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**COMIRB No: 22-0968**

**Version Date:** 4.6.23

**Study Title:** Beginning Early and Assertive Treatment for Methamphetamine Use Disorder (**BEAT Meth**)

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You are being asked to participate in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

### Why is this study being done?

This research study is being done to learn more about how we can help people who use methamphetamines. The goal of this research project is to develop and evaluate a program that helps patients like you start treatment.

You are being asked to be in this research study because you have had a visit at Denver Health relating to methamphetamine use.

### Other people in this study

Up to 250 people may participate in this study.

### What happens if I join this study?

If you are eligible to join the study and agree to take part in the study, you will:

1. Be asked to complete 3 research visits. Visits may include personal questions, such as questions about your drug and alcohol use, treatment, and general and mental health. We will also collect information about where you live, your access to transportation, your housing status, your employment, and other demographic information such as your age, gender, race, and education background. Research visits will occur upon enrollment in this study, 30 days after your first visit, and 90 days after your first visit. Your first research visit will occur in-person with study staff in a private space at Denver Health. You will have the choice to complete your second and third visits either in-person at Denver Health, or over the phone with study staff.

2. Be placed into 1 of 2 different groups of research subjects like you. To decide which group you will be in, we will use a method of chance. This method is like flipping a coin or rolling dice. Each group will get slightly different care. You will be assigned to a group at the end of your first research visit. You will have an equal chance of being placed in one of two groups:

a) Group 1: If you are assigned to group 1, you will receive usual treatment with your Denver Health providers which may include referrals to social support services, reminders for appointments, and other services you may need that the clinic may be able to assist you with.

b) Group 2: If you are assigned to group 2, you will be assigned a care navigator who will work with you after enrollment. You may receive incentives for meeting with the care navigator. You will meet with the care navigator immediately after completing the first study visit with study staff. The care navigator will talk to you about your needs and connecting to care. You will work together to develop an action plan and meet throughout the study period. The care navigator will assist you with scheduling appointments (for example, primary care) as well as help you access social services, transportation, and other needs that you may need assistance with.

The researchers will have access to your medical record at Denver Health. Some information from your medical record will be collected for the purposes of this research study, such as the type of methamphetamine-related encounters you have had. Your participation in this study will not affect the care you receive at Denver Health.

**How long will I be in this study?**

If you choose to participate in the study, you will be the study for up to 90 days or until you complete your third research visit.

**What are the possible discomforts or risks?**

There are minimal risks from being in this study. The risks associated with this research study include:

1. Most common-- Discomfort answering questions during research visits. You will be asked questions about your general health and mental health status, drug and alcohol use, and other questions. It is possible that these questions might make you feel uncomfortable. You may withdraw from the study if you find the questions troubling, or you may choose not to answer the questions. All answers you give are confidential and will be kept private.

2. Less common-- There is a risk related to loss of confidentiality. We will take every step to keep all the information you provide private, including obtaining a Certificate of Confidentiality and keeping all data secured and protected by coded passwords.

The study may include risks that are unknown at this time.

**What are the possible benefits of the study?**

This study is designed for the researchers to learn more about how to help individuals start and engage in treatment for methamphetamine use disorder. Depending on the group you are put into, you may receive additional help from a care navigator with engaging in care at Denver Health.

However, there is no guarantee that your health will improve if you join this study.

**Who is paying for this study?**

This research is being paid for by the Center for Disease Control and Prevention (CDC).

**Will I be paid for being in the study? Will I have to pay for anything?**

You will be paid $50 for completing your first research visit, $50 for completing your 30-day follow-up visit, and $75 for completing your 90-day follow-up research visit. This will add up to a total of $175. If you leave the study early, or if we have to take you out of the study, you will be paid only for the visits you have completed.

If you are assigned to Group 2, you may earn additional money by meeting with the care navigator. It is impossible to know how much money you could earn through these extra sessions, because the money is awarded randomly by spinning a wheel. On average a person who meets with the care navigator could earn about $85.00.

Payments for taking part in this research study will be put onto a "ClinCard." ClinCard is managed by a company named Greenphire. ClinCard works like a gift card and can be redeemed where Mastercard is accepted. At a minimum, your name and date of birth will be given to Greenphire for study payments to be loaded onto a ClinCard. Let the research staff know if you have concerns about using ClinCard.

**Will I have to pay for anything?**

You or your insurance company may be billed for any standard medical care that you seek while participating in this research study.

You may want to talk with your insurance company about its payment policy for standard medical care you seek during the research study. If your insurance company does not pay, you may be billed for those charges.

**Is my participation voluntary?**

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

## Can I be removed from this study?

The researchers carrying out this study may decide to stop your participation without your permission if they think that being in the study may cause you harm, or for any other reason. Also, the sponsor may stop the study at any time.

## What happens if I am injured or hurt during the study?

Every effort to prevent any injury resulting from this study will be taken by the researcher carrying out this study. If you have an injury while you are in this study, you should call Dr. Deborah Rinehart at (303) 602-2743. For medical emergencies please first contact 911. Necessary care, emergency treatment, and professional services will be available to you, just as they are to the general community.

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

## Who do I call if I have questions?

The researcher carrying out this study is Dr. Deborah Rinehart. You may ask any questions you have now. If you have questions later, you may call Dr. Rinehart at (303) 602-2743.

You may have questions about your rights as someone in this study. You can call Dr. Rinehart with these questions. You can also call the Colorado Multiple Institutional Review Board (COMIRB at 303-724-1055).

A description of this clinical trial will be available on http://www.Clinical Trials.gov, as required by U.S. 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.

This research is covered by a Certificate of Confidentiality from the Centers for Disease Control and Prevention. The 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, for example, if there is a court subpoena, 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 except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if 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 the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the CDC which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you 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 researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law such as child abuse and neglect or harm to self or others.

The Certificate of Confidentiality will not be used to prevent disclosure for any purpose you have consented to in this informed consent document, such as research data in the medical record.

The data we collect will be used for this study but may also be important for future research. Your data may be used for future research or distributed to other researchers for future study without additional consent if information that identifies you is removed from the data.

**Who will see my research information?**

Denver Health has rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include:

- Denver Health and Hospital Authority
- City and County of Denver
- Colorado Department of Public Health and Environment
- Colorado Hospital Association

**Data Sharing**

I authorize Denver Health to disclose my name and date of birth to the following entities for the purpose of obtaining data specific to me for research purposes:

| | | |
|---|---|---|
| City and County of Denver | Yes ☐ | No ☐ |
| Colorado Department of Public Health and Environment | Yes ☐ | No ☐ |
| Colorado Hospital Association | Yes ☐ | No ☐ |

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use, and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Denver Health may not be covered by this promise.

We will do everything we can to keep your records private. It cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Primary Investigator, at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

*Deborah Rinehart, PhD*
*Denver Health and Hospital Authority MC 6551*
*777 Bannock Street*
*Denver, CO 80204*

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information.

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study PI and the rest of the study team.
- The Centers for Disease Control and Prevention, who is the company paying for this research study.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

Some things we cannot keep private. If you give us any information about child abuse or neglect we have to report that to Social Services. If you tell us you are going to physically hurt yourself or someone else, we have to report that to the police. Also, if we get a court order to turn over your study records, we will have to do that.

You have the right to request access to your personal health information from the Investigator. To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study has been completed.

**Information about you that will be seen, collected, used and disclosed in this study:**

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Your social security number
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit records
- Psychological and mental health tests
- Alcoholism, Alcohol or Drug abuse
- Testing for or infection with diseases reportable to the Public Health department, including but not limited to: Human Immunodeficiency Virus (HIV), hepatitis (all forms), tuberculosis, or other sexually transmitted diseases
- Other (please specify): visits to Denver Health

**Agreement to be in this study**

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a copy of this consent form. By signing this consent form, I have not given up any of my legal rights.

Signature:_____ Date:_____

Print Name:_____

Witness Signature: Date:_____

Witness Printed Name:_____

Consent form explained by:_____ Date:_____

Print Name: _____