UNIVERSITY OF CALIFORNIA, SAN DIEGO
CONSENT TO PARTICIPATE IN RESEARCH

1. Study Title and Number

Title: **Efficacy and implementation considerations for a peer-led motivational interviewing intervention to promote uptake of drug checking services and safe drug use behaviors to reduce overdose and HIV/HCV incidence**
Study # ***810285***

2. Principal Investigator

Steffanie Strathdee, Harold Simon Distinguished Professor, UCSD Division of Infectious Diseases and Global Public Health Department of Medicine, Co-Director, Center for Innovative Phage Applications & Therapeutics (IPATH) and,
Annick Borquez, Associate Professor, Division of Infectious Diseases and Global Public Health, UCSD Department of Medicine

3. Principal Investigator Phone Number, Research Team Number, and Emergency Contact Number

PIs Phone Numbers: 858-822-1952 and 619-957-8010
Research Team Number: 844-267-3370

Emergency Contact:
Carlos Vera
619-603-1639

4. Study Sponsor

The National Institute on Drug Abuse within National Institutes of Health, the study sponsor, is paying UC San Diego to conduct this research study.

5. Study Overview

This research study is being conducted to see if motivational interviewing, involving education and problem-solving, increases use of drug checking services and safer drug use behaviors and reduces drug overdose (OD) among people who use drugs and risk of HIV/HCV infection in San Diego County. You will be asked to participate in a brief educational and/or behavioral session, and then offered free drug checking services. You will also be asked to complete behavioral interviews and blood testing for HIV/Hepatitis C status. once every six months for 30 months.

We are inviting you to participate in a research study because of your past or present drug use.

This form explains the research so that you may make an informed decision about participating.

- Research is voluntary - whether or not you participate is your decision. You can discuss your decision with others (such as family, friends or another physician).
- You can say yes, but change your mind later.
- If you say no, we will not hold your decision against you.
- You can say no even if the person inviting you is part of your healthcare team.
- Your decision will not affect your health care, access to harm reduction services or other benefits you may be entitled to.
- Please ask the study team questions about anything that is not clear, and feel free to ask questions and mention concerns before, during, and after the research.

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- You may consult with friends, family, a personal doctor, or anyone else before deciding whether or not to be in the study.
- You will be given a copy of this consent form and the Participant's Bill of Rights.

The purpose of this research study is to see if education, motivational interviewing and problem-solving increases use of drug checking services, safer drug use behaviors and reduces OD and HIV/HCV infection among people who use drugs in San Diego County.

You will complete a brief questionnaire to determine if you are eligible for the study. If you are eligible, you will be assigned to receive a one-time, individual informational session (control) or an active, motivational interview (intervention) over a period of 30 minutes.

You will also be asked to complete a behavioral interview that asks questions about your lifestyle, attitudes, behaviors, health issues and about OD experiences, and any medical attention received after an OD and blood testing for HIV/Hepatitis C status. Your participation in the study will be for 30 months. During that time, you will complete behavioral surveys and blood testing for HIV/Hepatitis C status every 6 months and each follow up visit will last 30-45 minutes.

You will be asked to sign a medical records release form/HIPPA authorization form to allow the study team access to some of your medical records.
The most commonly expected risks of the study are that interviews may make you feel uncomfortable or upset. You can ask any of the researchers to leave or stop talking to you at any time and change your mind about agreeing to participate even after we have started. If you would like to see a counselor after talking with us, we can arrange for that without any cost to you.
The most serious risk of this study may include loss of confidentiality. Although at no time will individual results or responses to questions be available to persons outside the study and study forms and data will not contain your name, there is a small chance that someone may discover that you participated in this study.
A complete listing of possible risks and discomforts associated with this study can be found in Section 9 of this document.

You may benefit from free confidential drug OD and naloxone education and drug testing and counseling which may potentially help you prevent having an OD or other health harms caused by drug contamination.

You will also receive free confidential testing and counseling for HIV/ Hepatitis C, as well as facilitated referrals for medical/social care, which may potentially lead to early identification and early treatment of HIV/HCV

The alternative to joining this study is not to participate. We will still provide you with referrals for free or low-cost HIV/HCV testing and drug checking services and drug OD prevention services in San Diego County including the Harm Reduction Coalition San Diego (HRCSD) services who provide pre- and post- drug testing counseling for free.

More detailed information about this research study is provided below.

6. Whom can I talk to if I have questions?

If during your participation in the study you have questions or concerns, or if you think the research has hurt you, contact the research team at the numbers listed in Section 3 on the first page of this form. You should not agree to participate in this study until the research team has answered any questions you have about the study, including information contained in this form.

If before or during your participation in the study you have questions about your rights as a research participant, or you want to talk to someone outside the research team, please contact:

- UC San Diego Office of IRB Administration at 858-246-4777 or irb@ucsd.edu

7. How many people will take part?

We plan to learn from 588 people who use drugs. The research will take place across all Safe Syringe Services Programs in the community run by HRCSD, spanning San Diego County.

8. What happens if I take part in the research?

Here is what will happen to you if you agree to be in this study:

If you decide to join the MI-CHANCE study, we will ask you to participate in an interview that asks questions about your lifestyle, attitudes, behaviors, health issues and whether or not you have ever tested your drugs and undergo blood testing for HIV/Hepatitis C status by providing fingerstick or venipuncture blood specimens up to the amount of 4ccs of blood, or approximately up to one tablespoon of blood at each visit.

We will ask you to take a picture of your face to issue a study participant photo ID that will include your name, date of birth and the name of the study. This will be used by study staff to more easily identify you as a participant in the study. Next, study staff will give you a laminated coupon with the address and schedule for a nearby site of the HRCSD Syringe Service Program. Attending HRCSD locations is voluntary. HRCSD runs a syringe service program that offers free services at several locations around San Diego County, which includes free drug checking services.

You will be "randomized" into one of 2 study groups described below.

MI-CHANCE participants in the control group will receive Overdose Education and Naloxone Distribution materials (this is called "the standard of care") and additional Flu and Hepatitis A didactic information (this is the control). MI-CHANCE participants in the intervention group will receive the Overdose Education and Naloxone Distribution materials and motivational interviewing counseling (this is the intervention).

Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researchers choose which group you will be in. Depending on which week of the month you visit the HRCSD syringe service program, you will have a 50/50 percent chance to be enrolled in the control or in the intervention group.

When you visit HRCSD straight after joining MI-CHANCE, their staff will assign you a unique identifier (ID) if you have never used their program before. These IDs are generated using 1&3 letters of both first and last name, date of birth, and a gender identifier M-1, F-2, Other-3. You do not need to use your real initials and birth date if you decide not to, but you need to remember the information you used for your unique ID so you can use it when you use services from HRCSD. HRCSD peer support specialists will ask you to complete a short 5-minute interview.

Then, the HRCSD peer support specialist will talk to you about Overdose Education and Naloxone. If you are assigned to the control group, the peer support specialist will then also talk to you about Flu and Hepatitis A, including information about the virus, how it is spread, what kinds of health problems it causes and what vaccines and treatments are available for it. If you are assigned to the intervention group, the peer support specialist will also talk to you about motivational interviewing to problem solve and address concerns around testing your drugs.

The HRCSD peer support specialist will answer any questions you may have. No matter which HRCSD location you visit or what week of the month it is, this session will be completed within 45 minutes. You can refuse to participate in the MI-CHANCE intervention and still have access to free drug testing services and Naloxone® at syringe service programs across California.

No matter what group you are enrolled in, you will then take part in study visits every 6 months for 30 months. These visits will involve a similar interview to the first one you will have completed.

We will also ask you to sign a release of medical information to be used to collect information on health problems or ODs you may have, and health services you may use from other places such as the HRCSD/OnPoint, San Diego Health and Human Services database, accessing your electronic health records from hospitals or drug treatment programs, and Centers for Medicare and Medicaid Services, among others.

9. What are the risks and possible discomforts?

Participation in this study may involve risks or discomforts. In addition to the risks described at the beginning of this form:

1. The collection of blood specimens may present a risk of bruising or discomfort during the procedure. However, every precaution will be taken to reduce the risk of the blood draw as our staff is well-trained and has extensive experience.
2. Being tested for HIV/HCV can make you feel nervous or anxious about the test results. A positive test result indicates that you are infected with HIV or HCV, but no one knows for certain when, if ever, your health condition may worsen. Receiving positive results may make you very upset. If other people learn about your positive test results, there might be a risk that you could be treated unfairly or badly, and even have trouble obtaining employment. To the extent permitted by law, the researchers will keep your test results confidential and will not release them to anyone without your written permission. If you test positive, California law requires health care providers and clinical laboratories to report the HIV/HCV test results with your personal identifying information to the local health department.
3. Testing your drugs can make you feel nervous or anxious about the test results. Receiving a positive result for a specific drug that you did not expect may make you very upset. HRCSD staff will be available to discuss with you the results of your drugs checked.
4. There is legal risk if information on illegal behavior (i.e., drug use, drug dealing activities) were to become public knowledge. The data will also be protected in the United States by a Federal Certificate of Confidentiality which can be used in US courts to refuse to disclose information that may identify you in any US federal, state, or local civil, criminal, administrative, legislative, or other proceedings. A court subpoena can override the federal certificate of confidentiality in exceptional circumstances primarily related to organized crime and capital crime cases, but historically it has proved effective for routine misdemeanor and felony charges.
5. As mentioned earlier, there is the potential for the loss of confidentiality. The personally identifying information such as name and address contained in the locator forms will be kept under locked, separate cabinets at the study offices at all times only available to study staff. It is also your choice whether or not to tell people that you have taken part in this study. There is also a very small chance that someone could learn the answers you have given to the questions asked in the MI-CHANCE intervention. If this were to happen, it could affect your employability and/or insurability.
6. Risks of Collection of Sensitive Information: Some of the questions we will ask you are personal. You may feel embarrassed or stressed. You may ask to see the questions before deciding whether or not to take part in this study
7. Risks of Interviews that Discuss Sensitive Issues: Some of these questions may seem very personal or embarrassing. They may upset you. You may skip any question that you do not want to answer. If the questions make you very upset, we will help you to find a counselor, refer you to an appropriate clinic for follow up, or you can contact the San Diego Access and Crisis Line at 1-888-724-7240 for appropriate referrals.
8. Possible Unknown Risks: In addition, there might be risks that we cannot predict at this time. These unknown risks may be temporary, mild, and last only while you are actively participating in the research, or they may be serious, long-lasting, and may even cause death. You will be informed of any

new findings that might affect your health or welfare, or might affect your willingness to continue in the research.

10. How will information about me be protected?

While we cannot guarantee complete confidentiality, we will limit access to information about you. Only people who have a need to review your information, documents, or specimens will have access. These people might include:

- Members of the research team and other staff or representatives of UCSD whose work is related to the research or to protecting your rights and safety.
- Representatives of the study sponsor or product manufacturer
- Representatives of Federal and other regulatory agencies who make sure the study is done properly and that your rights and safety are protected.

Your privacy is very important to us. We will take great care to protect your privacy. However, there is always a chance that, even with our best efforts, your identity and/or information collected during this study may be accidentally released or seen by unauthorized persons. Here are a few steps we will take:

- Everyone working on this study has been trained to respect the privacy of study participants. They will never discuss what you have told them in a way that could identify you.
- Your name or other identifying information contained in the locator forms will not be on any notes or data. This consent form and the locator form will be the only form with your name on it. It will be stored at the University of California, San Diego, in La Jolla CA in a locked drawer. We will never reveal that you participated or any other information about your visit to anyone else as far as the law will allow us. Your survey information will be labeled only with a study number and not your name.
- Data will be stored on protected, secure and encrypted computer systems. We will limit and keep track of who can see these data. Our study team will use computers managed by our UCSD Health IT department, equipped with malware and anti-virus software, TPM security chips, and will operate on a VPN.
- Anyone who can see these data will have to use a password.
- We will take steps to protect your information from others that should not be able to see it.
- When your data are shared with other researchers, they will not have information that can identify you.
- After such removal, the information could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

This research will be covered by a Certificate of Confidentiality from the United States Government. Researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless there is a federal, state, or local law that requires disclosure (such as to report child abuse, elder abuse, intent to hurt self or others, or communicable diseases), you have consented to the disclosure, including for your medical treatment; or it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute on Drug Abuse (NIDA) which is funding the project or for information that must be disclosed in order to meet the requirements of the Food and Drug Administration (FDA). You should also understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care

provider, or any other person not connected with the research, you must provide consent to allow the research to release it.

Under California law, we must report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. If any investigator has or is given such information, he or she may be required to report such information to the appropriate authorities.

As a part of this study, photographs will be taken of your face and/or parts of your body. These photographs will be subject to the same confidentiality conditions described above. Even so, someone who knows you well, may be able to identify you from the photos and know you are participating in this study. To minimize this risk, we will take the following precautions: photos will not be used in publications, eyes will be blurred in face photos, unique markings/tattoos will be covered/removed, photos will only be used for participant identification by study staff.

11. Will I need to pay to participate in the research?

There will be no cost to you for participating in this study.

12. What if I agree to participate, but change my mind later?

You can withdraw from the study at any time. If you decide that you no longer wish to continue in this study, you will be asked by Dr. Annick Borquez or Dr. Steffanie Strathdee whether you wish to take back your consent to use information gathered up to that point. You may inspect and make a copy of the records of your participation in this subject. You will be told if any important new information is found during the course of this study that may affect your wanting to continue.

In addition, the study principal investigator or sponsor may stop the study or take you out of the study at any time, even if you would like to continue. This could happen due to the nature of scientific research. You may also be withdrawn from the study if you do not follow the instructions given you by the study personnel.

13. What will happen to information and/or biospecimens collected from me?

The data and specimens we collect with your identifiable information (for example, your name, medical record number, or date of birth) as part of this study may be used to answer other research questions or may be shared with other investigators for other research. If we do so, we will remove all identifiable information before use or sharing. Once identifiers have been removed, we will not ask for your consent for the use or sharing of your data in other research.

Information from analyses of your information will be put into one of the National Institutes of Health (NIH) databases along with information from the other study participants and will be used for future research. While these databases will be accessible by the Internet, only anonymous information from the analyses will be put in a public database. Common identifying information about you, such as your name, address, telephone number, or Social Security number, will not be placed in the public database.

Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.

We will gather data (information) about your counseling session, whether you tested your drugs at the HRCSD syringe service program site. We will gather some of these data from you directly which will be shared with

MI-CHANCE staff. To protect your confidentiality, a record linkage will be done without using name information (i.e., only based on your date of birth and gender, the combination of which is unique to you).

We will also audio record 10% of the MI-CHANCE counseling sessions for quality purposes. These audio recordings will be destroyed within one month, immediately after being reviewed by the Dr. Harvey Vera and/or Patterson. The transcript of the audio recordings will be kept for the remainder of the recruitment period so that these can be compared across time.

I agree to have my MI-CHANCE counseling session audio recorded for quality control purposes.

_____ Yes _____ No
Initials Initials

We may gather some of the data from other places where you may later receive treatment for drug overdose. Examples of the information that we may collect from you or other places include, but are not limited to the HRCSD/OnPoint, San Diego Health and Human Services database, accessing your electronic health records from hospitals or drug treatment programs, and Centers for Medicare and Medicaid Services, among others.

Although your data will not be linked to your name, we will keep your data securely (which means with extra protection). Researchers will use the data to learn more about drug overdose and drug testing and other conditions.

We will hold all the non-identifiable information you agree to give.

- You will be assigned a study code and you will only be identified in this database by this study code.
- It will not contain your name or other information that could easily identify you.
- We plan to transfer and keep these non-identifiable data in a secure database for drug overdose research at the NIH. Other researchers may use these data for studies, other than the ones stated in this consent form.
- Researchers will only have access to your non-identifiable data and cannot link the data back to you.
- Because the data cannot be linked back to you, we will not contact you to inform you or ask your permission before sharing the data with researchers.

I agree to let HRCSD and MI-CHANCE link my identifiable and non-identifiable data without using my name.

_____ Yes _____ No
Initials Initials

14. What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for completing your baseline and follow-up behavioral assessments in a timely manner biannually and completing your participation in the behavioral intervention.

15. Will I be compensated for participating in the research?

If you agree to take part in this research, you will need to complete the behavioral survey and get tested for HIV/Hepatitis C to be compensated $20 upon completion of your MI-CHANCE interview. You will be compensated a one-time $10 for your first visit to HRCSD upon completion of the intervention or control activities. Through La Frontera, you will be compensated $5 upon completion of the locator form at the mid-point between follow-up surveys. You will also be compensated $20 upon completion of each biannual follow-up survey for the 30-month duration of the study. By the end of the study you would be compensated a possible total of $380 through La Frontera project.

16. What else is important for me to know?

We will provide you with free pre- and post- test counseling for testing your drugs through HRCSD even if you decide not to participate in the study as well as referrals for free or low-cost drug testing or treatment services in San Diego County. The data obtained from your participation as well as the participation of all 588 MI-CHANCE participants will be analyzed as a group and will inform the development of more effective strategies to mitigate the public health risks of other people in similar situations.

If you are injured as a result of being in this study, UC San Diego will provide necessary medical treatment. The costs of the treatment may be covered by the University of California or the study sponsor, or billed to you or your insurer just like other medical costs, depending on a number of factors. The University and the sponsor do not normally provide any other form of compensation for injury. For more information about this, you may contact the UC San Diego Office of IRB Administration at 858-246-4777 or irb@ucsd.edu

18. Additional Choices to Consider

The study team would like your permission for medical release and record linkages to obtain your health information. You may also change your mind about this choice. Please initial your choice below:

_____YES, you may access/link my medical health records to obtain health information
_____NO, you may NOT access/link my medical health records to obtain health information

We would like to offer the opportunity to receive general results of the research. You may also change your mind about this choice. Please initial your choice below:

_____YES, send me a summary of the research results
_____NO, do NOT send a summary of the research results

The study team would like your permission to contact you about participating in future studies. You may still join this study even if you do not permit future contact. You may also change your mind about this choice. Please initial your choice below:

_____YES, you may contact me
_____NO, you may NOT contact me

UNIVERSITY OF CALIFORNIA, SAN DIEGO

CONSENT TO PARTICIPATE IN RESEARCH

Signature Block for Adults Able to Provide Consent

Participant

I have received a copy of this consent document and a copy of the "Experimental Participant's Bill of Rights" to keep. I agree to participate in the research described in this form.

Printed Name of Participant

Signature of Participant Date

Person Obtaining Consent

I document that:

- I (or another member of the research team) have fully explained this research to the participant.
- I have personally evaluated the participant's understanding of the research and obtained their voluntary agreement.

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent Date

Witness (if applicable)

I document that the information in this form (and any other written information) was accurately explained to the participant. The participant appears to have understood and freely given consent to join the research.

Printed Name of Witness

Signature of Witness Date

UNIVERSITY OF CALIFORNIA, SAN DIEGO
CONSENT TO PARTICIPATE IN RESEARCH

Experimental Participant's Bill of Rights

Every individual asked to participate in a research study has the right to be:

1. Informed about the nature and purpose of the study.

2. Provided an explanation of the procedures to be followed in the research study, and whether any of the drugs, devices, or procedures is different from what would be used in standard practice.

3. Given a description of any side effects, discomforts, or risks that you can reasonably expect to occur during the study.

4. Informed about any benefits that would reasonably be expected from the participation in the study, if applicable.

5. Informed about of any alternative procedures, drugs, or devices that might be helpful, and their risks and benefits compared to the proposed procedures, drugs or devices.

6. Told of the types of medical treatment, if any, available if complications should arise.

7. Provided an opportunity to ask any questions concerning the research study both before agreeing to participate and at any time during the course of the study.

8. Informed that individuals can refuse to participate in the research study. Participation is voluntary. Research participants may refuse to answer any question or discontinue their involvement at any time without penalty or loss of benefits to which they might otherwise be entitled. Their decision will not affect their right to receive the care they would receive if they were not in the experiment.

9. Provided a copy of the signed and dated written consent form and a copy of this form.

10. Given the opportunity to freely decide whether or not to consent to the research study without any force, coercion, or undue influence.

If you have any concerns or questions regarding the research study contact the researchers listed at the top of the consent form.

If you are unable to reach a member of the research team and have general questions, or you have concerns or complaints about the research study, research team, or questions about your rights as a research participant, please contact:

- UC San Diego Office of IRB Administration at irb@ucsd.edu or 858-246-4777