - Positive for fentanyl

2 lines - Use caution

Read your test results. One line means that your drugs have fentanyl in them. **No drugs are 100% safe.**

What can I do after I get my test result?

1. I can have naloxone with me
2. I can have someone with me who can call 911 and give me naloxone if I overdose
3. I can go slow and use less

Find out more at **PreventOverdoseRI.org**

Prevent Overdose RI

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STEPS OF NALOXONE ADMINISTRATION

STEP 1: IDENTIFY OVERDOSE

Opioid overdose occurs when a person is unresponsive and not breathing or struggling to breathe.

Signs of opioid overdose:

- Does not wake up, even if you shake them or call their name
- Slow or no breathing
- Blue, grey, or pale skin color
- Small pupils
- Snoring sound

STEP 2: CALL 9-1-1

STEP 3: GIVE NALOXONE

INJECTION INTO MUSCLE

Needle-Syringe and Vial:

1. Open cap of naloxone vial.
2. Remove cap of needle, and insert into vial.
3. With the vial upside down, pull back plunger and draw up **1mL (1cc) of naloxone**. Naloxone vial may only have one dose, or may be a multi-dose vial.
4. Using a needle at least 1 inch long, inject into muscle in the upper arm.

OR

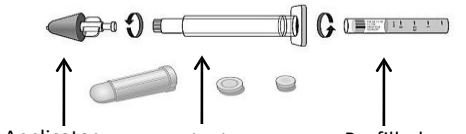
Auto-injector: Follow visual and voice instructions. Package contains instructions and a training device.

NASAL SPRAY

Multi-step nasal spray:

1. Remove yellow caps from ends of applicator.
2. Twist nasal adapter on tip of applicator until tight.
3. Take purple cap off of naloxone syringe, insert in other side of applicator and twist in until tight.

Push half of the naloxone (1mL/1cc) into each nostril. The naloxone vial contains 2mL, so you are giving **one half in one nostril and one half in the other nostril**.



OR

Single-step nasal spray: Peel back tab with circle to open, insert tip into either nostril and administer full dose. Entire dose is administered with one spray.

STEP 4: GIVE CPR AND/OR RESCUE BREATHING

If victim is not breathing or only gasping, begin CPR. CPR technique should be based on rescuer's level of training.

After giving naloxone **stay with the victim**.

Continue rescue breathing with **1 breath every 5 seconds**. If the victim is still not responding in **3 to 5 minutes**, give a second dose of naloxone. Continue rescue breathing until emergency responders arrive and make sure the victim does not take any more opioids.

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RESCUE POSITION:

If you have to leave someone alone at any time, like to call for help or to get naloxone, make sure that they are in the **rescue position**. Put the victim on his/her side with the top leg and arm crossed over the body. This makes it difficult for the victim to roll over, and lessens the chances that he/she will choke on vomit.

RESCUE BREATHING:

- Make sure nothing is in the person's mouth blocking their breathing.
- Place one hand on the chin and tilt the head back. With the other hand pinch the nose closed.
- Administer two slow breaths and look for the chest to rise.
- Continue administering 1 breath every 5 seconds until the person starts breathing on his or her own.
- If the victim is not responding in 3-5 minutes, give a second dose of naloxone and continue CPR/rescue breathing until help arrives.

WHO SHOULD GET NALOXONE?

- A person overdosing on opioids
  - Not responding to yelling or shaking
  - Not breathing or struggling to breath
- Overdose risk is greater when
  - People take increased amounts of opioids
  - Mix opioids with other drugs or alcohol
  - Have changes in opioid tolerance

WHAT IS NALOXONE?

Naloxone is a special medication used to stop an overdose. Opioid pain medications or drugs such as heroin can slow breathing and cause overdose. Naloxone is safe, effective, and easy to use.

EXAMPLES OF OPIOIDS:

MORPHINE (MS Contin®)
CODEINE
HYDROCODONE (Vicodin®, Norco®)
HYDROMORPHONE (Dilaudid®)
OXYCODONE (Percocet®, OxyContin®)
OXYMORPHONE (Opana®)
FENTANYL (Duragesic®)
METHADONE

The Rhode Island Good Samaritan Overdose Prevention Law protects people who overdose or seek help for someone overdosing from being charged or prosecuted for drug possession. Protection does not extend to drug trafficking or distribution charges.

For assistance with finding **addiction treatment, support groups, or recovery support services** in your community please call Rhode Island's dedicated hotline at **1-401-942-STOP**, or 1-401-942-7867

PREVENT OVERDOSE:

- Only take medication prescribed to you, and take it as directed
- Don't mix opioids with drugs or alcohol
- Store your medication in a safe and secure place and dispose of any unused medication
- Not taking opioids for a while changes tolerance levels, which means if you restart you need to start at a lower dose
- Teach your family and friends how to respond to an overdose

PRESCRIBE TO PREVENT

For more information about naloxone and opioid safety please visit, **www.prescribetoprevent.org**

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ATTACHMENT C: RECRUITMENT TEXT

Proposed text for online advertising and printed flyers:

Brown University Research Study: 18-65 year olds

Call or Text to see if you qualify: 401-441-9367

Are you 18-65 years old?

Do you live in Rhode Island?

Have you used drugs in the past 30 days?

If so, you might qualify for a research study about overdose in Rhode Island.

For this study, we are asking for SIX visits in person over the next year to meet with our trained research staff. Each visit will last one hour.

If you participate, you will get $35 for first and the last two visits, and $25 for the other three. You will get a total of $180 if you complete all visits. You will also get an additional $5 at three of the study visits if you agree to provide us with a blood sample from a finger stick. You will be compensated up to $195 for your participation. Participation is voluntary. You can find out more at sites.brown.edu/rapidsstudy.

Call or Text to see if you qualify: 401-441-9367
Email: rapids@brown.edu

If you have any questions about the study, Protocol# 1904002388, you can email Dr. Brandon Marshall at Brandon_Marshall@brown.edu

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Alternative text proposed for online advertising and printed flyers?

Are you interested in participating in a research study about overdose in Rhode Island?

Call or Text to see if you qualify: 401-441-9367

We are looking for people who:

- **Are 18-65 years old**
- **Live in Rhode Island**
- **Have used drugs in the past 30 day**

To participate in a research study about overdose in Rhode Island.

For this study, we are asking for SIX visits in person over the next year to meet with our trained research staff. Each visit will last one hour.

If you participate, you will get $35 for first and the last two visits, and $25 for the other three. You will get a total of $180 if you complete all visits. You will also get an additional $5 at three of the study visits if you agree to provide us with a blood sample from a finger stick. You will be compensated up to $195 for your participation. Participation is voluntary. You can find out more at sites.brown.edu/rapidsstudy.

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Alternative text proposed for online advertising and printed flyers

Would you like to learn of ways to better protect yourself from an overdose?

The RAPIDS study, a Brown University research study is seeking to help stop drug overdoses in Rhode Island. Adults 18-65 who live in Rhode Island and have used drugs in the last 30 days are invited. We will meet with you in person six times for about an hour over the course of a year. There is no cost for participation, and volunteers will be compensated up to $195 for participating in this research study. You can find out more at sites.brown.edu/rapidsstudy.

Or you can contact us by call, text, or email to see if you qualify to participate: (401) 441-9367, rapids@brown.edu

If you have questions about the protocol #1904002388, you can email Dr. Brandon Marshall, at Brandon_marshall@brown.edu

Alternative text proposed for online advertising and printed flyers

Are you interested in learning ways to better protect yourself from an overdose?

The RAPIDS team at Brown University is seeking to help stop drug overdoses in RI. Adults who have used drugs in the last 30 days and live in RI are invited. We will meet with you in person six times for about an hour over the course of a year. Participation is free and volunteers will be compensated up to $195 for participating in the study. You can find out more at sites.brown.edu/rapidsstudy.

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Alternative text proposed for online advertising and printed flyers

Do you use drugs and wonder how you can better protect yourself from an overdose?
Do you have thoughts on fentanyl you'd like to share?

The RAPIDS team at Brown University is seeking to help stop drug overdoses in RI. Adults who have used drugs in the last 30 days and live in RI are invited. We will meet with you in person six times for about an hour over the course of a year. Participation is free and volunteers will be compensated up to $195 for participating in the study. You can find out more at sites.brown.edu/rapidsstudy.

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Text to be used for Today@Brown

Subject line: Would you like to learn of ways to better protect yourself from an overdose?

The RAPIDS study, a Brown University research study is seeking to help stop drug overdoses in Rhode Island. Adults 18-65 who live in Rhode Island and have used drugs in the last 30 days are invited. We will meet with you in person six times for about an hour over the course of a year. There is no cost for participation, and volunteers will be compensated up to $195 for participating in this research study. You can find out more at sites.brown.edu/rapidsstudy.

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Use of Today@Brown for recruiting participants has been approved by Brown's Human Research Protection Program.

Alternative text for Today@Brown

Subject line: Are you interested in sharing your thoughts on fentanyl?

The RAPIDS team at Brown University is seeking to help stop drug overdoses in RI. Adults who have used drugs in the last 30 days and live in RI are invited. We will meet with you in person six times for about an hour over the course of a year. Participation is free and volunteers will be compensated up to $195 for participating in the study. You can find out more at sites.brown.edu/rapidsstudy.

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Alternative text for Today@Brown

Subject line*:* Do you wonder how you can better protect yourself from an overdose?

Do you have thoughts on fentanyl you'd like to share?

The RAPIDS team at Brown University is seeking to help stop drug overdoses in RI. Adults who have used drugs in the last 30 days and live in RI are invited. We will meet with you in person six times for about an hour over the course of a year. Participation is free and volunteers will be compensated up to $195 for participating in the study. You can find out more at sites.brown.edu/rapidsstudy.

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Text for radio advertisement

Brown University is recruiting for a Research Study. Are you 18-65 years old? Do you live in Rhode Island? Have you used drugs in the past 30 days? If so, you may qualify for a research study about overdose in Rhode Island. The study includes six in person meetings for an hour over the course of a year. Study participants will be compensated up to $195 for participating in this research study. Call or Text to see if you qualify: 401-441-9367 that's 441-9367.

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Revised Fliers

RAPIDS

Brown University Research Study

Do you use drugs and wonder how you can better protect yourself from an overdose? Do you have thoughts on fentanyl you'd like to share?

The RAPIDS study team of researchers at Brown University are seeking to help stop drug overdoses in RI.

Adults who have used drugs in the last 30 days and live in RI are invited. We will meet with you in person six times for about an hour over the course of a year. Participation is free and volunteers will be compensated up to $195 for participating in the study. You can find out more at sites.brown.edu/rapidsstudy.

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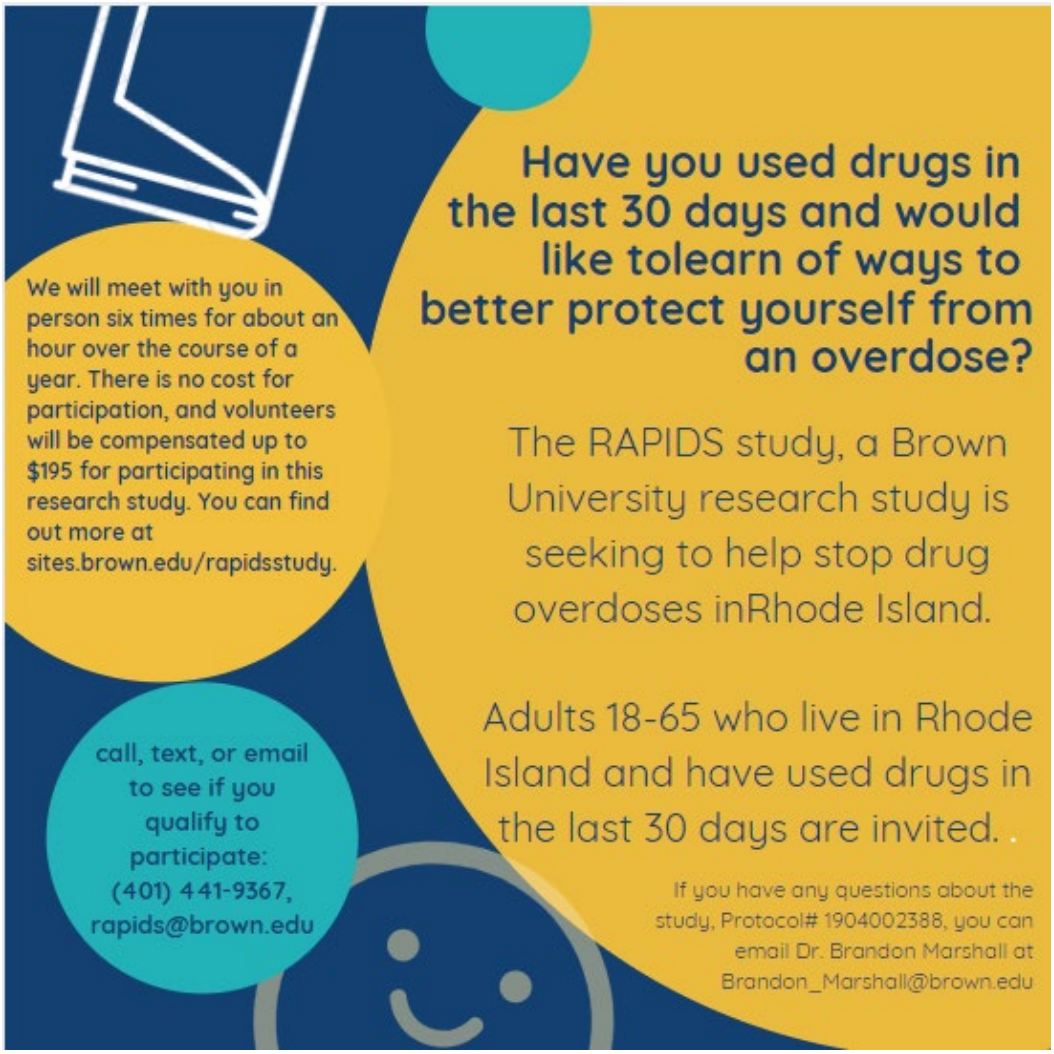

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THE RAPIDS TEAM AT BROWN UNIVERSITY IS SEEKING TO HELP STOP DRUG OVERDOSES IN RI.

ADULTS WHO HAVE USED DRUGS IN THE LAST 30 DAYS AND LIVE IN RI ARE INVITED. WE WILL MEET WITH YOU IN PERSON SIX TIMES FOR ABOUT AN HOUR OVER THE COURSE OF A YEAR. PARTICIPATION IS FREE AND VOLUNTEERS WILL BE COMPENSATED UP TO $195 FOR PARTICIPATING IN THE STUDY.

FIND OUT MORE AT SITES.BROWN.EDU/RAPIDSSTUDY.

YOU CAN CONTACT US BY CALL, TEXT, OR EMAIL TO SEE IF YOU QUALIFY: (401) 441-9367, RAPIDS@BROWN.EDU

IF YOU HAVE QUESTIONS ABOUT THE PROTOCOL #1904002388, YOU CAN EMAIL DR. BRANDON MARSHALL, AT BRANDON_MARSHALL@BROWN.EDU

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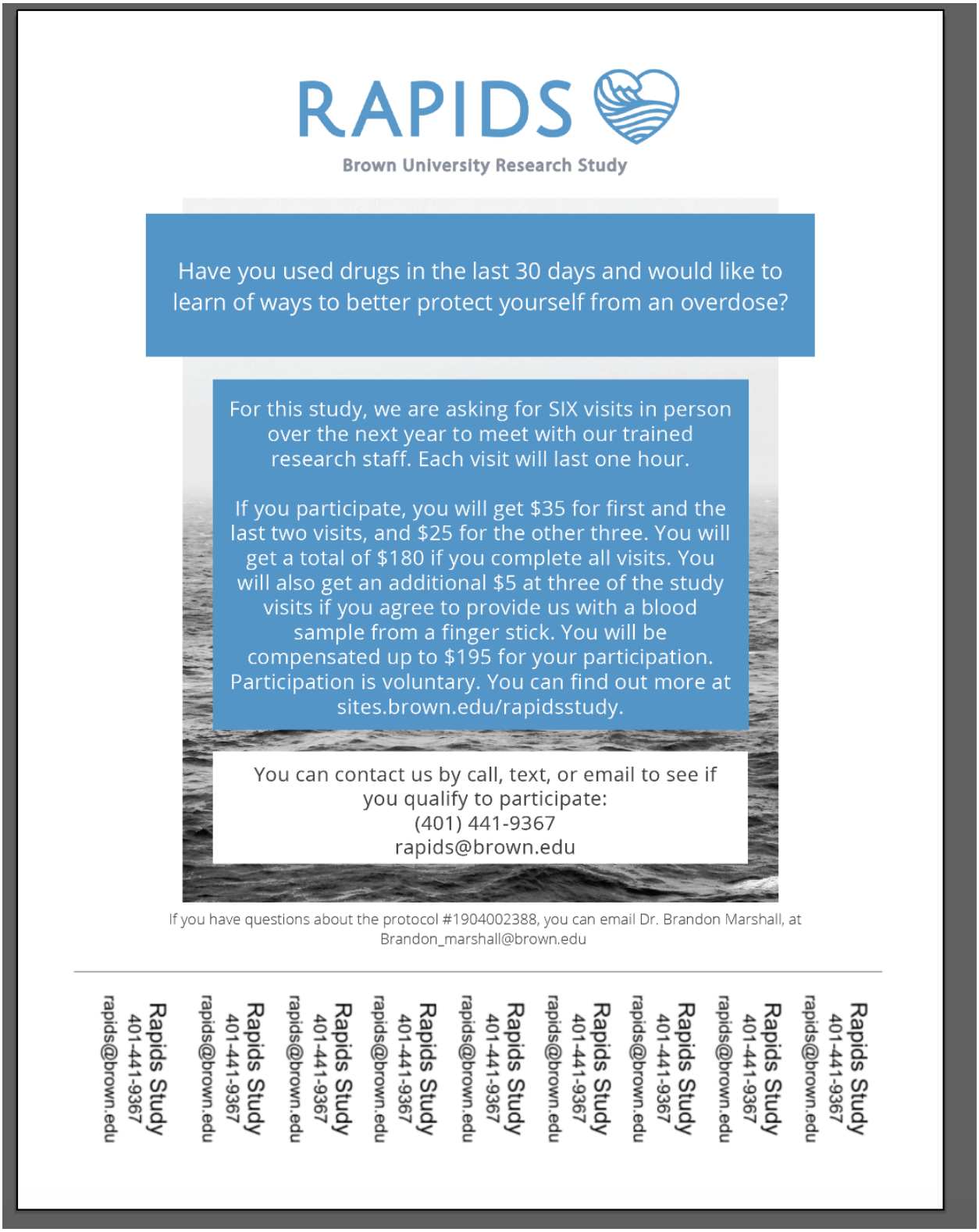

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Appointment cards:

(Front)

Call, text, or email: 401-441-9367, rapids@brown.edu

(Back)

Your next visit:

Date:_____

Time:_____

Place:_____

Call, text, or email to reschedule: 401-441-9367, rapids@brown.edu

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Hello,

We have tried to reach you about the RAPIDS study at Brown University to schedule your next study visit. Please give us a call or come to our office at 121 S. Main Street, Providence so we can schedule your visit.

From,
The RAPIDS Study

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Call, text, or email to reschedule: 401-441-9367, rapids@brown.edu
Or visit us at 121 S. Main Street, Providence, RI, 02912

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Call, text, or email: 401-441-9367, rapids@brown.edu

Screenshots from Website:

RAPIDS

Have you used drugs in the last 30 days and would like to learn of ways to better protect yourself from an overdose?

The RAPIDS study, a Brown University research study is seeking to help stop drug overdoses in Rhode Island. Adults 18-65 who live in Rhode Island and have used drugs in the last 30 days are invited. We will meet with you in person six times for about an hour over the course of a year. There is no cost for participation, and volunteers will be compensated up to $195 for participating in this research study.

You can contact us by call, text, or email to see if you qualify to participate: (401) 441-9367, rapids@brown.edu

Click to download our consent form for the screening process.

Click to download our list of harm reduction, treatment and general healthcare resources.

You can find us at 121 South Main street.

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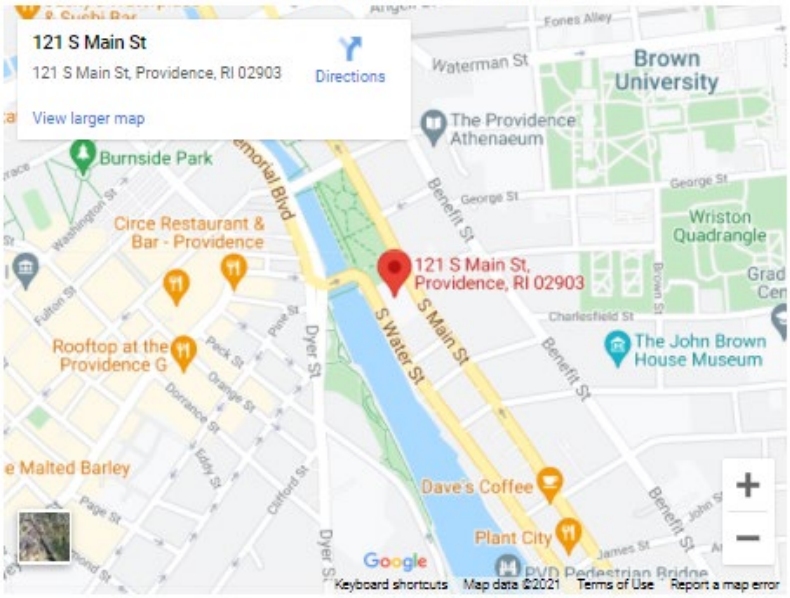

If you have any questions about the study, Protocol # 1904002388, you can email Dr. Brandon Marshall at Brandon_Marshall@brown.edu

PPHC people place & health collective

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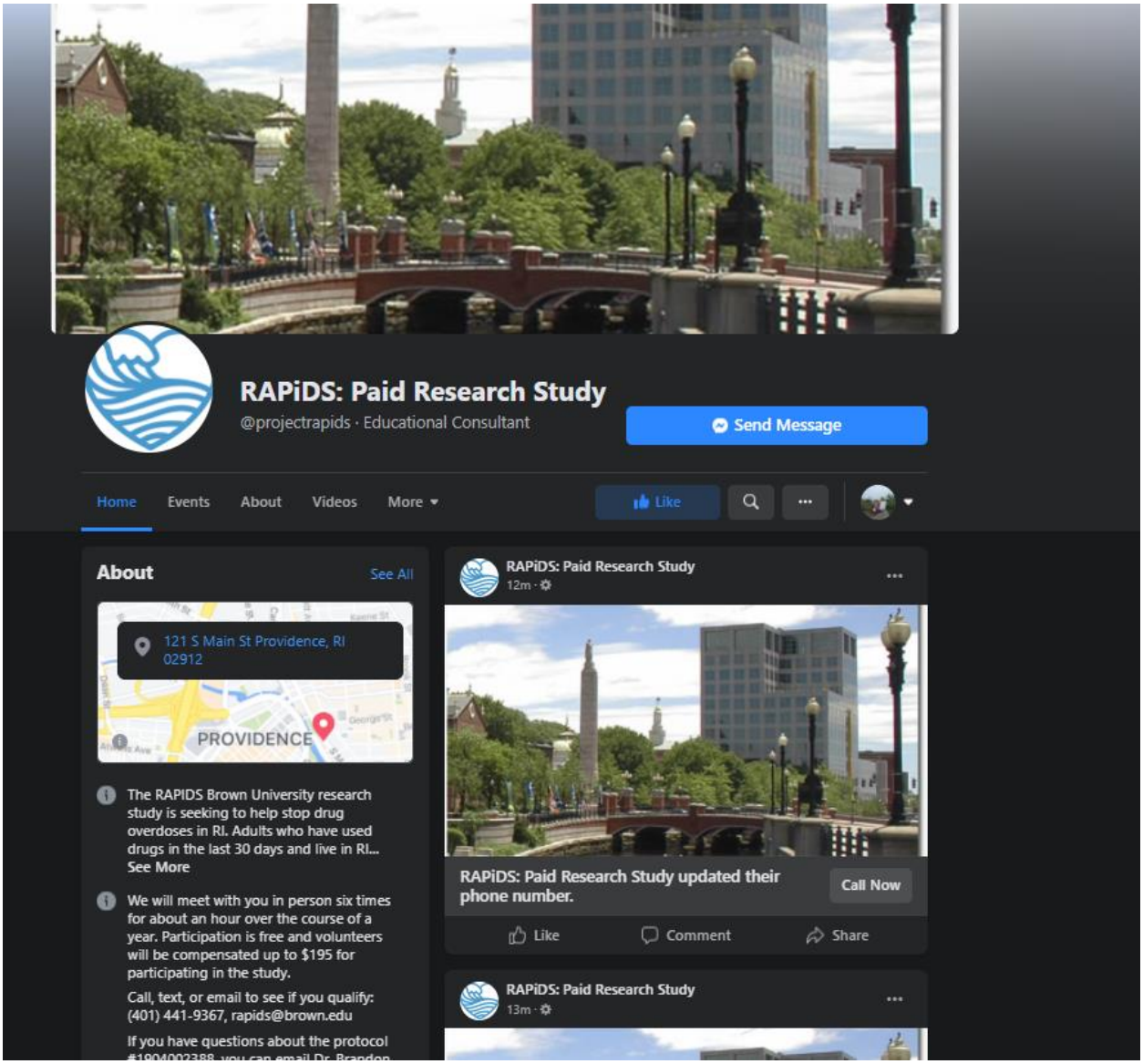

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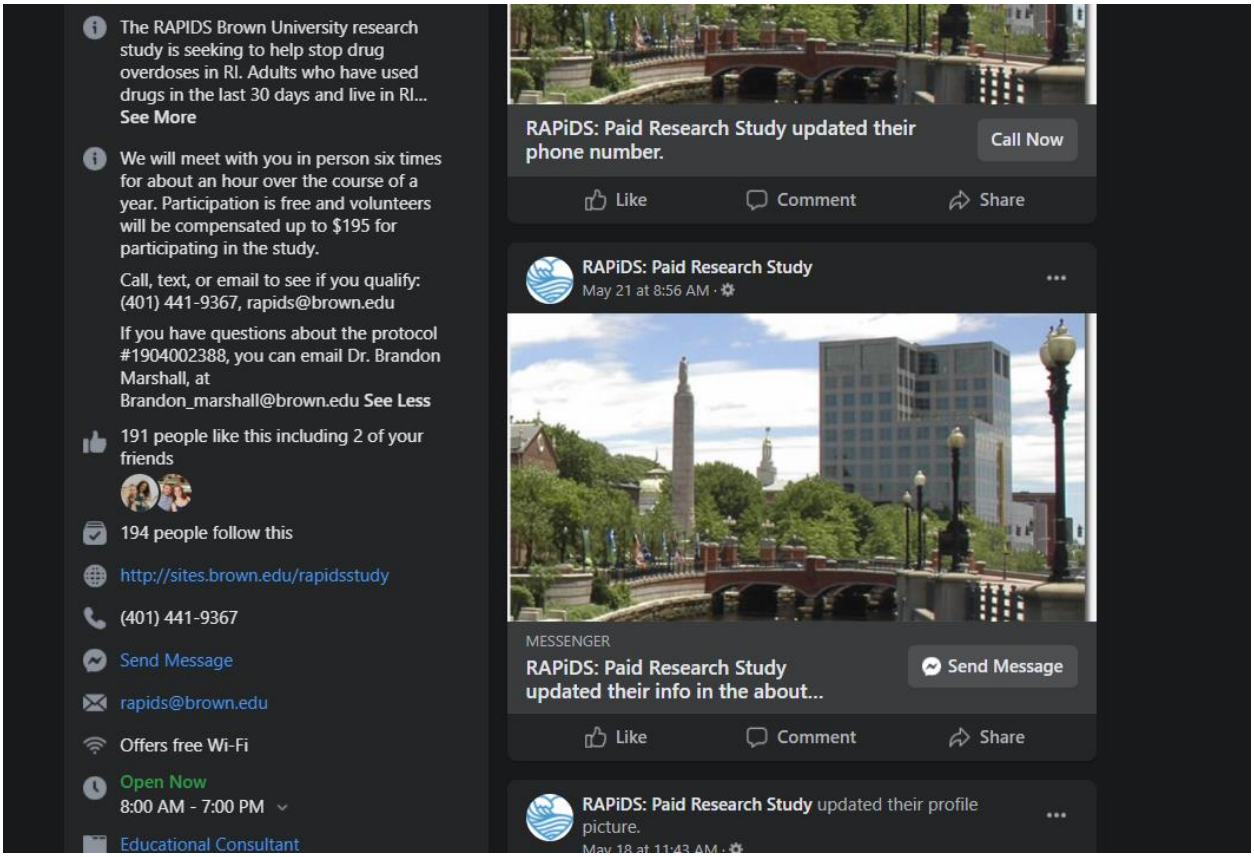

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ADDENDUM XIX
BUSINESS ASSOCIATE AGREE MENT

Ex:cept as otherwise provided in this Business Associate Agreement Addendum, **BROWN UNIVERSITY,** (hereinafter refened to as "Bus in ess Associate"), may use, access or disclose Protected Health Information to perfmm functions, activities or services for or on behalf of the State of Rhode lsland, Department of Health (hereinafter referred to as the "C overed Ent ity"), as specified herein and the attached Agreement between the Business Associate and the Covered Entity (hereinafter referred to as "the Agreement"), which this addendum supplements and is made part of, provided such use, access, or disclosure does not violate the Health Insurance Portability and Accountability Act (HIPAA), 42 USC 1320d et seq., and its implementing regulations includin g, but not limited to, 45 CFR, parts 160, 162 and 164, hereinafter referred to as the Privacy and Security Rules and patient confidentiality regulations, and the requirements of the Health Information Tec hnology for Economic and Clinical Health Act, as incorporated in the American Recovery and Reinvestment Act of 2009, Public Law 111-5 (HITECH Act) and any regulations adopted or to be adopted pursuant to the HITECH Act that relate to the obligations of business associates, Rhode Island Mental Health Law, R.l. General Laws Chapter 40.1-5-26, and Confidenti ality of Health Care Communica tions and Tnfonnation Act, R.I. General Laws Chapter 5-37.3-1 et seq. Business Associate recognizes and agrees it is obligated by law to meet the applicable provisions of the HITECH Act.

1. Definitions

A. Generally:
(1) Terms used, but not otherwise defined, in this Addendum sha11 have the same meaning as those terms in 45 C.F.R. §§ 160.103, 164.103 , and 164 .304, 164.501 and 164.502.

(2) The following terms used in this Addend um shall have the same meaning as those tenns in the HIPAA, the Privacy and Security Rules and the HITECH Act: B reach, Data Aggregation, Designated Record Set, Disclosure, Heal th Care Oper a tions, Individual, Minllnum Necessary, Notice of Privacy Practices, Protec ted Health Infonnatibn, RequiredBy Law, Secretary, Security Incident, Subcontractor, Unsecured Protected Health Information, and Use.

B. Specific:

(1) "Addendum " means this Business Associate Agreement Addendum .

(2) "Agreement" means the contractual Agreement by and between . the State of Rhode Island, Department of Health and Business Associate, awarded pursuant to State of Rhode Island ' s Purchasing Law (Chapter 37-2 of the Rhode Island General Laws) and Rhode Isla nd Depaitment of Administration, Division of Purcb ases, Purchasing Rules, Regulations , and General Conditions of Purchasing.

A. "Business Associate" generally has the same meaning as the tenn "business associate" at 45 CFR 160.103, and in reference to the party to this Addendum, shall mean **BROWN UNTVERSJT Y.**
B. "Client/Patient" means Covered Entity funded person who is a recipient and/or tbe client or patient of the Bus iness Associate.
C. "Covered Entity" generally has the .same meaning as the term "covered entity" at 45 CFR 160.103 , and in reference to the party to this Addendum, shall mean Department of Health.
D. "Elect ronic Health Record" means an electronic record of health-related info1mation on an individual that is created, gathered, managed or consulted by authorized health care clin icians and staff.
E. "Electronic Protected Health Information" or "El e ctron ic PHI" means PHI that is transmitted by or mainta ined in electronic media as defined in the HIPA Security Regulat ions.
F. "HIPAA" means the Health Insurance Portability and Accountability Act of 1996, Public Law 10.4-191.
G. "HIPAA Privacy Rule" means the regulations promulgated under HlPAA by the United States Depmtment of Health and Human Services to protect the privacy of Protected Health Infom1ation in cluding, the Privacy, Sec urity, Breach Noti fication, and Enforcement Rules at 45 CFR Part 160 and Part 164.
H. "HJTECH Act" means the privacy, security and security Breach notification provisions applicable to Business Associate under Subtitl e D of the Health lnfortnation Technology for Economic and Clinical Health Act, which is Title XU of the American Recovery and Reinvestment Act of 2009, Publ ic Law I 11-5, and any regulations promulgated thereunder and as amended from time to time.

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I. "Secured PHl" means PHI that was rendered unusable, unreadable or indecipherable to unauthorized individuals through the use of technologies or methodologies specified under or pursuant to Section 13402 (h)(2) of the HITECH Act under ARRA.

J. "Security Incident" means any known successful or unsuccessful attempt by an authorized or unauthorized individual to inappropriately use, disclose , modi fy, access, or destroy any information.

K. "Security Rule" means the Standards for the security of Electronic Protected Health lnfonnation found at 45 CFR Parts 160 and 162, and Part 164, Subparts A and C. The application of Security provisions Sections 164.308, 164.310, 164.312, and I 64.316 of title 45, Code of Federal Regulations shall apply to Business Associate of Covered Entity in the same manner that such sections apply to the Covered Entity.

L. "Suspected breach" is a suspected acquisition, access, use or disclosure of protected health information ("PHl") in violation of HIPPA privacy rules, as referenced above, that compromises the security or privacy of PH1.

M. "Unsecured PHl" means PHI that is not secured as defined in this section, through the use of a technology or methodology specified by the Secretary of the U.S. Department of Health and Human Services.

2. Obligations and Activities of Business Assocjate

A. Business Associate agrees to not use or further disclose PHI other than as permitted or requlred by this Addendum or as required by Law, provided such use or disclosure would also be permissible by law by Covered Entity.

B. Business Associate agrees to use appropriate safeguards to prevent use or disclosure of the Pffi other than as provided for by this Addendum. Business Associate agrees to implement Administrative Safeguards, Physical Safeguards and Technical Safeguards ("Safeguards") that reasonably and appropriately protect the confidentiality, integrity and
availability of PHT as required by the "Security Rule."

C. Business Associate agrees to mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a use or disclosure of PHI by Business Associate in violation of the requirements of this Addendum.

D. Business Associate agrees to report to Covered Entity any use or disclosure of the PH[not provided for by this Addendum, including breaches of unsecured PHI as required by 45 C.F.R. § 164.410, and any Security Incident ofwhicb it becomes aware, within five (5) days of theincident.

E. Business Associate agrees to ensure that any agent, including a subcontractor or vendor, to whom it provides PHI received from, or created or received by Business Associate on behalf of Covered Entity agrees to the same restrictions and conditlons that apply through this Addendum to Business Associate with respect to such information through a contractual an-angement that complies with45 C.F.R. § 164.314.

F. Business Associate agrees to provide paper or electronic ae-cess, at the request of Covered Entity and in the time and manner designated by Covered Entity, to PHI in a Designated Record Set to Covered Entity or, as di rected by Covered Entity, to an Individual in order to meet the requirements under 45 C.F.R. § 164.524. lfthe Individual requests an electronic copy of the information, Business Associate must provide Covered Entity with the infonnation requested in the electronic form and format requested by the Individual and /or Covered Entity if it is readily producible in such form and format; or, if not, in a readable electron ic form and format as requested by Covered Entity.

G. Business Associate agrees to make any amendment(s) to PHI in a Designated Record Set that Covered Entity directs or agrees to pursuant to 45 *C.F*.R. §164.526 at the request of Covered Entity or an Individual, and in the time and manner designated by Covered Entity. If Business Associate receives a request for amendment to PHI directly from an l□dividua l, Business Associate shall notify Covered Entity upon receipt of such request.

H. Business Associate agrees to make its internal practices, books, and records relating to the use and disclosure of PHI received from, created or received by Business Associate on behalfof Covered Entity available to Covered Entity, or at the request of Covered Entity to the Secretary, in a time and manner designated by Covered Entity or the Secretary, for the purposes of the Secretary determining compliance with the Privacy Rule and Security Rule.

I. Business Associate agrees to document such disclosures of PHI and information related to such disclosures as would be required for Covered Entity to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with 45 C.F.R. §164.528.

J. Business Associate agrees to provide to Covered Entity or an Individual, in a time and manner designated by Covered Entity, infonnation collected in accordance with this Addendum, to pe1mit Covered Entity to respond to a request by an individual for an accounting of disclosures for PHI in accordance with 45 §C.F.R. 164.528.

K. If Business Associate accesses, maintains, retains, modifies, records, stores, destroys, or otherwise holds, uses, or discloses Unsecmed Protected Health Information (as defined in 45 C.F.R. § 164.402) for Covered Entity, it shall, following the discovery of a breach of such info rmation, notify Covered Entity of such breach within a period of five
(5) days after discovery of the breach . Such notice shall include: a) the identification of each individual whose

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Unsecured Protected Health Infonnation has been, or is reasonably believed by Business Associate to have been accessed, acquired or disclosed during such breach; b) a brief description of what happened, including the date of the reach and discovery of the breach; c) a description of the type of Unsecured PHI that was involved in the breach; d)

a description of the investigation into the breach, mitigation of harm to the individuals and protection against further breaches; e) the results of any and all investigation performed by Business Associate related to the breach; and t) contact information of the most knowledgeable individual for Covered Entity to contact relating to the breach and its investigation into the breach.

L. To the extent the Business Associate is carrying out an obligation of the Covered Entity's under fhe Privacy Rule, the Business Associate must comply with the requirements of the Privacy Rule that apply to the Covered Entity in the performance of such obligation.

M. Business Associate agrees that it will not receive remuneration directly or indirectly in exchange for PHI without authorization unless an exception under 45 C.F.R. § 164.502(a)(5)(ii)(B)(2) applies.

N. Business Associate agrees that it will not receive remuneration for certain communications that fall within the exceptions to the definition of Marketing under 45 C.F.R. §164.501, unless permitted by 45 C.F.R. § 164. 508(a)(3)(A)-(B).

0. If applicable, Business Associate agrees that it will not use or disclose genetic information for underwriting purposes, as that term is defined in 45 C.F.R. § 164.502.

P. Business Associate hereby agrees to comply with state laws and rules and regulations applicable to PHJ and personal information of individuals' information it receives from Covered Entity during the term of the Agreement.

i. Business Associate agrees to: (a) implement and maintain appropriate physical, technical and administrative security measures for the protection of personal information as required by any state law and rules and regulations ; including, but not limited to: (i) encrypting all transmitted records and files containing personal infonnation that will travel across public networks, and encryption of all data containing personal infonnation to be transmitted wirelessly; (ii) prohibiting the transfer of personal information to any portable device unless such transfer has been approved in advance; and (iii) encrypting any personal information to be transferred to a portable device; and (b) implement and maintain a Written Information Security Program as required by any state law as applicable.

ii. The safeguards set forth in this Addendum shall apply equally to PHI, confidential and "personal information." Personal information means an individual's first name and last name or first initial and last name in combination with any one or more of the following data elements that relate to such resident: (a) Social Security number; (b) driver's license number or state issued identification card number; or (c) financial account number, or credit or debit card number, with or without any required security code, access code, personal identification number or password, that would permit access to a resident's financial account; provided, however, that "personal information" shall not include information that is lawfully obtained from publicly available information, or from federal, state or local government records lawfully made available to the general public.

3. Permitted Uses and Disclosures by Business Associate

A. Except as otherwise limited to this Addendum, Business Associate may use or disclose PHI to perform functions, activities, or services for, or on behalf of, Covered Entity as specified in the Service Arrangement, provided that such use or disclosure would not vioJate the Privacy Rule if done by Covered Entity or the minimum necessary policies and procedures of Covered Entity required by 45 C.F.R. § 164.514(d).

B. Except as otherwise limited in this Addendum, Business Associate may use PHI for the proper management and administration of the Business Associate or to can-y out the legal responsibilities of the Business Associate.

C. Except as otherwise limited in this Addendum, Business Associate may disclose PHI for the proper management and administration of the Business Associate, provided that disclosures are Required By Law, or Business Associate obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as Required By Law or for the purpose for which it was disclosed to the person, and the person notifies the Business Associate of any instances of which it is aware i:n which the confidentiality of the information has been breached.

D. Except as otherwise limited in this Addendum , Business Associate may use PHI to provide Data Aggregation services to Covered Entity as permitted by 45 C.F.R. §164.504 (e)(2)(i)(B).

E. Business Associate may use PHI to report violations oflaw to appropriate Federal and State authorities, consistent with 45 C.F.R. §164.502U)(l).

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4. Obligations of Covered Entity

A. Covered Entity shall notify Business Associate of any limitation(s) in its notice of privacy practices of Covered Entity in accordance with 45 C.F.R. § 164.520 , to the extent that such limitation may affect Business Assoc.iate's use or disclosure of PHI.

B. Covered Entity shall notify Business Associate of any changes in, or revocation of, pe1mission by an Individual to use or disclose PHl to the extent that such changes may affect Business Associate's use or disclosure of PHI.

C. Covered Entity shall notify Business Associate of any restriction to the use or disclosure of Pl-II that Covered Entity has agreed to in accordance with 45 C.F.R. § 164.522, to the extent that such restriction may affect Business Associate's use or disclosure of PHI.

5. Permissible Requests by Covered Entity

Covered Entity shall not request Business Associate to use or disclose PHI in any manner that would not be pem,issible under the Privacy Rule if done by Covered Entity, provided that, to "the extent permitted by the Service A1Ta ngement , Business Associate may use or disclose PHI for Business Associate's Data Aggregation activities or proper management and administrative activities.

6. Term and Termination

A. The term of this Addendum shall begin as of the effective date of the Service Arrangement and shall terminate when all of the PHI provided by Covered Entity to Business Associate, or created or received by Business Associate on behalf of Covered Entity, is destroyed or returned to Covered Entity, or, if it is infeasible to return or destroy PHI, protections are extended to such information, in accordance with the termination provisions of this Section.

B. Upon Covered Entity's knowledge of a material breach by Business Associate, Covered Entity shall either:

   i. Provide an opportunity for Business Associate to ci.ire the breach or end the violation and terminate this Addendum and the Service Arrangement if Business Associate does not cure the breach or end the violation within the time specified by Covered Entity .
   ii. Immediately terminate this Addendum and the Service arrangement if Business Associate has breached a material term of this Addendum and cure is not possible .

C. Except as provided in paragraph (d) ofthis Section, upon any termination or expiration ofthis Addendum, Business Associate shall return or destroy all Pm received from Covered Entity, or created or received by Business Associate on behalf of Covered Entity. This provision shall apply to PHI that is in the possession of subcontractors or agents of Business Associate. Business Associate shall retain no c;opies of the PHI. Business Associate shall ensure that its subcontractors or vendors return or destroy any of Covered Entity's PHI received from Business Associate.

D. In the event that Business Associate determines that returning or destroying the PHI *is* infeasible , Business Associate shall provide to Covered Entity notification of the conditions that make return or destruction infeasible. Upon Covered Entity's written agreement that return or destruction of PHI is infeasible, Business Associate shall extend the protections of this Addendum to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Business Associate maintains such PHI.

7. Miscellaneous

A. A reference in this Addendum to a section in the Privacy Rule or Security Rule means the section as in effect or as amended.

B. The Parties agree to take such action as is necessary to amend this Addendum from time to time as is necessary for Covered Entity to comply with the requirements of HIPAA, the Privacy and Security Rules and HITECH.

C. The respective rights and obligations of Business Associate under Section 6 (c) and (d) of this Addendum shall survive the termination of this Addendum.

D. Any ambiguity in this Addendum shall be resolved to pe1mit Covered Entity to comply with HIP AA and HiTECH.

E. Business Associate is solely responsible for all decisions made by Business Associate regarding the safeguarding of PHI.

F. Nothing express or implied in this Addendum is intended to confer, nor shall anything herein confer upon any person other than Covered Entity, Business Associate and their respective successors and assigns, any rights, remedies, obligations or liabilities whatsoever.

G. Modification ofthe terms of this Addendum shall not be effective or binding upon the parties unless and until

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suc;h modification is committed to writing and executed by the parties hereto.

H. This Addendum shall be binding upon the parties hereto, and their respective legal representatives, trustees, receivers, successors and permitted assigns.

I. Should any provision of this Addendum be found unenforceable, it shall be deemed severable and the balanc e of the Addendum shall continue in full force and effect as if the unenforceable provision had never been made a part hereof.

J. This Addendum and the rights and obligations of the patiies hereunder shall in all respects be governed by, and construed in accordance with, the law s of the State of Rhode Tsland, including all matters of construction, validity and per formance.

K. Al l notices and comm unications required or permitted to be given hereunder shall be sent by certified or regular mail, addressed to the other part as its respective address as shown on the signature page, or at such other address as such party shall from time to time designate in writing to the other party, and shall be effective from the da te of mailing .

L. This Addendum , including such portions as are incorporated by reference herein , c onsti tutes the entire agreement by, between and among the parties, and such parties acknowledge by their signature hereto that they do .not rel y upon any representations or undertakings by any person or party, past or future, not expressly set forth in writing herein.

M. Busi11ess Associate shall maintain or cause to be maintained sufficient insurance coverage as shall be necessary to insure Business Associate and its employees, agents, representatives or subcontractors against any and all claitns or claims for damages arising under this Addendum and such insurance coverage shall apply to all services provided by Business Associate or its agents or subcontractors pursuant to this Addendum . Business Associate shall indemnify, hold hannless and defend Covered Entity from and agains t any and all claims, losses, liabilities, costs and other expenses (including but not limited to, reasonable attorneys' fees and costs, administrative penalties and fines, costs expended to notify individuals and/or to prevent or remedy possible identity theft, financial hann, reputation al haim , or any other claims of ham1 related to a bre ach) incurred as a result of, or arising directly or indirectly out of or in connection with any acts or ornissions of Business Associate, its employees, agents, repres entatives or subcontractors, under this Addendum, including, but not limited to, negligent or intentional acts or omissions. This provision shall survive termination ofthis Addendum.

8. Acknowledgment

The undersigned affirms that he/she is a duly authorized representative of the Business Associate for which he/she is signing and has the authority to execute this Addendum on behalfofthe Business Ass ociate.

Acknowledged and agreed to by:

Rhode Island Department of Health

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Nicole Alexander-Scott, MD, MPH
Director of Health

Date: \..J. / L{I

BROWN UNIVERSITY

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Patrice A. Carroll, Director
Office of Sponsored Projects
Brown University

Patrice Carroll
Brown University

Date: 12:2ft2a £1

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DATA AND SAFETY MONITORING PLAN

Protocol Title: The Rhode Island Prescription and Illicit Drug Study (RAPIDS): Responding to Fentanyl and Associated Harms

NIH Grant Application Number: R01DA047975-01
Institution: BROWN UNIVERSITY
Principal Investigator: Brandon DL Marshall, PhD

IRB STATUS: Submitted 12/13/2018, Revised 03/31/2019, Conditionally Approved 04/18/2019, Resubmitted 5/20/2019

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A1. Summary of the Protocol

Study Design

We will enroll 550 adults into a two-arm, randomized clinical trial. Interviewer-administered questionnaires will be conducted at baseline, along with follow-up visits at 4-, 8-, and 12- months post-randomization. Experimental arm participants will receive the RAPIDS intervention and will be provided with ten fentanyl test strips for personal use. Motivational interviewing "booster" sessions (with additional test strips distributed on an as-needed basis) will be conducted a 1, 2, and 3, months. Participants in the attention-matched control arm will be followed at the same intervals and will receive a standard overdose education and naloxone distribution (OEND) training program. To meet our recruitment goals, we aim to conduct 20 baseline visits per month starting in Year 1, Quarter 3 and continuing until full enrollment is reached.

Primary and Secondary Outcome Measures

The primary outcome will be the rate of self-reported overdose observed over the 12-month follow up period. We will supplement the primary endpoint with data on fatal overdose events ascertained through a CDC-funded statewide overdose surveillance system.

Inclusion/Exclusion Criteria

Inclusion Criteria: We will enroll adults who: (a) are 18 to 65 years of age; (b) reside in Rhode Island; (c) are able to complete interviews in English; (d) are able to provide informed consent; and (3) self-report use of heroin, illicit stimulant use (e.g., powder cocaine, crack, methamphetamine), injection drug use, or use of counterfeit prescription pills (defined as prescription pills obtained through the illicit drug market) in the past 30 days (regardless of treatment status). Participants who refuse consent to participate, are unable to provide informed consent due to altered mental status, or who cannot adequately hear and/or comprehend either consent process, will not be enrolled. To assess counterfeit prescription pill use, participants will be asked if they purchased any prescription medications "on the street" (e.g., from a drug dealer), including opioids, benzodiazepines, and stimulants. We will not enroll vulnerable populations such as prisoners, children, etc.

Exclusion Criteria: We will exclude participants who exclusively misuse medications obtained from a physician or diversion from someone else's prescription.

Power Calculation and Sample Size

We are seeking IRB approval for *n*=550 participants enrolled in the study. We provide power calculated for key outcomes below, based on an enrollment of 500 participants (n=250 per arm) to account for attrition. The following assumptions are based on findings from our pilot intervention study. First, at baseline, 37% of participants reported a lifetime history of overdose, and 11% reported an overdose in the past six months. As such, for the primary analyses, we assumed that 20% of participants in the control arm will experience an overdose during the 12-month follow-up period. Second, we conservatively assumed an 80% retention rate in the trial, although we were able to retain 90% of pilot participants.

Given these assumptions, we have >80% power to detect a 50% reduction in overdoses (i.e., the primary endpoint for Aim 1, see Research Strategy section C.9, Figure 6A). Similar effect sizes were assumed for an ED-based overdose prevention intervention,[214] and have been deemed as a benchmark for success by key stakeholders. For the second endpoint in Aim 1 (time to first fatal overdose or ED visit related to an overdose), we conservatively assumed that only 38% of self-reported overdoses would result in death or presentation to the ED, based on previously published data,[65] for a rate of 8 per 100 person-years in the control arm. As

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shown in Figure 6B (see section C.9), we have ≥80% power to detect a 50% reduction in the hazard of fatal overdose or ED visit for an overdose. Finally, we used a method to estimate sample size for evaluating mediation by joint testing of both links in an indirect pathway from exposure to mediator to outcome (Aim 2).[215] Given the assumptions described above, we have >80% power to detect a statistically significant mediated effect for a coefficient for exposure on mediator and mediator on outcome of at least 0.8, respectively.

B1. Trial Management

List of Data Collection Centers

The study will consist of interviewer-administered, computer-assisted surveys conducted by professionally trained and supervised interviewers at the centrally located Brown University School of Public Health in Providence, Rhode Island.

Target population distribution (eg women, minorities, etc)

(Also included in the Inclusion and Enrollment Report of the PHS Human Subjects and Clinical Trials form)

Based on preliminary data, we predict the following enrollment:

Race:

American Indian/Alaska Native	2% (n=10)
Asian	1.5% (n=8)
Native Hawaiian/Other Pacific Islander	1% (n=5)
Black or African American	20% (n=100)
White	60% (n=302)
Mixed race	15% (n=75)

Ethnicity:

Hispanic/Latino Ethnicity	15% (n=75)

Gender:

Female	33% (n=165)

Table 1. Projected Timetable

(Also included in section 2.7 of the PHS Human Subjects and Clinical Trials form)

Table 1. Project Timeline	**Year 1**				**Year 2**				**Year 3**				**Year 4**				**Year 5**			
Key Activities ***(Quarters)***	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**	**1**	**2**	**3**	**4**
Phase 1: Trial Preparation	x	x																		
Hiring & training of Interventionists (i.e., trainings include motivational interviewing, drug user stigma, Human Subjects Research Protection-CITI Training, survey administration for RAPIDS intervention, overdose prevention and response, naloxone administration)	x	x																		

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Finalize survey instruments, build participant databases, and develop online survey tools	x																		
Finalize project protocols, register as clinical trial	x	x																	
Finalize IRB certification, finalize Data Safety Monitoring Board (DSMB) and establish quarterly meetings	x	x																	
Develop and purchase advertising (field & internet)		x																	

Phase 2: Implementation			x	x	x	x	x	x	x	x	x	x	x	x			x			
Recruitment and screening of potential participants			x	x	x	x	x	x	x	x										
Randomization of participants to Arm 1 or Arm 2 at baseline visit			x	x	x	x	x	x	x	x										
Annual IRB re-certification, quarterly progress reporting to NIDA and DSMB					x				x				x				x			
Booster sessions at 1mo, 2mo, 3mo (post-baseline)				x	x	x	x	x	x	x	x	x	x	x						
Assessment at 4mo, 8mo, 12mo (post-baseline)					x	x	x	x	x	x	x	x	x	x						
Phase 3: Analyses				x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Data cleaning and management				x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
Prepare & submit abstracts for scientific conferences and meetings											x	x		x	x	x	x	x		
Write and submit manuscripts (Aim 1: assess efficacy of RAPIDS intervention—baseline and final at 12 months)											x	x	x	x	x	x	x	x		
Write and submit manuscripts (Aim 2: mediation analysis)														x	x	x	x	x		
Write and submit manuscripts (Aim 3: treatment heterogeneity analyses)																	x	x	x	x

C1. Data Management and Analysis

The primary source of data will be survey responses, including self-reported behaviors. Surveys will be conducted on touch-screen tablets using REDCap™ (Research Electronic Data Capture) software, which allow for direct, secure, and remote data entry. Similar to other studies, we have found the combined computer-assisted personal interview and computer-assisted self-interview (CAPI/CASI), conducted by trained, in-person interviewers, acceptable to the study population and efficient to administer. These procedures will protect against loss of confidentiality, improve reporting of sensitive behaviors, and reduce participant burden.

A second source of data will be datasets owned by the Rhode Island Department of Health (RIDOH). Specifically, secondary outcomes will include fatal overdose events among participants during the study period, as determined through linkage to administrative records. All fatal overdose events occurring in the state are certified and investigated by the Rhode Island Office of State Medical Examiners. These

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administrative records are reviewed regularly as part of ongoing surveillance efforts and represent comprehensive sources regarding overdose events occurring in Rhode Island. We will adhere to strict data security and confidentiality protocols when accessing administrative datasets, as outlined in our existing BAA with RIDOH and as approved by the Brown IRB.

Data acquisition and transmission:

Stronghold computing environment: We will obtain a central storage service hosted by Brown University's Computing & Information Services (CIS) Stronghold project. Stronghold is a HIPAA-aligned (Health Insurance Portability and Accountability Act), secure computing environment developed for housing, sharing, and analyzing sensitive data. The project's Biostatistician will oversee the database architecture, dataset storage, and all input/output (i.e., RIDOH data transfer) regulations. Stronghold is highly secure computer and storage Windows-exclusive environment for research needs that involve very sensitive data needing special handling, data usage agreements, etc. See section F1. Trial Safety for additional information about Stronghold security.

All Stronghold users must:

- be approved by the Principal Investigator, authorized in writing to Brown University Computing & Information Services (CIS);
- complete appropriate training for working with sensitive data (e.g. CITI training);
- be in compliance with all relevant Institutional Review Board protocols;
- be in compliance with any data use agreements or other agreements governing the use of the data stored on Stronghold; and
- complete an on-boarding process led by the Principal Investigator or Senior Research Assistant, which includes a review of data security protocols and a guided walkthrough of accessing the Stronghold virtual environment.

Data Transfers – there are select methods to import data, including but not limited to:

- Select Rhode Island state agencies and other offices using a secure VPN tunnel
- Encrypted USB drives
- Secure transfer through firewall exception
- Import and export servers

For the proposed project, the Senior Research Assistant will conduct and automate secure data transfer of administrative overdose records with RIDOH on a monthly basis (according to the timeline outlined in our existing data use agreement).

Data Entry Methods

Survey data will be collected on password-protected tablets and computers within the Centers for Epidemiology and Environmental Health (CEEH) at the Brown University School of Public Health. The REDCap™ platform exceeds patient confidentiality and data security requirements for clinical trials, and are both HIPAA compliant and fully validated for FDA 21 CFR Part 11.

The project's Biostatistician will manage the REDCap™ database architecture, dataset storage, and all input/output (i.e., data transfer) regulations.

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For all analyses, a series of routine procedures will first be conducted to ensure data accuracy/adequacy. Descriptive statistics will provide examination of the variables' distributional properties; if required, data will be transformed to achieve normality. For all analyses, we will adopt an intention-to-treat (ITT) approach to address potential problems inherent in following only intervention completers (e.g., self-selection effects, differential attrition across groups). Prior to examining intervention effects, we will first assess the success of randomization on pre-intervention characteristics using one-way analysis of variance (ANOVA), with intervention group as the predictor variable. The extent to which groups differ on baseline characteristics will determine whether any of these should be included as covariates in the primary analyses (see below). Missing covariate data will be handled using multiple imputation performed in two stages using chained equations that specify the conditional models for all of the variables with missing values.[207-209]

Assessing intervention efficacy in reducing self-reported overdose (Aim 1, primary endpoint). First, in the ITT analysis, we will determine the efficacy of the intervention by comparing self-reported rates of overdose among those assigned to the intervention arm versus the control group. First, we will use logistic regression to determine the independent effect of the intervention on the proportion reporting an overdose over the follow-up period, adjusting for baseline covariates as needed. Second, we will use generalized linear mixed effects models (GLMMs) with a logit link function to examine differences in self-reported overdose rates at each time point by incorporating fixed effects representing time, an intervention assignment indicator, and an interaction term that assesses the significance of the intervention influence over time. Third, in a per-protocol sub-analysis, we will determine the effect of the intervention on self-reported overdoses among those who used the fentanyl test strips.

Per-protocol analyses will be based on principal stratification. Principal stratification is a statistical technique that is used to adjust for a post-treatment variable (e.g., utilization of fentanyl test strips), and treatment effects are estimated within each stratum of that variable.[210] We can then estimate the effect of the intervention in reducing rates of self-reported overdoses, conditional on whether participants used the test strips.

Examine whether the treatment effect is mediated by differential uptake of risk reduction behaviors in the intervention arm (Aim 2). If the RAPIDS intervention shows efficacy in reducing overdose rates among the sample (Aim 1), we will explore the extent to which this relationship works through several possible mediators (see Figure 4). For mediation analyses, first, we will examine, in multivariable regression models, which mediators, if any, are significantly changed by the intervention (i.e., the rate of change differed by treatment assignment). For those that are significantly impacted by the intervention, we will conduct path analysis using structural equation modeling to determine whether the effect of the intervention on overdose was through the hypothesized mediator(s). Structural equation modeling (SEM) allows for the simultaneous estimation of total, direct, mediated and indirect effects of a causal variable (i.e., the intervention) on the outcome (i.e., overdose) through a set of mediator variables.[211] SEM can handle outcomes and mediators with a variety of distributions (including, Gaussian, Poisson and Binomial).[212] Inferences for indirect effects can be estimated using bootstrapped confidence intervals.[213]

Determine whether intervention efficacy varies across participant subgroups (Aim 3). We will examine if heterogeneity of intervention effect is modified by key baseline characteristics of interest, including: age; sex; type, frequency, and route of drug use; baseline level of overdose risk (e.g., lifetime history of overdose); and pre-intervention motivations for fentanyl test strip utilization. We will perform stratified subgroup analyses to determine if treatment effects vary between groups of individuals.

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D1. Quality Assurance

Quality Assurance Plan

Prior to making any changes to the protocol, we will seek approval from the NIDA program officer (PO) as well as the Brown University IRB. Significant protocol changes will be uploaded to clinicaltrials.gov upon IRB and NIDA approval.

The project's Biostatistician will manage the database architecture, dataset storage, and all input/output regulations for the RIDOH data transfers and storage, as well as storage of the the primary data from the trial. The database will be maintained under several firewalls, with restricted access to the Internet except for data imports and software installations. Control systems will be implemented to prevent data migration without authorization, complete with real time notifications of breaches. The data will routinely undergo backup procedures to ensure in the event of system failure, the data is recoverable.

Data Quality and Data Protocol Monitoring

Frequent scanning of Stronghold servers will be done to identify potential security vulnerabilities. The Stronghold Team will attempt to make this service available as requested 24 x 7 x 365 at all times outside of the planned maintenance window.

The Stronghold Team monitors and records all activity on the Stronghold system, including networking and access events, which may depend on classification of the data and any applicable regulations. Project staff receive notification of any activity on the Stronghold system. Notifications include alerts when data is imported to or exported from the transfer server. These alerts are emailed to the Principal Investigator and other project staff on fifteen minute intervals, detailing the name of the person who transferred the data, as well as the file description. Automated reports are also sent out monthly which detail the users who are currently approved to access Stronghold. There reports also include information about which users have read and write permissions to the secure transfer server.

All Center for Epidemiology and Environmental Health (CEEH) offices are connected into a single virtual local area network (LAN) by the central Brown Computing and Information Services group. Servers are located in a physically secured, temperature-controlled environment. All external network access is limited to a single gateway. Network traffic is filtered by type. Network traffic that would present a major security risk is disallowed. Protocol filters that limit the nature and type of network traffic likewise defend the servers. These machines host a complete suite of Internet-working facilities as well as data storage and backup. The CEEH uses a variety of security techniques including firewalls and antivirus software to maintain a secure and reliable computer environment.

Protocol Deviations and Noncompliance Reporting

Protocol deviations and noncompliance reporting will be the responsibility of the Project Investigator and Project Director. Such issues will be monitored on a consistent basis, and if any deviations are found they will be reported promptly to the Brown IRB.

Staff Training: Research Protections

All staff will receive Brown's mandated CITI online training for all Human Subjects Research, as well as additional HIPAA-specific training, Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus), and Social and Behavioral Research Best Practices for Clinical Research. All training will occur prior to working with study data or research participants.

Staff Training: Overdose Response (see also: Safety Protocol)

Additional in-person training will be provided to all staff by the community-based partner **Rhode Island Disaster Medical Assistance Team's Medical Reserve Corps (**RIDMAT), or the Project Director or RA who as attended the RIDMAT Train the Trainer program, on the following topics:

- Overdose recognition and response (1 hour)
- How to administer naloxone (1 hour)

Program-specific trainings will be offered by the RAPIDS Project Director on the following:

- Safety Procedures and Response (see procedures below) (1 hour)
- Motivational Interviewing and Brief Intervention for RAPIDS (6 hours)

All research staff will be trained on how to recognize and response to a drug overdose prior to working directly with participants, as well as how to administer naloxone in the event of a suspected overdose.

*NOTE: we are NOT clinicians or medical professionals and so we are limited in the scope of what we are able to offer someone in these circumstances, but we are expected to call for immediate medical help if someone is unresponsive. If you or another staff are trained on recognizing and responding to an overdose, then you may proceed with the protocol for responding to a suspected overdose using a "naloxone kit."***

In the event of an overdose, the primary staff person is responsible for documenting the situation thoroughly and following-up with the Principal Investigator and Project Director immediately.

All staff persons involved in witnessing or responding to an overdose should check in and debrief with the Project Director as soon as possible or before they leave for the day**.**

****The Naloxone Kit**: Includes two naloxone vials for administration, accompanied by latex gloves and an infographic on how to administer the naloxone. These items are kept in a pouch, clearly labeled "Naloxone Kit," and there will be one at each study staff workstation in an unlocked drawer, and in each interview room at the School of Public Health. The RAPIDS Research Assistant is responsible for monitoring the expiration dates of naloxone, discarding all naloxone doses as the law allows, as they expire, and re-ordering new Naloxone Kits from their community partner or supplier. The School of Public Health also has a publicly-accessible naloxone kit on the 3rd floor, directly across from the elevators.

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OVERDOSE RESPONSE INSTRUCTIONS

If you witness a participant as suddenly unconscious, not breathing, cannot be woken, or is turning blue, you are expected to respond immediately.

- You are now the **"PRIMARY STAFF PERSON"** and are the main person responsible for getting medical help.
    - Your role is to find one other staff person nearby and tell them how to help you respond to the medical situation (specifically, ask them to call 911).
    - Your role is to stay with the participant until medical help arrives.
    - Disclose at least the first name of the participant to First Responders, as well as any relevant health information (if received), and that this may be an opiate overdose.
    - Ensure that the participant receives thorough care and has all of their belongings prior to leaving by ambulance if possible.
- The other staff person is now the **"SECONDARY STAFF PERSON"** and they are responsible for calling 911 and making sure the First Responders can find the participant.
    - They should also notify a supervisor or Full Time staff person immediately to support the Primary Staff Person.

A Naloxone Kit may be administered under the following circumstances:**

- When a participant cannot be woken,
- When medical help is on the way,
- The staff person is trained to recognize an overdose AND administer naloxone,
- **The staff person follows instructions using bullets 1-8 below.**

OVERDOSE RESPONSE WITH NALOXONE INSTRUCTIONS:

- **Primary Staff Person**:
    - Verify that the participant cannot be woken up by yelling their name loudly.
    - Then do a sternum rub on the participant's chest using your knuckles.
    - Loudly announce to the participant, **"I am going to call 911 to get you medical help."**
- **Primary Staff Person:** Ask a nearby staff person to be in the *"Secondary Staff"* role.
    - Tell them to "Call 911" and report, "a person is unconscious/not breathing" and give the location at 121 South Main Street, 2nd floor.
- ***Secondary Staff Person*:**
    - "Call 911" and report, "a person is unconscious/not breathing" and give the location at 121 South Main Street, 2nd floor.
    - Give First Responders and Building Security the exact location of the participant within the building.

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Brown University IRB Amendment Approval: 11/22/2019
Brown University IRB Amendment Approval: 8/10/2020
Brown University IRB Amendment Approval: 10/15/2020
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Brown University IRB Amendment Approval: 12/13/2021

- Notify the Project Coordinator or another Full Time staff person on the team to stay with the participant and the primary staff person.
- Go to the building entrance to meet EMS and direct them to the participant.

- **Primary Staff Person:**
  - You are to stay with the participant until help arrives.
  - Please clear the immediate area so First Responders have room to respond and get to the participant when they arrive.
  - Please limit the number of people near the participant so there is room for the first responders when they arrive. No crowds.
- **Primary Staff Person (IF trained on naloxone administration):**
  - If you assess the participant according to your training and determine that they meet the criteria for naloxone, loudly announce to the participant, **"I am going to give you naloxone now."**
  - You may administer the Naloxone Kit** according to the instructions, starting with one dose of naloxone. The administration of the Naloxone Kit covers up to two doses.
- **Primary Staff Person:**
  - Notify the First Responders immediately if naloxone is administered, and how much was administered.
  - Disclose at least the first name of the participant to First Responders, as well as any relevant health information (if received), and that this may be an opioid overdose.
- ***All Staff Involved:***
  - Once the First Responders arrive to the location and have located the participant, these professional medical staff become immediately responsible for all first aid procedures.
  - Back away and give the First Responders space. Make sure the area is clear so they can leave quickly if needed.

E1. Regulatory Issues

Reporting of Unanticipated, Adverse, or Severe Adverse Events (SAEs)[1]

The overall data and safety monitoring will be the responsibility of the Principal Investigator (PI), Dr. Brandon DL Marshall, PhD. The PI is also responsible for executing the Data and Safety Monitoring Plan (DSMP), and complying with the reporting requirements. The PI will provide a summary of the DSMP report to the National Institute on Drug Abuse (NIDA) on an annual basis as part of the progress report.

The PI will ensure that all study procedures are in place prior to the initiation of the protocol, and that all study procedures and reporting of adverse events are performed according to the protocol. Severe adverse events (SAEs) will be monitored by the investigative team in near real-time throughout the trial. In addition, a Data Safety Monitoring Board (DSMB) will also provide independent study monitoring during all patient recruitment activities as described below.

The PI will monitor for adverse events that change study risk level. If an adverse event occurs which changes the study risk level, the Study PI will immediately report this event to the IRB (Brown University), DSMB, and NIDA, and will oversee the process of modifying the study as appropriate to

[1] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.32

address the change in risk. The PI will also provide annual reports summarizing SAE data to the IRB.

Given the nature of our eligibility criteria, the most severe adverse event may include fatal overdose among participants in the clinical trial. Overdose fatalities in Rhode Island are at crisis levels. Therefore, we may reasonably expect an outcome of fatal overdose among some participants. Given the severity of such an event, the PI will also monitor for self-reported, nonfatal overdoses (at follow-up visits). Each self-reported or fatal overdose will qualify for review by the DSMB to ensure any overdoses among our participants are not related to their participation in the research and are not more prevalent than expected (see below: *Collection and Reporting of Adverse Events [AE] and Severe Adverse Events [SAEs]*). All fatal overdose events occurring in the state are certified by the Office of State Medical Examiners within 90 days. To ascertain fatal overdose events, we will obtain consent from participants at the start of the trial to link to overdose surveillance datasets with participant data using a probabilistic linkage with the following combination of identifiers: first and last name, date of birth, and sex.

Report of Changes or Amendments to the Protocol

All changes or amendments to the protocol will be submitted in writing and will receive prior approval from the Brown University IRB. We will also seek approval from the NIDA program officer (PO) as well. Significant protocol changes will be uploaded to clinicaltrials.gov upon IRB and NIDA approval.

Trial Stopping Rules

Interim analyses of study data are planned according to the alpha spending rule [Lan and DeMets, 1994][2]. The proportion of expected events (i.e., self-reported non-fatal overdose) is considered as the information statistic. The *p*-values will be constructed to maintain the overall study power of 0.05, two-sided. If the test statistic exceeds the boundary, then the study could be considered for early termination due to emerging differences between the two arms. The PI will recommend to the DSMB that two interim analyses should be conducted over the course of the study.

The study investigators will report all adverse events and significant adverse events to the DSMB (see below). Moreover, all adverse and significant adverse events will be summarized by the study Biostatistician each quarter, and all categories with a statistically significant (at a $p < 0.05$, two-sided) excess incidence in the intervention group will be flagged. These flags will be reviewed and commented on by the DSMB, which may recommend early termination of the trial given evidence of harm based on these and other safety data.

Finally, the entire trial will stop if any investigator judges it necessary for medical, safety, regulatory, or other reasons consistent with applicable laws, regulations, or good clinical practice. Once a concern of this proportion is raised, the decision to stop the trial will be made through immediate consultation with the IRB, the DSMB, and NIDA.

Disclosure of any Conflict of Interest

All data sharing partners (e.g., RIDOH) and project investigators will agree to specific terms of use for the data according to a signed Data Use Agreement, which includes a request to disclose any potential conflicts of interest.

All individuals who meet the definition of Investigator will participate in Brown's FCOI or equivalent

[2] https://www.ncbi.nlm.nih.gov/pubmed/7973215

training, and sign all necessary forms related to disclosure of conflicts of interest.

Data Safety

This project will use Brown University's Stronghold secure computing environment. As described in section F1, this computing environment is HIPAA aligned, and developed for housing, sharing, and analyzing sensitive data.

F1. Trial Safety

Potential Risks and Benefits for Participants: Loss of Confidentiality

This project uses primary and secondary data regarding illicit drug use and overdose events; therefore, confidentiality of study data is of utmost importance. Access to such records for legitimate research purposes has been approved by our data sharing partner, RIDOH, and our team has worked carefully to ensure the protection of these data.

We recognize that a loss of confidentiality may also result in psychological harm to individuals or in social harm. As such, the research team will be using Brown's state of the art Stronghold computing environment for the transfer, analysis, and protection of all research data. Data sharing partners will share only the required datasets and variables. Additionally, only select members of the analytic team will have access to any identifiable datasets. All data transfer procedures, analytic plans, and use of administrative datasets will be approved by the Brown IRB.

Potential Risks and Benefits for Participants: Referrals for services or treatment

To determine if participants would benefit from referrals for treatment or social services, we will offer all participants a community resources packet at the end of the baseline visit. These resources will include information regarding addiction treatment (including MAT), syringe exchange, peer counseling, and mental health care. We will then ask if they would be willing to hear about programs or organizations pertaining to those services most important to them. Based on their responses, we can then refer them to those specific organizations.

Potential Risks and Benefits for Participants: Fentanyl Test Strips

This study will use Fentanyl Test Strips purchased from BTNX, Inc. These are single-use, lateral flow immunoassay test strips for the qualitative detection of fentanyl in liquid and powder substances at the cut-off concentration of 20 ng/mL.

BTNX, Inc. is aware of the research study and have pledged their support. Additionally, they have offered to individually number test strips for use in the study as well as provide technical expertise and assistance to ensure that the diagnostic abilities and limitations of the test strips are communicated effectively to participants. In addition, they will ensure that our team is kept abreast of new information regarding the ability of the test strips to detect additional novel fentanyl analogs.

All participants in the Intervention Arm will receive face-to-face training on how to use the test strips, and the risks of using the test strips. Participants will be given plain-language handouts to take with them at each visit that reiterate the main training points and risks.

The study will also include information in the consent form that will detail the use of fentanyl test strips, sample text is below:

> · *RISKS: ….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.*
>
> · *BENEFITS.....If you are in the group that receives fentanyl test strips, the strips may provide you with additional information about what is in your drugs.*

Research Database Infrastructure:

This project will benefit from data security resources provided by the Brown University "Stronghold" computing system. Stronghold is a secure computing and storage environment that enables Brown researchers to analyze sensitive data, while complying with regulatory or contractual requirements. Stronghold is currently self-certified to meet the security requirements and controls for HIPAA (Health Insurance Portability and Accountability Act) and is undergoing the certification process for FISMA (Federal Information Security Management Act) and CJIS (Criminal Justice Information Security). We will use the Stronghold secure computing environment to store, maintain, and transfer dataset between Brown University and RIDOH.

Stronghold is a secure virtual compute environment designed for remotely analyzing sensitive data. It uses encrypted SSH (Secure Shell) with two-factor authentication for remote access. Access to each virtual network is limited to a single PI and any additional students or staff who the PI authorizes in writing to Brown University Computing & Information Services (CIS). The PI enters into a written agreement with CIS that authorized users must comply with all necessary training requirements. CIS staff who have access to Stronghold have completed CITI course modules for working with human subject data as required by Brown's Office of Research Protection.

Stronghold is accessible only from within the Brown campus network and by Virtual Private Network connections (using two-factor authentication) from outside the campus network. All network connections to Stronghold pass through at least two firewalls: a dedicated firewall on the Brown campus network and a host-based firewall in the Stronghold environment. Stronghold uses a Windows-exclusive virtual environment when accessed through a Virtual Private Network (VPN).

The Stronghold system is physically located in a locked rack in a CCTV monitored data center on the Brown campus. Only certain authorized CIS staff have access to this locked rack. Entry to the data center is limited to authorized Brown IT personnel and their guests, and all entries are logged.

This service is customized to the needs of individual users and their data use agreements. Each investigator is given a dedicated environment for their project to support their co-investigators, graduate students, research assistants, interviewers, and other collaborators. Access to the Internet is restricted except for required locations for data imports or necessary software downloads. Import and export controls are in place to limit who can perform data migration, where sensitive data can come from and where desensitized or anonymized data can be moved to. Sensitive data is subject to file system auditing, and real-time alerting is available at the request of the PI.

Stronghold Data Security Policies for Investigators:

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The PI may impose additional requirements regarding credentials, connections methods, or clients based on the nature of the data.

1. All systems (workstations, laptops, etc.) used to connect to Stronghold-must have the following security precautions in place:
    a. A password-protected lock-out screen that appears after inactivity of 5 minutes or less.
    b. Up-to-date antivirus and malware installed.
    c. An up-to-date operating system with all currently available updates installed.
    d. Physical security (either card access or keyed locks) that prevents unauthorized users from physically accessing the system while it is connected to Stronghold.
    e. All connections to Stronghold-will be through a Virtual Private Network (VPN). Currently, Stronghold supports the OpenVPN client.

2. Restricting the import and export servers to the Principal Investigator and Senior Research Assistant.
3. Removal of previously authorized Stronghold users if they leave the research team. The Principal Investigator will contact Brown University Computing & Information Services (CIS) to authorize the removal of Stronghold users.
4. Study reports, results, and published manuscripts will suppress all identifiable information, and include only aggregated results.

Collection and Reporting of Adverse Events (AE) and Severe Adverse Events (SAEs)[3]

FDA Definitions

SAEs must be reported to the NIDA PO within 24 hours of the event by email. At a minimum this 24 hour notification should include a brief explanation of the SAE and when it occurred. A written follow up must be received within 72 hours of the event. The written follow up should include information on the date of the event, what occurred, actions taken by project staff, planned follow up (if any), the intervention group/study arm of the affected participant, whether the event appears to be related to the intervention, and whether participant will continue in the study).

AEs must be reported to the NIDA PO at least once per year and can be reported as a part of the annual progress report. At a minimum, this report should describe the event, when it occurred, the study arm of the participant, and the outcome/resolution. If there were no AEs, a statement that no AEs occurred should be included in the progress report or communicated to the PO in writing.

Our research team will follow FDA federal guidelines for reporting of all Adverse Events and Severe Adverse Events. The level of study risk, Adverse Events, and Severe Adverse Events will all be monitored and managed throughout the study by the Project Investigator with support from the Project Director.

Consultation from the Brown IRB will be immediately available to the PI to address any required actions, investigations, or changes to the risk level of the study.

[3] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.32

The DSMB will be notified within 24 hours of any severe adverse events, and will be asked to convene at the earliest possible time to discuss, but no greater than 30 days from the time of the severe adverse event notification. A detailed summary of AEs will be reported to the DSMB on a quarterly basis.

The following AEs will be reported to the DSMB:

- Participant concerns or complaints regarding the fentanyl test strip devices
- Findings from other studies regarding device risk
- Self-reported nonfatal overdose (determined through study assessments)
- Severe discomfort due to assessment procedures
- Significant embarrassment in disclosing sensitive personal information

The following SAEs will be reported to the NIDA PO and the DSMB:

- Violation of confidentiality or breach of participant records with PII
- Overdose death (determined through record linkage)
- Death from other causes (determined through participant follow-up procedures)
- Overdose on-site at the research study
- Unanticipated adverse device effects
- Disclosure of information about current and/or intended physical harm to persons; current and/or intended abuse of children that would be reported to a child welfare agency; and/or an investigation of such allegations(s) that could ensue

G1. Trial Efficacy

Plans for Interim Analysis of Efficacy Data

The primary data will be analyzed and reviewed on a monthly basis by the Biostatistician, and on quarterly intervals by the project Investigators. For the overdose surveillance data that are provided by RIDOH, the Data Analyst and Senior Research Assistant will analyze and clean those data on a monthly basis and present summarized results to the project investigators quarterly.

H1. Data and Safety Monitoring Plan for Administration

Responsibility for Data and Safety Monitoring

The Principal Investigator, Brandon Marshall, PhD is ultimately responsible for data safety and monitoring. This process will be monitored on a weekly basis by his team, including the Project Director, Data Analyst, and Senior Research Assistant, with quarterly updates to the entire team of Co-Investigators. The project team will be responsible for ensuring that all policies and processes outlined in the Data Use Agreements are followed accordingly, and that data are transferred and shared on the agreed-upon timeline, using the IRB-approved data transfer methods. Additional reporting for data and safety monitoring include quarterly updates to the DSMB, and annual reports to the IRB and NIDA.

Content of the Annual DSM Report:

a. Brief description of the trial
b. Summary of qualifying data events observed during the annual time period

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c. Q.A. issues
d. Regulatory issues
e. AEs
f. SAEs
g. Efficacy of the trial, interim analyses

I1. Data Safety Monitoring Board (DSMB) Plan

- **Members and Affiliation, Conflict of Interest**

A single Data Safety Monitoring Board (DSMB) will be appointed to oversee this project. The DSMB must include a minimum of 3 individuals with expertise relevant to the research. Board members must have no direct involvement with the intervention or study and no other conflict of interest with the intervention or study. The PI will consider the inclusion of a statistician/methodologist and/or ethicist as part of the board. Any potential conflicts of interest must be disclosed during the application process. The NIDA PO will ultimately approve the membership and Safety Monitoring Plan for the DSMB, which will also be included in the IRB application/amendment.

- **Frequency of Meetings & Protection of Confidentiality**

The DSMB will meet on a quarterly basis with the PI and Project Director present to review DSMP protocol adherence. All members of the DSMB will receive a copy of the protocol. The protocol includes the data safety monitoring plan, which is to be used as a guide during the DSMB meetings. In addition, the DSMB will be responsible for the following:

- Review any issues related to deviations from the protocol and reported adverse events.
- Review and approve the studyprotocol prior to the start of the study, and review major amendments to the protocol.

A report on DSMB meetings and activities should be sent to the NIDA PO by the PI within 30 days of each DSMB meeting. The update will include the following:

- meeting dates (past and upcoming if known)
- meeting minutes or summary
- current board membership
- changes in membership (if applicable)
- information about any new member(s) (if applicable) including statement that new members have no conflict of interest specific board recommendations regarding the research project (if any)

- **Monitoring Activities**

The DSMB will be notified within 24 hrs of any serious adverse event (e.g., breach of confidentiality, overdose death) and the DSMB will convene at the earliest possible time to discuss, but no greater than 30 days from the time of the adverse event notification. At the conclusion of each meeting, the DSMB will make a recommendation on study continuation, with a particular regard to safety and confidentiality issues. The DSMB will also provide written reports to be shared with the IRB which summarizes oversight activities and recommendations, and any concerns regarding study safety.

The DSMB will provide this recommendation in the form of study comments to the Co-PIs and IRB. IN addition, the DSMB will determine if there is sufficient concern to stop the trial.

- **Communication Plan to IRB, NIDA**

The Principal Investigator and the Project Director will coordinate all communication and grant reporting to the necessary parties, with the goal of transparency across oversight boards (IRB, DSMB) and the funding institution. Examples of communication shared by the PI include annual progress reports to NIDA, annual recertification of the IRB protocol, and quarterly updates to the DSMB. Any Adverse Effects or Severe Adverse Effects will be reported by the PI to the DSMB, and if required, the program officer at NIDA. Results of any DSMB or IRB comments will be shared as needed. If there were no AEs, a statement that no AEs occurred should be included in the progress report or communicated to the PO in writing. Any changes to the protocol we will seek approval from the NIDA program officer (PO) as well as Brown University's IRB. Significant protocol changes will be uploaded to clinicaltrials.gov upon IRB and NIDA approval.

The DSMB will be asked to provide written documentation confirming review of the protocol and agreement with the study design and the data safety monitoring plan (DSMP). The DSMB will assure that all severe adverse events are reported to the IRB by the Project Investigator, according to policies and procedures.

Stronghold-PORI
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Stronghold-PORI
Memorandum of Understanding-2018

Last Updated: 06/27/2018
Prod Services Completion Date: 06/27/2018
Expiration Date: 06/27/2019

Brown University Memorandum of Understanding

This agreement is made between Stronghold researchers and Computing and Information Services (CIS). There are Memorandum of Understanding documents for each environment in separate documents.

This agreement remains valid from the dates signed below until one year. The agreement will be reviewed annually. Minor changes may be recorded on the form at the end of the agreement, providing they are mutually endorsed by all parties and managed through the Change Management process.

Signatories

Name: Brandon Marshall **Position**: Principal Investigator
Department: Public Health-Epidemiology

Signature:  **Date: 6/28/2018**

Name: Mete Tunca **Position**: Assistant Director, Research Data Services
Department: Computing and Information Services
Signature:_____ **Date:** _____

Name: Geoffrey Greene **Position**: Director, Departmental Systems
Department: Computing and Information Services
Signature:_____ **Date:** _____

Service Description & Scope of Agreement
Stronghold is a highly secure compute and storage Windows & Linux environment for research needs that involve very sensitive data needing special handling, data usage agreements, etc.

Stronghold Technical Diagram

This agreement covers system support for the production Stronghold environment.

Stakeholders

CIS / IT Service owner: Mete Tunca
IT Service Owner Responsibilities
CIS / IT Contract owner: No contract at this time
CIS Technical Support Teams: CIS-Stronghold@Brown.edu and designated administrator (if applicable)
Business Service Owner: Brandon Marshall

Primary Stakeholders:
Principal Investigator and all users with accounts on the system

Stronghold-PI@brown.edu
Stronghold - Tenant Information

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CIS holds standup meetings, technical meetings and architecture meetings at regular frequencies.

Terms of Service

1. Access and User Accounts – The PI is responsible for maintaining an up-to-date list of accounts that should be able to log into Stronghold, and to communicate this to CIS through the Administrative Contact and to alert the contact when a user should no longer be allowed access. Users that leave the university will have access terminated along with their Brown account, per CIS Policies: Computing Privileges: Access to Electronic Services. All users must:
    - complete appropriate training for working with sensitive data (e.g. CITI training);
    - be in compliance with all relevant Institutional Review Board protocols;
    - be in compliance with any data use agreements or other agreements governing the use of the data stored on Stronghold.
2. Data Transfers – There are select methods to import data, including but not limited to:
    - Select State offices use a VPN tunnel
    - Encrypted USB drives
    - Secure transfer through firewall exception
    - Import and export servers
3. Backups – For information regarding Stronghold data protection, please reference the document below:
    - https://docs.google.com/document/d/16b0PyaLgIbiYiyfibQvWsKe2eC6qzUI0y1b68Hj41DQ/edit#heading=h.lp9x2xwxtn1v
4. Termination of Service – Requests for termination of services should be made to the Administrative Contact. Services will be terminated by the next business day following the request. All data stored on Stronghold that is associated with the terminated account will be deleted upon termination of services.
5. Denial of Access – In the event that a user fails to comply with the policies and procedures for accessing and using Stronghold, or in the case of a suspected or real security breach, CIS staff can temporarily deny access to Stronghold for the user and suspend all retrieval of information until approval is received from a designated authority.
6. Research with Human Participants – PIs must be in compliance with all Institutional Review Board requirements (if applicable).

Remote Connections

- Users connect to Stronghold using their existing Brown credentials and must comply with CIS Policies: Computing Privileges: Access to Electronic Services.
- Users must also use a two-factor mechanism for additional security. Currently, Stronghold supports DUO as the two-factor client.
- CIS may impose additional requirements regarding credentials, connections methods, or clients. In this case, CIS will provide at least 7 days notice to the user of these additional requirements.
- All systems (workstations, laptops, etc.) used to connect to Stronghold-must have the following security precautions in place:
    i. A password-protected lock out screen that appears after inactivity of 5 minutes or less.
    ii. Up-to-date antivirus and malware installed.
    iii. An up-to-date operating system with all currently available updates installed.
    iv. Physical security (either card access or keyed locks) that prevents unauthorized users from physically accessing the system while it is connected to Stronghold.
- All connections to Stronghold-will be through a Virtual Private Network (VPN). Currently, Stronghold supports the OpenVPN client.

Unplanned Outages and Communication Procedures

Unless otherwise specified in this MOU, the CIS Incident Manager will communicate all unplanned outages of this service as specified below.

If a stakeholder becomes aware of a system outage (e.g., web server or application down) or

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During Business Hours

1. Send email to CIS-Stronghold@Brown.edu
2. Call or email: CIS-Production-Services@brown.edu (401) 863-7562 who will immediately take the following actions:
    a. issue an Internal Service Alert which will notify all technical teams, Operations, the IT Service Center, Production Services, and CIS Directors, Administrative Contact and stakeholders
    b. after stakeholders / CIS validate that the service is incurring an outage, Production Services issues an external CIS Service Alert to all customers and stakeholders
    c. Start a bridge line, if needed.

During Non-Business Hours

1. Send email to CIS-Stronghold@Brown.edu
2. **Call the IT Service Center** at (401) 863-4357 to report the outage. The number still works and redirects to different people depending on the time - just listen to the menu and **press 0 at the appropriate time to report the outage.**
3. The CIS Incident Manager will take the same actions as defined in number 2 above under "During Business Hours".

Contact points

Production Services team at CIS-Production-Services@brown.edu @ (401) 863-7562

Karen Sylvester	(401) 863-7376	cell: (401) 935-9325
Laura Dark	(401) 863-7473	cell: (401) 338-9352
Jennifer Germano	(401) 863-7262	cell: (401) 368-9185
Steve Lawton	(401) 863-7380	cell: (401) 225-9164

IT Service Center at cis-helpdesk@brown.edu @ (401) 863-4357

Don Rogers	(401) 863-7319	cell: (401) 339-1810
Gena Burke	(401) 863-2094	cell: (401) 368-8703

Monitoring

- Monitor and record all activity on the Stronghold system, including networking and access events, which may depend on classification of the data and any applicable regulations
- CIS defines monitoring with a specific level of criticality that is defined in the doc **Operations Escalation & Support Info**. Monitoring for the Stronghold service are or will defined at this level of criticality: **Critical**
- **CIS-OPS & CIS-Stronghold will receive email notification**
    - If predictive trending is showing potential issues
    - Outage occurs

Change Management / Planned Outages

CIS conducts extensive change management procedures for all changes related to infrastructure and applications. All changes to infrastructure that support the **Stronghold** application will be conducted in the following **established maintenance windows**:

- Monday through Friday, 5:00 am to 8:00 am
- Saturday 3:30 am to 8:00 am
- Sunday 5:00 am to noon

CIS Maintenance Definitions:

- **Heavy Usage maintenance period -** during a heavy usage maintenance period CIS may perform maintenance as needed without obtaining proper signoff from all primary stakeholders as long as maintenance is completed in established maintenance windows

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- **Frozen maintenance period** - during a frozen maintenance period CIS may only perform maintenance after obtaining proper signoff from all primary stakeholders
- **Critical time period** - during a critical time period no maintenance may be done to any application or service. During critical maintenance time periods, no people are allowed in the data center to perform any maintenance on any infrastructure for any application or service.
- For this reason, CIS limits the length of a critical time period to as short as possible, usually an hour or two.

There are no heavy, frozen or critical maintenance periods at this time.

CIS will communicate all proposed changes prior to the maintenance window, detailing the work to be done and the expected impact.

Certain system work will require validation from primary stakeholders. In those instances CIS will reach out to those who will need to be included in the validation process, supplying the necessary information.

SYSCHG Requirements
No SYSCHG required

- notifications will be sent to appropriate users, scmt@brown.edu and CIS-Stronghold@brown.edu
- install new software
- install addon package
- update to newer version of software package
- firewall changes (bastion)

SYSCHG Required

- server changes
- notification required beyond CIS-Stronghold group, notification will be sent to the Principal Investigator and all users with accounts on the system
- any change that affects all users of Stronghold

Windows patches/upgrades (if applicable)

- Will be done monthly and require reboots.

PRD patching always occurs on the Thursday following the 4th Tuesday of every month. Now and again, this will be the 5th Thursday, the Monday and Tuesday will follow that Thursday.
Upgrades/patches are accessed from the central server located in Data Center.

Linux (if applicable)

- Upgrades/patches will be done on the first Tuesday of each month during the maintenance window. If a reboot is required it will occur on the second Tuesday of the month. Production Services will be notify Stronghold-Linux@brown.edu, Stronghold-Windows@brown.edu, CIS-DBA@brown.edu in advance for patching and reboot. SYSChange tickets will be created for patching and reboot
- Upgrades/patches are accessed from the central server located in Data Center
- The latest version will be limited to whatever version the central server is using
- If a tenant desires a more recent version of Linux that exists on red hat, but does not yet exist on our central service, this will be addressed on case by case basis
- For major upgrades we will need to coordinate with the tenants on appropriate day/time, this will require user validation
- For minor versions and security patches, CIS will notify tenants that work will be done during the maintenance window

Non-standard software

- For non-standard end user requested software, it will be downloaded, tested and copied to requested Stronghold environment and install

Oracle Patching (if applicable)

- Will be completed as needed

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- No upgrades/patching from internet
- CIS DBA team downloads file
- File manually copied to Stronghold environment to execute database upgrade

Researchers Software package

- Researchers need latest version, cutting edge of software packages (python, etc) - open source software
- Will be upgraded strictly based on end user request; unless existing version is being sunsetted

Periodic Scanning

- Periodic scanning of Stronghold servers will be done to identify potential security vulnerabilities.

CIS will attempt to make this service available 24 x 7 x 365 at all times outside of the planned maintenance window.

Certain system work will require validation from primary stakeholders. In those instances CIS will reach out to those who will need to be included in the validation process, supplying the necessary information to them so they can participate in the validation process and confirm that application Stronghold is back up and running after maintenance has been performed.

Security

Authentication Method: Application specific-Gatekeeper
Access Request Form: Yes
Authorization:

- **How is authorization handled:** Requested
- **Who administers authorization:** Unix or Windows teams
- **Contains Data Sensitivity or Confidentiality:** Yes
- **Security Policies:** Authorized users are reminded of Brown University's Acceptable Use Policy, as well as the Computing Passwords Policy

JUSTIFICATION FOR NON-SIGNIFICANT RISK (NSR) DETERMINATION (21 CFR812.2b)

Protocol Title: "Rhode Island Prescription and Illicit Drug Study (RAPIDS)" *** title change*

Device Name: BTNX Inc. Rapid Response™ Single Drug Test Strip

Justification for NSR Determination

Description of the Device: The purpose of this study is to determine whether a fentanyl overdose prevention intervention involving the use of take-home fentanyl test strips reduces the risk of overdose among people who use drugs. The device, known as the BTNX Inc. Rapid Response™ Single Drug Test Strip, is a rapid, qualitative test for the detection of a selected drug in human urine. We propose to use the product off-label by asking study participants to test a small amount of an illicit drug sample dissolved in water. The fentanyl (FYL) test strip is a lateral flow chromatographic immunoassay for the qualitative detection of fentanyl, fentanyl metabolites (i.e., norfentanyl), and related analogues (e.g., carfentanil). Prior research conducted by researchers at Johns Hopkins University and Brown University has shown that the product has a detection limit of 0.13 micrograms/mL when used to test illicit drug samples dissolved in water (see Attachment B). The product has >90% specificity and >96% sensitivity when compared to a gold standard.[1] The test results appear on the strip within two minutes (see Attachment B).

Reports of Prior Investigations: To examine the feasibility and acceptability of using test strips to identify fentanyl contamination of illicit drugs prior to consumption, we conducted a pilot study involving 93 participants. After a brief training and being offered 10 test strip to use at home, willingness to use the test strips was high; overall, 95% agreed or strongly agreed that they planned to use the tests.[2] Almost all pilot study participants (99%) reported that it would be easy to use the test strips to identify fentanyl contamination in illicit drugs prior to consumption. Among persons who returned for follow-up, a total of 62 participants (77%) reported using at least one test strip.[3] Of these, 31 (50%) received at least one positive result. A positive result was associated with older age, homelessness, heroin use, injection drug use, ever witnessing an overdose, and concern about overdose or drugs being laced with fentanyl (all $p < 0.05$). Receiving a positive result was significantly associated with reporting a positive change in overdose risk behavior between baseline and follow-up ($p \leq 0.01$). Among all participants, 79 (98%) reported confidence in their ability to use the test strips and 77 (95%) wanted to use them in the future. A subsequent qualitative study found that the vast majority of participants found

[1] Johns Hopkins University. The FORECAST Study. Available from: https://americanhealth.jhu.edu/sites/default/files/inline-files/Fentanyl_Executive_Summary_032018.pdf

[2] Krieger MS et al. High willingness to use rapid fentanyl test strips among young adults who use drugs. *Harm Reduction Journal*. 2018;15:7.

[3] Krieger MS et al. Use of fentanyl test strips among young adults who use drugs. *International Journal of Drug Policy*. 2019;71:52-58.

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the fentanyl test strips to be straightforward to use and did not cite significant barriers to use.[4] The most challenging aspect of the test strips reported by participants was correctly reading the results, with one line indicating a positive and two lines indicating a negative. To avoid confusion, we affixed labels to every package that visually show how to properly interpret a result (see Attachment B). We will do so in the proposed clinical trial. After receiving a positive test result, many participants described precautions that they believed would prevent an overdose, such as using a drug with others around, keeping naloxone nearby, or using a "tester" (a small amount of drugs). We found no evidence to suggest that the test strips were used to purposely "seek out" fentanyl, or result in other drug-using behaviors that may increase overdose risk.

Proposed Investigational Plan: The clinical trial described herein proposes to use the fentanyl test strips in the same manner as that tested during the pilot study, but incorporates the product into a broader overdose prevention intervention that involves educational components, motivational interviewing, etc. (see Clinical Trial Protocol). The consent form clearly explains the potential risks and benefits of using the test strips to prevent accidental exposure to illicitly manufactured fentanyl. All study procedures involving the product are described in detail within the Clinical Trial Protocol.

Summary of NSR Determination: The results of our pilot study provide compelling evidence that fentanyl test strips may be a useful harm reduction intervention to reduce fentanyl overdose risk among people who use drugs. These results are consistent with a recently published study of 125 people who inject drugs in North Carolina.[5] The evidence collected to date strongly suggests that fentanyl test strips do not increase overdose risk or otherwise provide a false sense of security for the user. Therefore, we believe the study meets the criteria for an non-significant risk (NSR) device study under IDE regulations (21 CFR 812.b2). Nonetheless, we will carefully monitor the safety of all participants and will report adverse and severe adverse events to the Data Safety Monitoring board on a regular basis (see Attachment F - Data Safety Monitoring Plan).

[4] Goldman JE et al. Perspectives on rapid fentanyl test strips as a harm reduction practice among young adults who use drugs: A qualitative study. *Harm Reduction Journal*. 2019;16:3.

[5] Peiper NC et al. Fentanyl test strips as an opioid overdose prevention strategy: Findings from a syringe services program in the Southeastern United States. *International Journal of Drug Policy*. 2019;63:120-126.

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Rhode Island Prescription and Illicit Drug Study (RAPIDS)

SAFETY PROTOCOL

Safety Policies & Procedures *- The following are guidelines to help ensure the safety of all project staff on Dr. Marshall's research team. The safety of our staff remains our top priority as well as the safety of our research participants.*

General Safety Procedures

- All staff will be familiar with the safety protocol and will be given a copy of this protocol.

- **Primarily, participant visits for this research study will take place at the centrally located Brown University School of Public Health.** However, visits may also take place in semi-private locations outside of BUSPH where organizations have sufficient space and insurance coverage to comply with Brown University health and safety and social distancing standards (such as clinics or community partner agencies). The Project Coordinator or lead Research Assistant (RA) must be aware of scheduled participant visits and the room at BUSPH where they will take place.

- The **Primary Staff** (e.g. research assistant/interventionist) is the staff person conducting the interview and is responsible for overseeing the participant throughout the visit.

- A **Back-up, or Secondary, staff person** must be available and in close vicinity in the event of the Primary staff needing support. If a participant is scheduled outside of normal business hours, there must be two project staff on-site during the visit.
    - Under no circumstances are research staff to conduct a research study visit at a private residence or other private location.

- Primary and Secondary staff are to always carry a cell phone with them, which is to remain turned on during participant sessions, regardless of location. Please monitor the battery level and charge when necessary.

- Primary staff must check in with the Project Coordinator or Lead RA at the beginning and end of a scheduled session.

Field-Based Safety Measures

- There may be instances in which participant visits occur outside of the BUSPH. These visits will occur in locations that meet health, safety, insurance and social distancing standards of the IRB, IBC and other regulatory bodies.

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- Visits that occur outside of BUSPH must follow all of the same safety protocols that have been outlined for visits occurring on-site.
- Additionally, Research Assistants performing study visits in the field will go out in pairs so that no staff will ever be alone during a study visit. Research Assistants will also communicate with the Project Coordinator or Project Manager and check in at the beginning and end of each visit.

Bathroom Safety Procedures

- The Primary staff should chaperone the participant at all times while they are at the School of Public Health, including while in the elevator. One exception is when a participant is using the bathroom, when the staff person will remain outside the bathroom. Primary staff are to remind participants of the bathroom rules:
    - Personal belongings are not allowed in the bathroom.
    - Substance use is not allowed on-site or during the study visit.
  - If the participant is in the bathroom for more than 5 minutes, the Primary staff will knock on the bathroom door and ask if the participant is ok.
    - If there is no verbal response, or if there is a staff concern about participant safety, then the Primary staff will ask the Secondary staff for immediate support. The Primary staff will proceed by issuing a verbal warning and opening the bathroom door.
    - If there appears to be an emergency situation, the Secondary staff will assist with enacting the **Medical Response Procedure** outlined on **Page 6.**

Session Delivery Safety Procedures

- When in a respondent's presence, the Primary staff should:
    - Sit near the exit and in a location where you can leave quickly if needed. Keep all personal and study items close to you and within sight. Be aware of your environment at all times. If you have concerns about a situation, call the Project Coordinator and follow the "Dr. West" procedures outlined in this document (see below).
    - With the exception of your cell phone and study equipment, never take anything into a participant session that you do not absolutely need for the session (e.g., limit carrying personal items, extra cash, etc.).
    - Ensure that you have the Project Coordinator, Project Director, and study clinicians' cell phone numbers programmed into your cell phone for quick use. If there is a landline present in the study rooms, cell phone numbers for the Project Coordinator and Program Director are pre-programmed.
- If a respondent becomes agitated or confrontational with you about the study, try to address his/her concerns. If he/she still seems uncertain, direct them to the Project Coordinator. However, don't push the issue if you feel unsafe. If appropriate, offer to

call and reschedule for another time with the participant and leave the situation. Always call the Project Coordinator afterward to notify them of the situation and document the details of the event.

- If at any point during a participant session you feel you are in immediate danger, leave the situation immediately; no explanation to the respondent(s) is required. Once you are in a safe area, call the Secondary staff and Project Coordinator to inform them of the situation. ***You are in no way expected to stay in an unsafe situation in order to complete a research study visit.***

Calling "Dr. West" Safety Procedure

- If you do not feel that you are in immediate danger but feel uneasy about the situation, you should place a call to "Dr. West" (a study supervisor) to review the circumstances. We use the term "Dr. West" to immediately notify study supervisors of a possible serious situation.
    - To do this, you can say something like, "*It looks like I may be missing an important study document, will you hold on one moment while I place a call to my supervisor?*" When making the call to the Project Coordinator, you would say "*I need to speak with Dr, West..*"

- The Project Coordinator or staff who answers the call will then use YES/NO questions to understand the situation and determine the best course of action.
    - If the Project Coordinator determines you should end the interview prematurely, you then calmly explain to the respondent that you need to reschedule the interview. You can use any reason that seems plausible such as, the equipment isn't working properly, you don't have the proper consent form, or that you are just not feeling well.
    - Calmly apologize for the inconvenience and let them know that we will have to reschedule for another time. Follow up with the Project Coordinator immediately and document the incident.

Some examples of dangerous or unsafe situations might be:

- Drug use/sales
- Observation that respondent is high or intoxicated
- Violence or threats of violence toward you or others in the environment
- General sense of hostility or aggressiveness toward you
- Inappropriate language directed to you
- Sexual advances
- Any perceived threat or inappropriate behavior

Angry Respondents Procedure

- It is rare that the Primary Staff will encounter a situation where the respondent becomes angry. However, in the case that a respondent becomes angry, it is the role of the

Primary staff to evaluate the situation and employ de-escalation techniques. The goal in these situations is to calm the respondent down:

- Remain calm yourself.
- Try to find out what they are angry about.
- Listen.
- Acknowledge their concerns, by saying things such as, “Okay, I understand how that would be upsetting.”
- Apologize for any inconvenience, discomfort, etc.
- Validate their feelings.
- Let them know what you will do to address their concerns, such as, “Talk to your supervisor immediately,” or “Make the researchers aware of the problem”, etc.
- Actually write the concerns down in your notes in front of the respondent.
- Offer to have your Project Coordinator call them to discuss the situation further.
- Call or text the Secondary staff or Project Coordinator if you feel the situation is not calming down.

- No matter how angry or insulting a respondent may be, the Primary staff must remain polite and professional. They are not, however, required to remain in such a situation. If a participant is very angry, their participation is not likely going to be valid. Furthermore, we do NOT, at any point, want someone’s personal safety to be at risk.
- The Primary staff will end the conversation with a brief thank you, and leave the situation as unobtrusively as possible.

Participant Safety Planning Procedure

- If the Primary staff observe behavior where they feel the participant’s safety is at risk, or that the safety of others may be at risk, we encourage them to quickly involve the Secondary staff member, the Project Coordinator or Project Director. This includes observing behaviors that indicate the respondent may be high or intoxicated to the point of not being able to participate in the study, and/or are unable to leave the study site safely.

- When the Primary staff observes what they consider to be impaired functioning, visible intoxication, or concerning behaviors, they should:
    - Conduct a brief verbal assessment using the “Alert & Oriented X4” as outlined below in Section 4 to generate a discussion regarding their ability to be alert and oriented. This can be done at any point during the participant visit, including prior to a participant leaving the building. Staff may also express concern for the participant’s well-being.

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- If the participant struggles to answer the AOx4 questions or engage in a coherent discussion about the concerning behaviors, the Primary staff will engage the Secondary staff or other staff leadership.
  - The Secondary staff member will assist by reaching out for additional clinical input. This will be a phone call to the on-call clinician, BH Link, or 9-1-1, depending on the severity of the situation.
  - ***If there is an immediate threat to their safety, the Primary staff is instructed to always call 911, or directly ask the Secondary staff to call 9-1-1. The Primary staff should stay with the participant, and, if necessary, the Secondary staff should go down to the Lobby to direct first responders to the necessary location.***

- The Primary staff will explain to the participant their concerns about safety, and help them engage with the clinician via phone or video chat. The clinician will support the participant by creating a safety plan with the participant prior to them leaving the building. The Primary staff will support the safety plan by arranging alternative transportation and/or placing additional phone calls to BH Link mobile crisis unit or 9-1-1 if needed. All related transportation costs will be charged to the study.

- The Project Director will ensure all documentation policies are followed as needed (e.g. DSMB or IRB reporting and follow-up).

- All research staff will be trained on how to respond to suicidal ideation/threats prior to their work with research study participants.

<u>Harm to Self or Others Safety Procedure</u>

NOTE: we are NOT clinicians and so we are limited in the scope of what we are able to offer someone in these circumstances. However we should be empathetic and non-judgmental in our response to this information, and offer the best available resources.

- If the Primary research staff observe behavior where they feel the participant's safety is at risk due to suicidal ideation or threat of self-harm, or that the safety of others may be at risk due to threat of harm, we encourage them to quickly involve the Secondary staff member, the Project Coordinator or Project Director as available.

- We will not be collecting any information regarding suicidal ideation or behavior in this study. However, if a respondent indicates that they are suicidal, or you feel like they may harm themselves, ask if there is someone they can speak to about feeling that way and/or if there is someone you can call for them.

- The Primary staff will express concern for the participant by saying, "What you have told me is very heavy. I feel that it is important for us to call someone to talk to about these things."
- The Primary staff will instruct the Secondary staff to call the study clinician or BH link immediately. The Primary staff will stay in the room to support the participant.
- If the participant refuses, the Primary staff will again express concern and care for their safety and restate the ability to call a clinician or other support for them. The Primary staff can also suggest a referral to a medical or triage center where they can get the proper level of care, such as BH link.
    - The Primary staff will offer transportation options to a referral location, or offer to engage a mobile crisis unit that may come directly to the study site. All related transportation costs will be charged to the research study as needed.
- ***If there is an immediate threat to their safety, the Primary Staff is instructed to always call 911.***

- The Primary staff in this situation is responsible for expressing empathy and concern for their safety, and for ensuring another staff person is with them to support the next steps. Encourage them to speak with someone about their feelings and provide them with the phone number for RI's 24hr mental health and substance use triage center, **BH Link: 401-414-LINK(5465).** Other resources include the Samaritans – a suicide prevention hotline: (401) 272-4044, or any of the mental health and substance use resources listed in the Community Based Resources and Referrals handout.

- The Primary staff will let the participant know that they will inform the Project Director and Study Clinician about any safety procedures that were enacted. The Primary staff may tell the participant that they are doing so out of concern for their wellbeing.

- The Primary staff is responsible for documenting the situation thoroughly and following-up with the Project Director and Study Clinician immediately.

- The Project Director will ensure all documentation policies are followed as needed (e.g. DSMB or IRB reporting and follow-up).

<u>Overdose Response/Medical Issue Response Procedure</u>

All research staff will be trained on how to recognize and respond to a drug overdose prior to working directly with participants, as well as how to administer naloxone.

NOTE: we are NOT clinicians or medical professionals and so we are limited in the scope of what we are able to offer someone in these circumstances, but we are expected to call for immediate medical help if someone is unresponsive. If you or another staff are trained on recognizing and responding to an overdose, then you may proceed with the protocol for responding to a suspected overdose using a "naloxone kit."

In the event of an overdose, the primary staff person is responsible for documenting the situation thoroughly and following-up with the Principal Investigator and Project Director immediately. The Project Director will ensure all documentation policies are followed as needed (e.g. DSMB or IRB reporting and follow-up).

All staff persons involved in witnessing or responding to an overdose should check in and debrief with the Project Director as soon as possible or before they leave for the day**.**

If you witness a participant as suddenly unconscious, not breathing, cannot be woken, or is turning blue, you are expected to respond immediately. (See OVERDOSE RESPONSE INSTRUCTIONS below)

- You are now the **"PRIMARY STAFF PERSON"** and are the main person responsible for getting medical help.
    - Your role is to find one other staff person nearby and tell them how to help you respond to the medical situation (specifically, ask them to call 911).
    - Your role is to stay with the participant until medical help arrives.
    - Ensure that the participant receives thorough care and has all of their belongings prior to leaving by ambulance if possible.

- The other staff person is now the **"SECONDARY STAFF PERSON"** and they are responsible for calling 911 and making sure the First Responders can find the participant.
    - They should also notify a supervisor or Full Time staff person immediately to support the Primary Staff Person.

A Naloxone Kit may be administered under the following circumstances:**

- When a participant cannot be woken,
- When medical help is on the way,
- The staff person is trained to recognize an overdose AND administer naloxone,
- **The staff person follows instructions using bullets 1-8 below.**

1. **<u>OVERDOSE RESPONSE WITH NALOXONE INSTRUCTIONS:</u>**
    - **Primary Staff Person**:
        - Verify that the participant cannot be woken up by yelling their name loudly.
        - Then do a sternum rub on the participant's chest using your knuckles.
        - Loudly announce to the participant, **"I am going to call 911 to get you**

medical help."

- **Primary Staff Person:** Ask a nearby staff person to be in the *"Secondary Staff"* role.
  - Tell them to "Call 911" and report, "a person is unconscious/not breathing" and give the location at 121 South Main Street, 2nd floor.
- ***Secondary Staff Person*:**
  - "Call 911" and report, "a person is unconscious/not breathing" and give the location at 121 South Main Street, 2nd floor.
  - Give First Responders and Building Security the exact location of the participant within the building.
  - Notify the Project Coordinator or another Full Time staff person on the team to stay with the participant and the primary staff person.
  - Go to the building entrance to meet EMS and direct them to the participant.
- **Primary Staff Person:**
  - You are to stay with the participant until help arrives.
  - Please clear the immediate area so First Responders have room to respond and get to the participant when they arrive.
  - Please limit the number of people near the participant so there is room for the first responders when they arrive. No crowds.
- **Primary Staff Person (IF trained on naloxone administration):**
  - If you assess the participant according to your training and determine that they meet the criteria for naloxone, loudly announce to the participant, **"I am going to give you naloxone now."**
  - You may administer the Naloxone Kit** according to the instructions, starting with one dose of naloxone. The administration of the Naloxone Kit covers up to two doses.
- **Primary Staff Person:**
  - Notify the First Responders immediately if naloxone is administered, and how much was administered.
  - Disclose at least the first name of the participant to First Responders, as well as any relevant health information (if received), and that this may be an opioid overdose.
- ***All Staff Involved:***
  - Once the First Responders arrive to the location and have located the participant, these professional medical staff become immediately responsible for all first aid procedures.
  - Back away and give the First Responders space. Make sure the area is clear so they can leave quickly if needed.

***The Naloxone Kit includes two naloxone vials for administration, accompanied by latex gloves and an infographic on how to administer the naloxone. These items are kept in a pouch, clearly labeled "Naloxone Kit," and there will be one at each study staff workstation, and in each interview room at the School of Public Health. The RAPIDS Research Assistant is responsible for monitoring the expiration dates of naloxone, discarding all naloxone doses as the law allows,*

as they expire, and re-ordering new Naloxone Kits from their community partner or supplier. The School of Public Health also has a publicly-accessible naloxone kit on the 3rd floor, directly across from the elevators.

Medical Devices/ Investigator Checklist

Protocol title: Rhode Island Prescription and Illicit Drug Study (RAPIDS)

PI name: Brandon DL Marshall, PhD	Date: March 31, 2019

A device will **NOT** fall under the FDA regulations if all of the following statements are true:

1) Data will not be submitted to the FDA
2) Safety and/or effectiveness data will not be collected about the device
3) The device is used only as a tool to collect data to examine a physiologicprinciple

If ALL statements above are true, please initial here:_____

Please include this form and the device manual in your protocol submission to the IRB. No further information is required at this time.

This checklist serves as a guide to Sponsor-Investigators in determining and documenting information required by the IRB related to the use of a medical device which falls under the FDA regulations (21 CFR812) in a human subjects' research study and requires an Investigational Device Exemption (IDE). ***Sponsor-Investigator* is the individual who initiates and also conducts the study/clinical investigation. Typically this is the Principal Investigator (PI). A sponsor-investigator must comply with regulatory requirements applicable to both sponsors and clinical investigators (21 CFR312.3).** A device will fall under the FDA regulations if data will be submitted to the FDA **OR** safety and/or effectiveness data are collected about the device.

The IDE regulations (21 CFR812) describe three types of device studies: significant risk (SR), which require an IDE application approved by the FDA, non-significant risk (NSR) which must follow the abbreviated IDE requirements (21 CFR812.2b) and do not require a submission of an IDE application to the FDA or exempt from IDE regulations (21 CFR812.2b30. Please consult the cited regulations for additional information on these types of device studies.

Attached to this form is a flowchart that may also be helpful in determining if an IDE is required.

I.	Device name BTNX Inc. Rapid Response(TM) Single Drug Test Strip (Investigations with multiple devices must submit a separate form for each device) **Please include device information/manual or other documentation that describes the device/usage.**			HRPP USE ONLY: Confirm information for IRB review, (based on protocol submission and checklist) noting a check mark ✓
a.	Studies considered exempt from IDE regulations include:			
	• A legally marketed device when used in accordance with its' labeling.	☐ Yes	☒ No	
	• A diagnostic device if it complies with labeling in 809.10(c) and the testing is noninvasive, does not require an invasive sampling procedure that presents significant risk, does not by design or intention introduce energy into a subject, and is not used a diagnostic procedure without confirmation by another medically established diagnostic product or procedure.	☐ Yes	☒ No	
	• Consumer preference testing, testing of a modification or testing of a combination of devices if the device(s) have an approved Premarket Notification 510(k), or are exempt from 510(k) **AND** if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.	☐ Yes	☒ No	

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	If "Yes" to one of the bulleted items, the study is exempt from IDE regulations. Please provide/attach supporting documentation, e.g., letter from the FDA, or other information used to make this exempt determination. This form is complete. If "No" to all bulleted items, continue to next item.			
b	Does the research collect safety and/or efficacy data on medical devices in human participants or on human specimens? (An IDE must be submitted to the FDA if the sponsor-investigator intends to conduct a clinical investigation with an investigational new device to determine safety and effectiveness **unless** the investigation is considered to have an approved application for an IDE, or is exempt from the IDE requirements. (21 CFR 812.2)	☒ Yes	☐ No	
c	Has the FDA assessed the device for a risk determination? If yes, Please indicate if the FDA determination is: NSR_____(non-significant risk) SR_____(significant risk) *If "yes", provide the IRB with a copy of the FDA documentation, and this form is complete, the remaining items do not apply.	*☐ Yes	☒ No	
d	Has the sponsor-investigator made a risk determination? If yes, Please indicate if the determination is: NSR_X_____(non-significant risk) SR_____(significant risk) Please provide the IRB with a description of the device, reports of prior investigations with the device, the proposed investigational plan, and any other information that will assist the IRB in the review of this determination.	☒ Yes	☐ No	
e	Please provide the plan to securely obtain store, dispense/use, and dispose of the device. Attach a separate document that includes this information or note the location/section/page # where this information may be found in the protocol			
f	The informed consent process/document must include a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained **and the possibility that the FDA may inspect the records.** (21 CFR 50.25 (a) (5))			
g	Is the study an applicable clinical trial? *"Applicable clinical trials" generally include:* *(1)* Trials of Drugs and Biologics*: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation;* *(2)* Trials of Devices*: Controlled trials with health outcomes, other than small feasibility studies, and pediatric post-market surveillance.* *Complete statutory definitions and more detailed information on the NIH's current thinking about the meaning of "applicable clinical trials" may be found in the "Elaboration of Definitions of Responsible Party and Applicable Clinical Trial".* (if No, skip h)	☒ Yes	☐ No	
h	Is the clinical trial registered in Clinicaltrials.gov?	☒ Yes	☐ No	
	• Under federal regulation 21 CFR 50.25(c) the following statement must be reproduced word-for-word in informed consent documents for applicable clinical trials begun after March 7, 2012: "*A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time"*			
	Notes: The trial will be registered in ClinicalTrials.gov following IRB approval			

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Appendix D: Use of Devices Investigator Checklist

Protocol title:

Rhode Island Prescription and Illicit Drug Study

PI name:	Date:
Brandon DL Marshall, Phd	10/07/2020

Investigations with multiple devices must submit a separate form for each device.

Device name: Whatman 903 Protein Saver Card

A device will **NOT** fall under the FDA regulations if all of the following statements are true:

1) Data will not be submitted to the FDA
2) Safety and/or effectiveness data will not be collected about the device
3) The device is used only as a tool to collect data to examine a physiologic principle

If ALL statements above are true, please initial here: BDLM

Please include this form and the device manual in your protocol submission to the IRB. No further information is required at this time.

This checklist serves as a guide to Sponsor-Investigators in determining and documenting information required by the IRB related to the use of a medical device which falls under the FDA regulations (21 CFR812) in a human subjects' research study and requires an Investigational Device Exemption (IDE). ***Sponsor-Investigator* is the individual who initiates and also conducts the regulatory requirements applicable to both sponsors and clinical investigators (21 CFR312.3).** A device will fall under the FDA regulations if data will be submitted to the FDA **OR** safety and/or effectiveness data are collected about the device.

The IDE regulations (21 CFR812) describe three types of device studies: significant risk (SR), which require an IDE application approved by the FDA, non-significant risk (NSR) which must follow the abbreviated IDE requirements (21 CFR812.2b) and do not require a submission of an IDE application to the FDA or exempt from IDE regulations (21 CFR812.2b30. Please consult the cited regulations for additional information on these types of device studies.

	For additional guidance, this flowchart may be helpful in determining if an IDE is required.			HRPP USE ONLY: Confirm information for IRB review, (based on protocol submission and checklist) noting a check mark ✔.
a.	Studies considered exempt from IDE regulations include:			
	• A legally marketed device when used in accordance with its' labeling.	☐ Yes	☐ No	
	• A diagnostic device if it complies with labeling in 809.10(c) and the testing is noninvasive, does not require an invasive sampling procedure that presents significant risk, does not by design or intention introduce energy into a subject, and is not used a diagnostic procedure without confirmation by another medically established diagnostic product or procedure.	☐ Yes	☐ No	
	• Consumer preference testing, testing of a modification or testing of a combination of devices if the device(s) have an approved Premarket Notification 510(k), or are exempt from 510(k) **AND** if the testing is not for the purpose of determining safety or effectiveness and does not put subjects at risk.	☐ Yes	☐ No	

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	If "Yes" to one of the bulleted items, the study is exempt from IDE regulations. Please provide/attach supporting documentation, e.g., letter from the FDA, or other information used to make this exempt determination. This form is complete. If "No" to all bulleted items, continue to next item.			
b	Does the research collect safety and/or efficacy data on medical devices in human participants or on human specimens? (An IDE must be submitted to the FDA if the sponsor-investigator intends to conduct a clinical investigation with an investigational new device to determine safety and effectiveness **unless** the investigation is considered to have an approved application for an IDE, or is exempt from the IDE requirements. (21 CFR 812.2)	☐ Yes	☐ No	
c	Has the FDA assessed the device for a risk determination? If yes, Please indicate if the FDA determination is: NSR_____(non-significant risk) SR_____(significant risk) *If "yes", provide the IRB with a copy of the FDA documentation, and this form is complete, the remaining items do not apply.	*☐ Yes	☐ No	
d	Has the sponsor-investigator made a risk determination? If yes, Please indicate if the determination is: NSR_____(non-significant risk) SR_____(significant risk) Please provide the IRB with a description of the device, reports of prior investigations with the device, the proposed investigational plan, and any other information that will assist the IRB in the review of this determination.	☐ Yes	☐ No	
e	Please provide the plan to securely obtain store, dispense/use, and dispose of the device. Attach a separate document that includes this information or note the location/section/page # where this information may be found in the protocol			
f	The informed consent process/document must include a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained **and the possibility that the FDA may inspect the records.** (21 CFR 50.25 (a) (5))			
g	Is the study an applicable clinical trial? *"Applicable clinical trials" generally include:* *(1)* Trials of Drugs and Biologics*: Controlled, clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation;* *(2)* Trials of Devices*: Controlled trials with health outcomes, other than small feasibility studies, and pediatric post-market surveillance.* *Complete statutory definitions and more detailed information on the NIH's current thinking about the meaning of "applicable clinical trials" may be found in the "Elaboration of Definitions of Responsible Party and Applicable Clinical Trial".* (if No, skip h)	☐ Yes	☐ No	
h	Is the clinical trial registered in Clinicaltrials.gov?	☐ Yes	☐ No	
	• Under federal regulation 21 CFR 50.25(c) the following statement must be reproduced word-for-word in informed consent documents for applicable clinical trials begun after March 7, 2012: "*A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time"*			
	Notes:			

RAPIDS

RHODE ISLAND RESOURCE LIST

In this guide, you will find many local and statewide resources.

These are for you and we encourage you to reach out.

1 Get Help

BH Link	401-414-5465 http://bhlink.org 975 Waterman Ave East Providence, RI	BH Link is a behavioral health facility designed to provide immediate assistance to a person in crisis by providing innovative crisis intervention services, and connecting people to ongoing treatment and care.
National Suicide Prevention Hotline	1-800-273-8255	The National Suicide Prevention Lifeline is a national network of local crisis centers that provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week.
Rhode Island Coalition Against Domestic Violence	Hotline: 1-800-494-8100 www.ricardv.org	An organization dedicated to ending domestic violence through advocacy, community organizing, and resource sharing.
Sojourner House	401-658-4334; 401-765-3232 www.sojournerri.org	A comprehensive domestic violence agency which provides shelter, advocacy, education and support services.
Women's Resource Center	Hotline: 1-800-494-8100 www.wrcmbc.org	An organization working to end domestic by providing advocacy, education, and support services.
The Providence Center	401-766-0900 www.providencecenter.org info@provctr.org	The Providence Center provides comprehensive services to all individuals experiencing mental health, substance abuse, emotional and behavioral difficulties.

2 Safer Use

Project Weber/RENEW	401-383-4888 http://weberrenew.org 640 Broad Street Providence, RI 02907	A non-profit offering sexual health, harm-reduction and recovery support services in Rhode Island, with a focus on individuals who engage in sex work.
ENCORE	401-781-0665 rayj@aidscareos.org 557 Broad Street Providence, RI 02907	Provides comprehensive care to persons living with HIV/AIDS in Rhode Island. No medical coverage necessary.
Community Care Alliance	401-235-7000 401-766-0900 http://communitycareri.org	Offers more than 50 services and programs including addictions treatment, HIV/AIDS support, employment development and more. A hotline providing information about HIV/AIDS, treatment and services.

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3 Learn About Recovery

CODAC Behavioral Healthcare of Rhode Island	1-877-805-0152 www.codacinc.org	A non-profit based in Cranston which provides treatment, recovery and prevention services.
Anchor Recovery Community Center	www.anchorrecovery.org Pawtucket: 401-721-5100 Warwick: 401-615-9956 info@anchorrecovery.org	Anchor Recovery provides a safe, welcoming environment for all individuals in recovery from substance use disorders. Anchor offers a community center where members and recovery support specialists share their recovery experience, provide support through various peer-led groups, and offer resources to empower others in finding their pathway in recovery. They offer locations in Pawtucket and Warwick.
RICARES	401-475-2960 Ricares.org 134 Mathewson St. 3rd floor Providence, RI	RICARES views recovery as a social justice issue. We bring trauma, recovery, and social justice together. We view a Rhode Island where recovery is a mainstream lifestyle and we live free from stigma and discrimination. RICARES asserts that all pathways lead to recovery. Recovery does not require forced or coerced abstinence and is sustained as a chosen identification.
VICTA	401-300-5757 Victalife.com 110 Elmwood Ave Providence, RI 02907	VICTA is a privately owned outpatient substance abuse and mental health treatment program. VICTA if sounded by people that worked in this field for an extended period of time and wanted to make a difference in someone's life using their expertise and care.
Hope Recovery Alliance	401-619-1343 Hoperecoverycenter.org 50 Washington Square Newport, RI	At Hope Recovery Center of Newport County our approach is to offer support for people to choose recovery as an achievable way out of substance use and mental health challenges.

4 Get Health Care

Providence Community Health Center	www.providenceehc.org 401-433-0200 There are 13 locations around Providence	Providence Community Health Centers provide affordable, quality, primary health care to meet the community's medical needs. Patients receive coordinated physical, mental health and substance abuse care under one roof with access to community supports that promote a healthy lifestyle.
Butler Hospital	844-401-0111 www.butler.org 345 Blackstone Boulevard, Providence RI	A psychiatric and substance abuse hospital located on Blackstone Boulevard in Providence. Butler odders a wide variety of services including inpatient, outpatient and partial hospital programs.
The Kent Center	Emergency Services Program: 401-738-4300 Non-emergency services: 401-732-5656	A non-profit community based provider of mental health, substance abuse, and educational services affiliated with Brown University. Located on Post Road in Warwick.
Rhode Island Free Clinic	401-274-6347 www.rifreeclinic.org 655 Broad Street Providence, RI	Provides coordinated health services comprised of primary care, labs and diagnostics, specialty care, prescription medications, follow-up visits, counseling and wellness programs that help uninsured adults get and stay healthy.
Clinica Esperanza/ Hope Clinic	https://www.aplacetobe-healthy.org/ 60 Valley Street, Suite 104 Providence, RI	Offers primary medical care to RI residents without health insurance, with an emphasis on Spanish-speaking and culturally accustomed care
Thundermist Health Center	401-615-2800 http://thundermisthealth.org 450 Clinton Street Woonsocket, RI 186 Post Road, West Warwick, RI 1 River Street Wakefield, RI	Thundermist provides primary medical care to Rhode Island residents without health insurance, with speciality in Trangender health care, HCV treatment, and substance use.

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ATTACHMENT J: REOPENING PLAN

Description of the research to be done

We would like to resume in-person survey questionnaires with participants at SPH 121 South Main St. for our NIH-funded, R01 clinical trial, The Rhode Island Young Adult Prescription and Illicit Drug Study (RAPIDS). This study involves recruiting individuals for six in-person contacts over the course of one year. Each visit is approximately 60 minutes, with the initial baseline visit lasting up to 90 minutes. Participants are asked a series of questions, some are randomized to a 15-minute behavioral intervention session, and all participants are asked to give a urine sample for a drug screen. Participants are given a bag at the end of each session with naloxone and some also receive fentanyl test strips.

Justification for reopening the research space

The nature of the intervention is such that in-person participation is required. In particular, the fentanyl test strips and naloxone must be given to each participant at the end of an intervention session. Many participants do not have a regular address, so mailing these materials would be challenging, if not impossible. In addition, urine sample collection would be infeasible remotely, and would compromise the scientific rigor of the work, since past three-day drug use reported during the survey component will be correlated with the urine sample results. Urine samples provided several days after the self-reported data is ascertained would not provide the same level of fidelity and information.

List of personnel who will work in the research space

Only the fewest number of research staff necessary to conduct the research will work in person at 121 South Main. Specifically, two research assistants (Jackie Goldman, Tania Lobo Paz) will be asked to return to in-person work. Their supervisor (Jesse Yedinak) and the PI (Brandon Marshall) will continue to work remotely during this period, but will be available by email or phone during all scheduled participant visits. Please see the lab density sheet for more information.

Lab safety plan

General procedures:
Risks to staff and participants will be mitigated through the use of personal protective equipment (masks, gloves for handling study equipment, including distribution urine tests, naloxone to participants etc.), regular sanitizing of spaces after each participant, and by bringing back the fewest staff needed to complete the study visits (2). Social distancing guidelines will be followed by the 2 staff who are on-site, and they will wear masks whenever they are in a common space or near other

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people. They will be the only staff on the 2nd floor of SPH. Staff will be required to stay home and cancel study visits if they show any signs or symptoms of illness, and will contact their supervisor that same day to discuss their symptoms.

Work shift:

- On days where participant visits are scheduled, research staff will be working in-person. They will arrive an hour before the first participant visit in order to prepare for the study visit and perform requisite cleaning.
- When scheduling multiple visits in a day, there must be at least an hour in between visits to allot for disinfection procedures, to ensure that participant visits do not overlap should participant visits run overtime or a participant arrive early.
- After the final visit for the day, staff should plan to stay on site for an hour to clean and disinfect the study space as well as personal work space.
- Staff will only work in the building on days when participant visits are scheduled. Otherwise, staff will work remotely. If there are multiple visits during the day, that staff will stay on site between visits and be allowed to conduct their non-participant facing work, such as phone screens, attend zoom meetings related to this project or others, and perform other administrative work related to this project and others.
- Staff will be requested to eat in either rooms 240 or 247. Staff must maintain social distancing measures when they eat and wipe down high-touch surfaces before and after eating.

Procedures for social distancing:

- Each staff will have their own office in which to conduct their work and participant visits.
- Each staff will have their own laptop and phone. No other study equipment will be shared.
- Staff will agree to stay more than 6 ft apart when in a shared space.
- Participants will be given a disposable mask by staff in the Lobby if they did not bring their own.
- Participants will be instructed by staff on the social distancing procedures for the building and research study.
- Participants will be screened for all potential COVID-19 symptoms in the Lobby, per building guidelines.
- Participants will be escorted in the elevators or given the option to take the stairs. If only one person is allowed in the elevator at a time, one of the staff will greet the participant in the lobby and press the button for the second floor. The second staff member will wait on the second floor and escort the participant to the proper room. The first staff member will then meet the participant.
- In order to minimize time spent in direct proximity with participants, Staff will employ a mixture of in-person and virtual research methods. Participants and Staff will sit in separate rooms with a laptop. Survey administration and overdose education will occur over Zoom. The final piece of the intervention, which lasts between 10-15 minutes will take place in person. For the in-person parts of the study visit, both Staff and Participants will wear masks and use hand sanitizer before sitting in the same room.
- For the dried blood spot collection, staff and participants will be closer than 6 feet. This interaction will take no more than a few minutes. During that time, staff will be wearing face shields.

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- Each staff person will be limited to no more than 3 participant visits per day during Stage II of Brown University reopening. This will ensure that there will be ample time to disinfect the study space between visits and will minimize the number of interactions that the research staff have in the course of a day. We will re-evaluate the number of participant interactions in a day as the university transitions to different stages of re-opening.
- In order to adhere to Stage II building density guidelines, the portion of the study visit that will take place in person will occur in room 259. This will be reevaluated as Brown University moves to other stages of reopening.

Additional procedures for participant encounters/sessions:

- Staff will ensure there are sufficient cleaning supplies and personal protective equipment on-site at all times. Cleaning equipment will be stored in room 256.
- Staff will disinfect their work space upon entering the building and upon completion of their work day.
- At all times, participants will be seated more than 6ft apart from the research staff.
- Staff will conduct a health pre-screening with research participants prior to their study visits.
- Participants will enter and exit 121 South Main Street through the main entrance.
- Participants will be asked to use hand sanitizer immediately upon entering the building or will need to wash their hands when they arrive at the second floor. If the participant does not arrive wearing a mask, the participant will need to wash their hands or use hand sanitizer immediately after putting their mask on.
- Research staff will ask all questions out loud and will do all data entry for participants.
- All consent forms will be completed electronically.
- All surfaces will be disinfected after each participant visit. Additionally, all surfaces will be disinfected before the first visit and at the completion of the final study visit each day.
- Signs will be posted reminding participants of how to properly wear their masks and reminding them to wash their hands thoroughly after their visits.

Additional procedures for urine screening:

- There will be one dedicated restroom for participants to use for urine screens. No other staff or participants are allowed to use that restroom.
- Protective equipment, such as masks and gloves, will be worn at all times during urine drug screening, in accordance with the prior-approved protocols.
- The restroom will be wiped down with disinfectant after each use.

Finally, as the research involves in-person, on-campus human subjects research activities, the following is attested:

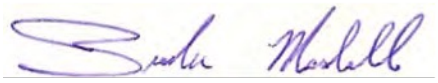
1) I affirm that the study team will conduct a health pre-screening with research participants at least a day prior to and on the same day as their study visits. If the health pre-screening and research participants' on-campus study visit are not within close proximity to one another, it is advised that the study team conduct another health screening when the research participant arrives for the study visit.

2) I affirm that the study team will discuss with research participants the safety protocols implemented at Brown to reduce risk of transmission of COVID-19 prior to their study visit. This must include any Expectations of study participants.
3) I affirm that the study team will inform research participants of the Brown University requirement that they wear a face covering during their study visit.
4) I affirm that the study team will provide research participants with information about the Centers for Disease Control and Prevention groups determined to be at higher risk for severe illness, either verbally via a script or via an electronic method (for example, sent via email or Qualtrics). This will enable participants to make an informed decision about personal risks related to COVID-19.
5) I affirm that the study team will remind research participants of the following Phase I State of Rhode Island guidance: "Older adults (65+) and those with underlying health conditions can go to work and go out for food or medicine. But in accordance with federal public health guidance, vulnerable individuals are strongly encouraged to otherwise stay home."

Contact tracing plan

- Contact tracing will be performed in accordance with the Brown University policy.
- Staff will log all participant's full name, phone number, location, date and time of contact.his log will be updated daily. This log will also include staff encounters for each day.
- Contact logs will be stored in the study team's REDCap database that is only accessible through Stronghold. Participants will be assured that all contact information will be stored behind two-step authentication. Participants' personal information will only be accessed by the study team and the Rhode Island Department of Health as needed. Contact tracing logs will be stored and maintained separate from research data collected as part of the RAPIDS study.
- Contact logs will be destroyed 30 days after the participant's study visit.
- Once the staff has been made aware of COVID-19 exposure, staff will contact participants immediately, and no later than 72 hours after the known exposure. Staff will contact HR immediately and follow HR's direction about how to proceed.
- At any point, if Brown University issues additional guidelines, the staff will follow those procedures in addition to/in place of these written guidelines, whichever are more strict.

Yours sincerely,



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Associate Professor
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THE RAPIDS CLINICAL TRIAL:
Appendix C: Dried Blood Spot Protocol

Dried Blood Spot Collection Policies & Procedures *- The following are instructions to guide the collection, handling and storage of dried blood spots.*

When collecting blood samples, always use Universal Safety Precautions. These include:

- *Treating all blood samples as though they are infectious;*
- *Washing hands;*
- *Wearing gloves;*
- *Taking precaution to avoid needle-stick injury; and*
- *Disposing of contaminated sharps and waste appropriately*

---

1. **Materials required**
   - Whatman 903 Protein Saver cards (DBS collection card)
   - Sterile, disposable lancets
   - Specimen bags (sealable plastic bags)
   - Humidity indicator cards
   - Desiccant packs
   - Absorbent underpads
   - Sterilising alcohol wipes
   - Gauze pads, cotton ball, and plaster/band-aid
   - Safety and clean-up materials including gloves, a sharps container, sani-cloth wipes, concentrated bleach for 10% bleach solution.

2. **Sample collection and testing procedure**

This section presents detailed instructions for collecting and storing a DBS sample. Please ensure that you read and understand the steps involved and collect each sample in accordance with these instructions. A simplified graphical representation of this procedure (Annex 1) is presented on page 4 for your future reference.

Please examine Annex 2 (page 5) to familiarize yourself with the appearance of a valid versus invalid DBS sample, and take note of the following tips for sample collection:

- Apply blood to only one side of the filter paper (DBS card)
- DO NOT press the filter paper against the puncture site
- DO NOT layer successive drops of blood or apply blood more than once in the same collection circle
- DO NOT "milk" the finger as excessive milking or squeezing the puncture site might cause hemolysis of the specimen (destruction of red blood cells) or result in collection of tissue fluids with the specimen, which might adversely affect the test result

Note: Three complete circles are better than five incomplete ones! While the collection card may include 5 circles, only one participant's blood may be collected on any given card.

3. **General test preparation**
   a) Gather the required materials and find a suitable surface to take the samples before putting on the gloves
   b) Label the DBS card with the encrypted study ID code and complete any clinical information required on the card.

4. **Fingerstick performed by the study team**
   a) Explain the procedure to the participant so that they know what to expect. Ask which finger they would like to use, noting that the ring finger (fourth from the thumb) is most practical for the procedure.
   b) Warm the participant's hands and fingers to increase blood circulation if possible. To further increase blood circulation, it sometimes helps to massage the whole hand and finger to be stuck, not just the fingertip. While the tester is organizing the specimen collection materials, they can also have the participant open and close ("pump") their hand or squeeze and release a stress ball several times to increase blood circulation. Having the participant hold their hand below the level of their heart before performing the collection increases blood circulation as well.
   c) Position the hand palm-side up. Choose the fingertip of the ring, or middle finger, whichever is the least calloused. You can also use the index finger or thumb if it's the least calloused finger.
   d) Clean that finger with the alcohol pad.
   e) Using a sterile contact activated lancet, puncture the skin just off the center of the finger pad. Hold the finger downward and apply gentle pressure beside the point of the puncture. Avoid squeezing the finger to make it bleed.
   f) Wipe away the first drop of blood, which tends to contain excess tissue fluid, with a sterile gauze or cotton ball. Allow a new drop of blood to form before collecting the blood specimen.
   g) Allow a large drop of free-flowing blood to collect at the puncture site. Working quickly, hold the DBS card by the edges, touch the filter paper gently against the large drop of blood, and in one step allow a sufficient quantity of blood to soak through and completely fill or saturate a circle.

DO NOT allow the finger to touch the card;
DO NOT layer successive drops of blood or apply blood more than once in the same collection circle.

   h) Repeat Step g), collecting enough blood on the DBS card to fill each of the 5 circles completely.
   i) Give the participant a gauze pad and ask them to apply pressure to their finger.
   j) Take the DBS card to a secure drying rack, ensuring it is labeled with the participant's

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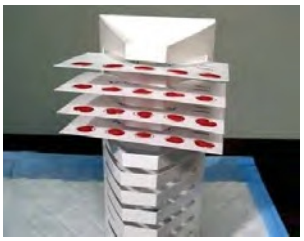
encrypted study ID code, and allow it to dry for a minimum of four hours before packing for storage.

k) Once the bleeding has stopped, use a Band Aid to bandage the participant's finger.

l) Discard your gloves in a biohazard container after the sample collection and don a fresh pair for each new participant.



5. <u>Cleanup and decontamination</u>

a) Dispose of used lancets and gloves in a sharps container. Once the sharps container is full, close firmly, and set in the designated area for pick up and destruction.

b) Due to the small amounts of blood being collected from each participant, it is unlikely that large spills will occur. However, it is important to treat any blood spilled as potentially infectious. Use a sani-cloth wipes to wipe up the blood. If more than a few drops of blood are spilled, use the 10% bleach solution and the sani-cloth wipes to clean the area. Dispose of the clinical wipes in a sharps container.

c) At the end of each day, wipe down completely all surfaces using Clorox Clinical Wipes, including tabletops, collection station chairs, and empty drying racks.

6. <u>Packaging DBS samples for long-term storage</u>

a) Once the DBS card has been allowed to dry for a minimum of four hours, follow the steps depicted in the figure to prepare the DBS kit for long-term storage

b) Fold the DBS card to protect the collected samples

c) Insert the DBS card into the sealable plastic bag, ensuring that the participant identification label will be visible without opening the bag

d) Add two desiccant packets to the plastic bag. These serve as a drying agent to protect the sample

e) Add a humidity indicator card, ensuring that it will be visible without opening the bag

f) Seal the bag and store in a cool, dry, dark place until it can be shipped to the biospecimen bank at Rhode Island Biobank. Humidity and UV light can damage the DBS samples so it is important they are stored appropriately.

Note: DBS samples can be stored at room temperature for a maximum of 14 days from the date of collection. After 14 days the samples must be transferred to a -70˚C freezer. The total time at ambient / room temperature should be minimised as much as possible.

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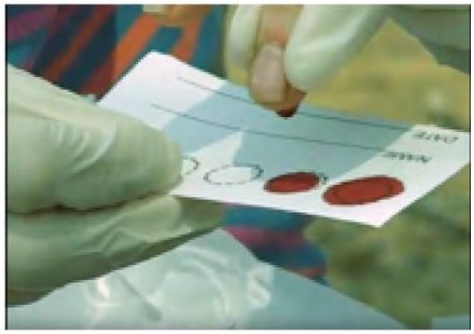
Annex 1: Summary of dried blood spot collection

STEP 1

Clean the finger and wipe with alcohol swab, then using a sterile lancet, puncture the skin just off the center of the 3rd or 4th finger pad

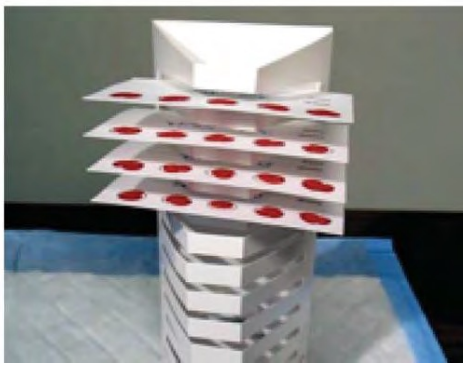
STEP 2

Wipe away the first drop using gauze or cotton ball*. Apply gentle pressure to the finger and allow a large drop of free flowing blood to collect at the puncture site. Drip enough blood onto the DBS card to fill each of the 5 circles completely*



STEP 3

Label the card with the participant's ID sticker and take the DBS card to a secure drying rack



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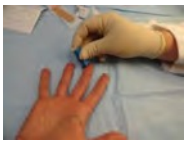
Before sticking the finger…

- Set out all supplies needed to collect blood; open band aid and alcohol pad
- Ask the participant which is their non-dominant hand
- Assess positioning of you and the participant to decide the easiest way to collect blood for the rapid test and DBS

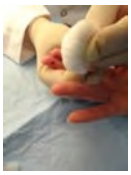
- Assess which finger is free of callouses and has the softest skin – this is typically the ring finger
- Even if the participant's hands are warm, massage the whole hand to increase circulation; hold participant's hand downward (below the heart) while massaging. Circulation can also be increased by asking the participant to pump their hand or squeeze a stress ball
- Ask participant to flick their hand in a downward motion
- Clean the finger with an alcohol pad

The stick…

- Lay the hand against a hard, flat surface



- Hold the lancet just off from the center of the fingertip pad and perpendicular to the ridges of the fingerprint; DO NOT STICK THE FINGER ON THE SIDE
- Massage from the base of the finger using a squeeze-release motion; it works well to wrap your fingers around the stuck finger and the finger next to it
- DO NOT SQUEEZE the tip of the finger



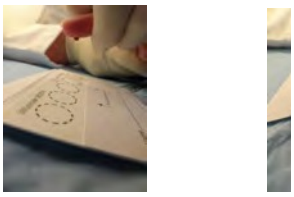
- Wipe away the first drop of blood with a cotton ball

- **If blood is not readily flowing:**

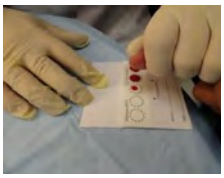
- Massage entire hand using both of your hands; one hand should continue with the squeeze-release of the fingers
- If participant is feeling okay, ask him to stand up to allow the hand to be held much lower than the heart
- Be patient and keep massaging; sometimes it takes time for the blood to start flowing

Specimen collection…

- Allow a new drop of blood to for the first drop with a cotton ball
- Collect specimen for rapid test
- Flip the hand downward towar card, continue massaging, allo time for a very large drop of blo before applying to the first circl



- Touch the drop of blood to the NOT TOUCH THE FINGER TO the card will wick the drop of b from the finger
- If one drop of blood does not fi entire circle, immediately apply drop of blood to that same circ
- Continue above procedures as move to next circle



- Upon completion, the circles sh

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Annex 2: Examples of valid and invalid dried blood spot specimens

VALID DBS SPECIMEN

This specimen is valid because:
- 100 µl of blood has been collected in each circle completely saturating or filling the circle
- The filter paper card has been labeled with appropriate identification.
- Blood is soaked through to the other side of the card.

On the card with MB/KP/120, the blood is spreading from one circle to another due to the anemia (anemic blood is more fluid). This is still considered a valid specimen.

INVALID DBS SPECIMEN

This specimen is invalid because quantity of blood is insufficient for testing

This specimen is invalid because it appears scratched or abraded.

This specimen is invalid because the specimen was not dry before mailing. DBS must dry a minimum of 4 hours before packaging and shipping.

This specimen is invalid because the specimen appears clotted or layered. This may have been caused by:
- Touching the same circle on the filter paper to blood drop several times
- Filling circle on both sides of filter paper

The volume of specimen will not be uniform between spots resulting in errors during the testing process.

This specimen is invalid because the specimen appears hemolyzed, discolored, or contaminated. This may have been caused by:
- Squeezing or "milking" of area surrounding the puncture site
- Allowing filter paper to come in contact with glove or ungloved hands or substances either before or after blood collection
- Exposing blood spots to direct heat

This specimen is invalid because the specimen exhibits serum rings – in other words, serum becomes separate from cells. This may have been caused by:
- Not allowing alcohol to dry at puncture site before making skin puncture
- Allowing filter paper to come in contact with alcohol, hand lotion, etc.
- Squeezing area surrounding puncture site excessively
- Drying specimen improperly

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