SCREEN, TREAT AND RETAIN METH-USING PEOPLE WITH OPIOID USE DISORDERS AT METHADONE CLINICS (STAR-OM)

NIH R01 DA050486

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INFORMED CONSENT FORM

Date of the document: June 02, 2021

Appendix 4.1 – Research Participation Agreement

HANOI MEDICAL UNIVERSITY CENTER FOR TRAINING AND RESEARCH ON SUBSTANCE ABUSE AND HIV

INFORMATION SHEET FOR PARTICIPANTS (ICF_V5_020621)

I. GENERAL INFORMATION

Study Title: Screen, Treat and Retain Meth-using People With Opioid Use Disorders at Methadone Clinics (STAR-OM)

Principal Investigators: Assoc. Prof. Dr. Le Minh Giang (Hanoi Medical University)
Prof. Steve Shoptaw (University of California, Los Angeles, USA)

Implementing Institutions: Hanoi Medical University, Ho Chi Minh City University of Medicine and Pharmacy, University of California, Los Angeles

Funder: National Institutes of Health (NIH), USA

Study Period: June 2020 to March 2025

Study Locations: Hanoi and Ho Chi Minh City

II. INTRODUCTION

Hello, thank you for taking the time for this interview.

My name is ..... I am a research staff member currently working at .....

We are conducting the study: Screen, Treat and Retain Meth-using People With Opioid Use Disorders at Methadone Clinics (STAR-OM)

Study Objective: To develop and evaluate optimal intervention models addressing methamphetamine use among individuals receiving methadone maintenance therapy in Vietnam.

I have been trained in research implementation procedures and am committed to complying with ethical standards and good clinical practice.

I am providing you with information about this study to invite you to participate. You are invited because you are currently receiving methadone treatment and have used methamphetamine (e.g., crystal meth, pills).

I will provide you with all necessary information about the study. If you have any questions during this explanation, feel free to ask so you can fully understand the study. You do not have to decide today. You can speak to anyone for further information before deciding. You may also ask me questions at a later time.

You have the right to participate or not. You may withdraw from the study at any time. Your decision to decline or discontinue participation will not affect your medical care or the benefits you are entitled to.

III. STUDY INFORMATION

1. Purpose of the Study: We are conducting this study to identify the most effective and appropriate intervention models to address methamphetamine use (e.g., crystal meth, pills) in order to improve service provision and support for methadone patients.
2. Type of Study and Participants: This is a behavioral intervention study. We are exploring interventions aimed at reducing or safely managing methamphetamine use and improving adherence to methadone treatment. If you are also receiving ARV treatment, the study may help you improve adherence to that as well.

Approximately 600 methadone patients in Hanoi and Ho Chi Minh City will participate in this study. Participants must be receiving methadone treatment, have a history of methamphetamine use, and consent to join the study.

3. Voluntary Participation: Your participation in this study is completely voluntary. Whether or not you participate is your decision. Regardless of your choice, all services you currently receive at this clinic will continue without change. You may change your mind and withdraw from the study at any time, even after initially agreeing.
4. Study Interventions:

- Motivational Interviewing: A counselor will explore your desire to reduce methamphetamine use and support you in maintaining that motivation.
- Contingency Management: We will monitor your progress in reducing use and provide small rewards.
- Group Education: We will provide information on substance use and harm, along with strategies for reducing use.
- Matrix Model: These are discussion sessions offering coping techniques for cravings and strategies for reducing use.
- SMS Reminders: Messages will be sent twice daily to reinforce your goals and provide tips to reduce methamphetamine use.
- Random Group Assignment: Since we do not know which intervention is most effective, we will randomly assign participants to groups using a computer program and compare the outcomes.

5. What Will You Do If You Agree to Participate? If you agree to participate, we will request at least three contact details, such as your home phone, mobile phone, or contacts of close relatives or friends. These will be used to send reminders about appointments and intervention activities. Your contact information will be stored separately from your consent form and used only for study purposes.

We also ask permission to access your methadone and ARV treatment records (if applicable) for research purposes.

You will participate for 48 weeks: 12 weeks in Phase 1 intervention, 12 weeks in Phase 2, and 24 weeks of follow-up.

You will be assessed before the study, after each intervention phase, and after 24 weeks of follow-up. These assessments include surveys, urine tests, HIV tests, and viral load tests (if you are HIV-positive). We will collect 20ml of urine and 15ml of venous blood at each relevant testing point. Additionally, during weeks 1 and 6, we will conduct brief interviews to assess intervention costs. Urine tests will also occur randomly twice a week for 24 weeks and at week 48.

During the intervention periods (Phases 1 and 2), you will receive appointment reminders three days in advance. If you miss an appointment, we will call to reschedule. If we cannot reach you, we will contact your provided alternative contact. We will also remind you about test result appointments and follow up if you miss them. We ask for permission to audio record individual and group counseling sessions to improve program quality.

6. What benefits might you receive from participating in the study? You will be able to participate in intervention activities that have been shown to be effective in reducing substance use and improving treatment outcomes for patients undergoing methadone maintenance therapy.

You will receive results from the tests conducted during this study. These tests will be provided at no cost to you. If the tests indicate that treatment would be beneficial, the counselors will inform you where, when, and how you can receive care, and may connect you to available healthcare services in the city.

You will also receive a stipend as compensation for your time, travel, and effort in participating. Payment will be made after each completed interview:

- Initial interview: 200,000 VND
- 12-week interview: 250,000 VND
- 24-week interview: 300,000 VND
- 48-week interview: 400,000 VND

7. What risks or inconveniences might you encounter when participating in the study? Some disadvantages you might face include feeling embarrassed, distressed, or uncomfortable when disclosing personal information. Although we

do not require you to reveal any identifying details, there is a chance you might do so during in-depth interviews. We guarantee that no identifiable information will be retained in our analysis.

You may stop answering questions or undergoing testing at any time by informing the researcher or clinician. Similarly, the research team may discontinue your participation if they believe it is in your best interest or if the study is halted entirely.

Providing urine samples will pose no physical risk. Drawing 15 ml of venous blood for HIV and viral load testing will follow proper medical procedures, ensuring sterility and minimizing infection risk. However, some minor pain may occur at the needle site.

8. If I do not participate in this study, will it affect my treatment at the clinic? Participation is voluntary. Refusing to participate will not impact your rights or current treatment. You may withdraw at any time. Counselors will still guide you on where, when, and how to receive treatment and may help connect you to healthcare services in the city based on your needs.

If you want to have these blood tests without joining the study, you may pay for them at this clinic or another recommended facility.

9. Will I be informed of my test results from this study? How will I receive them? Before sample collection, a healthcare professional will explain the procedures and answer your questions. They will also let you know when and how to obtain your test results.
10. How will my personal information and records be kept confidential? As a participant, your name, phone number, and email address will be recorded by the research team. Any identifying information will be kept strictly confidential. Although we will take every precaution to protect your data, absolute confidentiality cannot be guaranteed. Unexpected issues, such as a stolen computer (although highly unlikely), may occur. All research computers are encrypted and password-protected. Your name will never appear on interview transcripts.

According to law, representatives from the funding agency, the Ethics Committee of the University of California, Los Angeles, Hanoi Medical University, Ho Chi Minh City University of Medicine and Pharmacy, and other regulatory bodies may inspect the study records. All personal data available for inspection will be handled with strict confidentiality in accordance with data protection regulations. The Office for Human Research Protections (OHRP), NIH, and other agencies responsible for monitoring human subjects' safety may also access your records.

Measures to protect your information include:

a) All notes will be labeled with a code number and no personal identifiers.
b) All electronic data will be stored on encrypted, password-protected drives.

c) All documents will be stored in locked filing cabinets at the offices of Assoc. Prof. Dr. Le Minh Giang (Hanoi Medical University) and Assoc. Prof. Dr. Do Van Dung (Ho Chi Minh City University of Medicine and Pharmacy).

11. Who may inspect my personal records? Organizations that may view or copy your records for research, quality assurance, or data analysis purposes include the U.S. National Institutes of Health and the Ethics Committees of Hanoi Medical University and Ho Chi Minh City University of Medicine and Pharmacy. These records will be anonymized and cannot be linked back to you.
12. If I have further questions about the study, who should I contact?

- For study-related questions or in case of research-related injury: Contact Dr. Nguyen Thu Trang, Phone: 0988 424 871
- For questions regarding your rights as a research participant: Contact the Biomedical Ethics Committee, Hanoi Medical University, Phone: 0243 885 27622

CONFIRMATION OF CONSENT TO PARTICIPATE IN THE STUDY

I, _____ Study Code: _____

Confirm that:

- I have read the information provided about the study titled “Screen, Treat and Retain Meth-using People With Opioid Use Disorders at Methadone Clinics” (STAR-OM)
- I have had the opportunity to ask questions about this study and am satisfied with the answers and explanations given.
- I have had enough time and opportunity to consider participating in this study.
- I understand that I may refuse to participate or withdraw from the study at any time without affecting my employment, treatment, or any rights I am entitled to. The research team may also withdraw me from the study based on professional judgment.

I agree to participate in this study.

CONFIRMATION OF CONSENT TO ACCESS TREATMENT RECORDS

I, _____ Study Code: _____

Confirm that:

- I have read the information provided about the study titled "Screen, Treat and Retain Meth-using People With Opioid Use Disorders at Methadone Clinics" (STAR-OM).
- I have had the opportunity to ask questions about this study and am satisfied with the answers and explanations given.
- I have had enough time and opportunity to consider participating in this study.
- I understand that I may refuse to participate or withdraw from the study at any time without affecting my employment, treatment, or any rights I am entitled to. The research team may also withdraw me from the study based on professional judgment.

I agree to participate in this study. I agree to allow the research team to access and use information from my methadone treatment records, ARV treatment records (if any), and other relevant medical records (if any and necessary) for research purposes.