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# Research Subject Informed Consent Form



**Title of Study:** Adaption of the STAIR-NT Trauma Intervention for Polysubstance Populations  
s22-01058

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## 1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or this form, please ask us. If you decide to take part in this study, you must sign this form.

## **2. What is the purpose of this study?**

The purpose of this research study is to learn about the feasibility of adapting an evidence-based posttraumatic stress disorder (PTSD) intervention for use among individuals using opioids and cocaine in methadone maintenance treatment (MMT) programs.

## **3. How long will I be in the study? How many other people will be in the study?**

Your participation in this study will last 6 months. There are two study groups you may be assigned to: the intervention group, also known as treatment or the TAU group, also known as treatment as usual. Depending on which group you are assigned to, you will either have weekly treatment sessions for the first 6 weeks and three follow-up assessments following treatment, or continue your MMT treatment as usual with no additional treatment, and three follow-up assessments. Up to 120 people will be enrolled in this part of the study.

## **4. What will I be asked to do in the study?**

If you choose to take part in this study, we will ask you to sign this consent first. There are multiple (up to 5) components to this study:

1. You will complete a baseline survey assessment with a research assistant.
2. You will be assigned to either receive treatment for your PTSD or be assigned to TAU (treatment as usual). If you are assigned to the intervention (also known as treatment) you will receive eight 60-minute sessions (Group 1). If you are assigned to TAU you will not receive this intervention (Group 2). The research staff will not be aware of your assignment until they begin data entry. This randomization is like flipping a coin. There are no special requirements or criteria to be in either group. You will have a 50/50 chance of being assigned to either group.
3. For both groups, you will complete four assessments: start of study (baseline), follow-up interview 1 (7-13 weeks after baseline), follow-up interview 2 (3 months after baseline), and follow-up interview 3 (6 months after baseline).
4. At each assessment point you can provide a urine analysis.
  - a. Your urine analysis results will NOT become part of your START record and are exclusive to the THRIVE study.
5. Some individuals will be asked to complete a qualitative interview at the end of the study. Individuals are randomly selected (n=30).

## **Medical and Administrative Records**

Additional information on your medical record will be recorded by the research team. The research team will review your medical record to see the date you entered into treatment and then for the 6-month period you are enrolled in the study. We will review your medical records for information detailing your prior and current methadone treatment history, toxicology results, and additional health services.

Researchers may need to communicate with you about information relevant to the research study. The research team will usually contact you for these purposes by phone, but if you have given the Researchers your email address and mobile/cell phone number and permission to send a text message, the research team may contact you that way. When the research team uses texting over mobile/cell phones there is no way to encrypt the message. This means that information you send or receive by text message is unencrypted and could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier. Therefore, text messages carry security and privacy risks.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore are unsecure and may result in a breach of your confidentiality.
- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and START Treatment and Recovery Centers will not cover the cost related to any increased charges, data usage against plan limits or changes to data fees from the research texts
- Text messages will only be read during regular business hours. However, if you have a scheduled visit outside of business hours, you may receive a text in relation to this visit outside of regular business hours.
- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.
- You may decide to not send or receive text messages with staff associated with this research study at any time. You can do this in person or by sending the research number a text message that says "Stop Text."
- Your agreement applies to this research study only. Agreeing to other texts from START Treatment and Recovery Centers, for example appointment reminders, is a separate process. Opting out of other texts from START Treatment and Recovery Centers is a separate process as well.

Please make sure to keep the research team updated if your mobile/cell phone number changes during the study.

\_\_\_\_\_ Yes, I agree to receive texts from this research group.

\_\_\_\_\_ Initial here

\_\_\_\_\_ No, I do not agree to receive texts from this research group

\_\_\_\_\_ Initial here

## URINE TEST

1. I agree to take a urine test for drugs.

YES \_\_\_\_\_ Initials: \_\_\_\_\_

NO \_\_\_\_\_ Initials: \_\_\_\_\_

2. If "Yes" was selected, please indicate below whether you would like the results shared with you.

YES \_\_\_\_\_ Initials: \_\_\_\_\_

NO \_\_\_\_\_ Initials: \_\_\_\_\_

### **Are you interested in completing a qualitative interview at the end of the study?**

I am interested in completing a qualitative interview \_\_\_\_\_ Initial here

I am NOT interested in completing a qualitative interview \_\_\_\_\_ Initial here

## **5. What are the possible risks or discomforts?**

There are some risks associated with participating in this study. One risk is that you may feel uncomfortable answering certain interview questions or experience psychological distress due to the nature of the intervention or study assessments/interviews. As you will be revisiting stressful life events and experiences, worsening of PTSD symptoms is possible. However, research has shown with treatment completion, a significant decrease in symptoms is possible.

You will be informed that the baseline and follow-up survey assessments will ask about sensitive behaviors and histories, and you can decline to answer any questions. There is also a risk of loss of confidentiality, in which you may become known to be associated with this study to individuals outside of the research team. We will make every effort to ensure that all the information that you provide in this study will be kept confidential.

## **6. What if new information becomes available?**

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

## **7. What are the possible benefits of the study?**

If you are assigned to the intervention group, you may experience benefits related to a reduction in polysubstance use, PTSD symptoms, mood regulation, social functioning, and negative

affect. You will have the opportunity to provide feedback on treatment and the information you provide will help to inform a PTSD intervention to be used in MMT programs that might help to reduce polysubstance use and PTSD symptoms among people who are similar to you. If you are assigned to the TAU group, similarly, your participation provides important information to help inform a PTSD intervention to be used in MMT programs that may help reduce symptoms among people similar to you.

## **8. Will I be paid for being in this study?**

You will be paid for being in this study. You will be paid via debit card and receive \$40 for each assessment, and \$10 for each urine sample at each assessment visit. Individuals who complete a qualitative interview will receive \$50.

## **9. Will I have to pay for anything?**

There is no cost to you to participate, except if you have a cell phone data plan that charges for texts and you opt to receive them from the research team.

## **10. Can I leave the Study before it ends?**

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- in cases of harassment, intimidation, or discrimination against study team members,
- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

## **11. How will you protect my confidentiality?**

### **What is an Electronic Medical Record?**

An Electronic Medical Record (EMR) is an electronic version of your medical chart within START Treatment and Recovery Centers. An EMR is simply a computer version of a paper medical record. If you are or have been a patient at START Treatment and Recovery Centers in the past, you have an EMR at START Treatment and Recovery Centers. Information from your research participation will be added to this EMR.

### **What may be placed in the EMR?**

Information related to your participation in the research (e.g., research enrollment, research-related notes, and clinical procedures, etc.) will be placed in your EMR maintained by START

Treatment and Recovery Centers. **Non-research START Treatment and Recovery Center will not know the eligibility criteria for the study aside from the PTSD treatment focus.**

This means that non-research staff will not be aware of any substance use criteria that caused you to be eligible for the study.

This information will be accessible to other members of the START Treatment and Recovery Centers workforce that are not part of the research team. Information within your EMR may also be shared with others who START Treatment and Recovery Centers has determined may appropriately have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

### **CONFIDENTIALITY AND AUTHORIZATION TO USE AND DISCLOSE PERSONAL HEALTH INFORMATION**

Every effort will be made to keep your personal and medical information confidential. You will be assigned a unique study ID number, and your name will not appear on the questionnaires that you submit for this study. However, total confidentiality cannot be guaranteed. The study staff will use your medical information collected or created as part of the study, such as medical records, test results and research records. Some of this information may identify you by name or in another way. The following information may be used or shared with others in connection with this study:

- Your name, demographic information, and contact information.
- Your responses during sessions and assessments.
- Your urine analysis results.
- Information from your medical record about the care you received from your medical providers, prior and current health conditions, medications, and use of health services.

### **Certificate of Confidentiality**

To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information 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, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research. Federal regulations may also allow for the use or sharing of information for other scientific research.

By agreeing to be in this research and signing below, you are giving your consent to share research information with others at NYU Langone Health.

**What information may be used or shared with others in connection with this study?**

All information in your research record for this study may be used and shared with those individuals listed in this section.

**Who may use and share information in connection with this study?**

The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: National Institute on Drug Abuse (NIDA)
- Other study sites involved in the research

## **12. HIPAA Authorization**

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, and START Treatment and Recovery Center health care providers to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study- in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?

All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

**Who may use and share information in connection with this study?**

The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: National Institutes of Health
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Other study sites involved in the research
- Study related committees/boards/centers (Data & Safety Monitoring Board)

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

### **What if I do not want to give permission to use and share my information for this study?**

Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

### **Can I change my mind and withdraw permission to use or share my information?**

Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

### **How long may my information be used or shared?**

Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

## **13. The Institutional Review Board (IRB) and how it protects you**

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU Langone Health IRB Office number is 212-263-4110. The NYU Langone Health IRB is made up of:

- Doctors, nurses, non-scientists, and people from the Community

## **14. Who can I call with questions, or if I'm concerned about my rights as a research subject?**

If you have questions, concerns, or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the

research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the NYU Langone Health IRB at 212-263-4110 or the START IRB Chair at 917-969-5502.

If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the NYU Langone Health IRB at (212) 263-4110.

If you would like to speak with START Treatment & Recovery Centers, Inc, you may contact Ana Ventuneac via email [aventuneac@startny.org](mailto:aventuneac@startny.org) or at (718) 260-2900.

**When you sign this form**, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

\_\_\_\_\_  
Name of Subject (Print)

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

\_\_\_\_\_  
Name of Person Obtaining Consent (Print)

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date