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Official Title:	**Substance Use Treatment and Recovery Team**
NCT Number:	**NCT05086796**
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CONSENT FORM FOR RESEARCH

Study title: Substance Use Treatment and Recovery Team (START)

Sponsor: National Center for Advancing Translational Sciences (NCATS-NIH)

Principal Investigators: Itai Danovitch, MD, MBA; Allison Ober, MSW, PhD

Study contact phone number at Cedars-Sinai: 310-423-5413

After-hours emergency contact (24 hours): On-call psychiatrist, 310-423-4520

1. Key Information

We are asking for your consent to take part in this research study. This section provides key information about the study. The rest of this form has more detailed information.

- **Voluntary:** Taking part in this research study is your choice. You can also stop taking part at any time. You will not lose any services, benefits or rights you would normally have if you choose not to take part or stop taking part.

- **Purpose:** The purpose of this study is to see whether a special care team called the Substance Use Treatment and Recovery Team (START) can better help people who have problems with opioids compared with the care they usually would get while they are in the hospital. Specifically, the START will try to help people with opioid use disorders start medications to treat their opioid use and link them with treatment for their opioid use after they leave the hospital.

- **Procedures:** The main things that will happen in this study are: you will be assigned to receive either usual care or care from the START, and be interviewed at the beginning of your hospital stay and 1 month after you are discharged from the hospital. If you are assigned to the START group, your care will include talking with a care manager and addiction medicine specialist while you are in the hospital and once a week for 4 weeks after you leave. Treatment may include taking medications designed to treat opioid misuse, if appropriate for you. You are not required to take a medication for your opioid use disorder in either the START or standard care group.

- **Duration:** If you choose to take part in this study, the two interviews will last about an hour total. If you are placed in START group, talking to a care manager and addiction medicine

specialist will last about 4-6 hours while you are in the hospital and a total of about 1 hour during the month after you leave.

- **Risks:** All research studies involve some risk. Risks or discomforts from this study may be emotional discomfort or unintentional disclosure of confidential information. The risk of unintentional disclosure of confidential information is minimal because we take many steps to protect your privacy.

- **Benefits:** If you are assigned to the START group, the possible benefit of taking part in this study is you may receive more structured and targeted help with your opioid use in the hospital and help receiving care after you leave.

- **Alternatives:** You can choose not to take part. There may be other choices for you. Please talk about these choices with the study team. Some other choices may be to be treated following the usual clinical approach, to take part in a different study at CSMC or elsewhere, if one is available, or you could decide not to be treated.

Please take time to read this entire form. You should ask questions before deciding whether to take part in this study. You can talk with family, friends and/or healthcare providers before you decide.

During the study, we may find out new information about this research study. We will tell you about any important changes or new findings that may impact whether you want to continue taking part in the study.

2. Purpose of the Study

We are doing this study to test if a special Substance Use Treatment and Recovery Team (START) can help people with problems related to opioid use, compared to the standard care people usually get. We want to know if the START can help people with problematic opioid use start treatment for their opioid use while they are in the hospital and link to treatment after.

The START consists of an addiction medicine specialist and a care manager. These START members are experts in the treatment of substance use disorders. If you are assigned to START, they will work with your medical or surgical team to make sure you receive appropriate care. That care will include therapy, focused discharge planning, and if appropriate and desired, well-established medications. All interventions are voluntary, and there is no requirement to take medications or accept therapy. START will also help establish a follow-up plan so you can continue treatment after leaving the hospital.

You are being asked to take part in this research study because questions you answered when you came to the hospital suggest that you might benefit from treatment for your opioid use or because your doctor referred you.

The study will include up to 414 people in total across the three hospitals participating in the study (Cedars-Sinai Medical Center, University of New Mexico, and Baystate Medical Center).

3. Main Study Procedures

This section talks about what will happen in this study. When you read this section, also read the flowchart of procedures. The flowchart is given with this consent form.

The flowchart of procedures shows a timeline of the study. It shows which study procedures are research-related and which are standard of care (routine). **Research-related procedures** are procedures done only for the research study. They would not be performed for your routine care outside of the study. **Standard of care (routine) procedures** would be performed as part of your routine care even if you did not take part in this study.

Section 5 in this form describes the common medical procedures that will be done or repeated only for this research study.

Description of main research procedures:

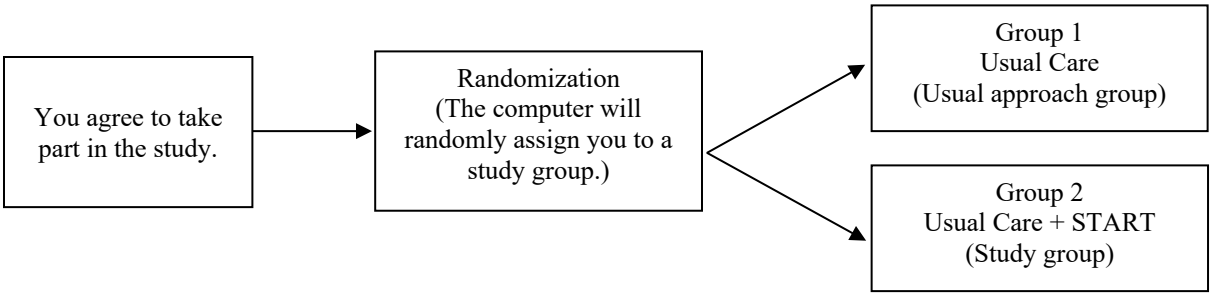
The main things that will happen in this study are:

1. An interview at the beginning of your hospital stay;
2. Another interview 1 month after you are discharged from the hospital;
3. The computer will assign you to one of two study groups:
    - Group 1 (Usual Care). In Group 1, you will be given the care generally given to individuals with your condition. The hospital may or may not have someone talk with you about your substance use and you may or may not be offered medication and other treatment for substance use.
    - Group 2 (Usual Care + START). In Group 2, a care manager and an addiction medicine specialist who are both experts in helping people with substance use problems will talk to you about your substance use, tell you about different treatments, including medication, and they will help you start treatment in the hospital and plan for and connect to treatment after you leave the hospital, if you want it.

This is a randomized, research study.

- This means that you will be put in a study group by chance (like flipping a coin). You will be randomly put in one of the above study groups. A computer will randomly put you in a study group. We do this because no one knows if the results in one study group are different than the others. The results could be better, the same or worse than the results in other groups. Once you are put in one group, you cannot switch to another group. You and your doctor cannot choose the group you are in.

The chart below outlines what will happen during the study.



How long will you be in the study ?
We think you will be in this study for about 5 weeks.

For the Usual Care Group, this includes:
- An in-person interview (30-40 minutes) at the beginning of your hospital stay,
- A telephone interview (30-40 minutes) 1 month after you leave the hospital.

For the START Group, this includes:
- An in-person interview (30-40 minutes) at the beginning of your hospital stay,
- The time you spend with START while you are in the hospital (4-6 hours),
- The time you talk on the telephone with the Care Manager after you leave the hospital (about 15-20 minutes a week over four weeks), and
- A telephone interview (30-40 minutes) 1 month after you leave the hospital.

Additional Information

To help us make sure you get the best care, we might ask you for additional permissions during certain parts of the study:

- If it's right for your care, we will ask for your verbal permission to discuss your study participation in front of family members, and to discuss your condition and study participation with family members when you are not present. You do not have to grant permission to include family members in these discussions. If you do give permission, you can specify which family members you do agree to.

- We may ask for your verbal permission to make an audio recording of one of your visits with the care manager or addiction medicine specialist. A few participants will be asked to do this to help us make sure you are getting high-quality care. If you are asked, you do not have to agree to have the visit recorded.

- To help us reach you for follow-up, we will collect contact information including phone numbers, emails, mailing addresses, and social medica accounts. If we are having trouble reaching you using the information you provide, we may look for additional contact information in your medical record. We will ask for your permission to use this additional contact information and which method(s) of contact you agree to. Additionally, if you go to a residential treatment or other care center after you leave the hospital, we may contact the center to confirm you are there, and ask to speak to you for follow-up. We will ask you to

sign a separate release form giving the research staff your permission to contact you at these centers. You are not required to sign this release form.

- To help us understand how research participants are doing after they leave the hospital, we may contact local health care and substance use treatment providers to ask for the dates participants came for a visit. We will ask you to sign a separate release form giving the research staff your permission to contact these types of providers to obtain dates you received services after leaving the hospital. You are not required to sign this release form.

4. Possible Risks and Discomforts of the Main Research Procedures

This section talks about the possible risks and/or discomforts of the study procedures.

Risks of common medical procedures performed for research purposes are described below in Section 5. Side effects and risks of standard of care procedures are not described in this consent form.

It is possible that some of the assessment procedures and interview questions may cause some emotional discomfort. However, they do not pose specific risks or discomforts beyond those of a standard clinical interview such as feeling upset talking about substance use or experiencing boredom or fatigue. You are not required to respond to any questions you do not wish to answer.

If you decide to take medication for an opioid use disorder, your doctor will speak with you about any risks associated with specific medications.

5. Common Medical Procedures Performed for Research Purposes and Risks

The procedures listed below are often part of routine care for a person with your condition. They are not experimental procedures. The procedures and their risks are research-related. This means they are being *repeated* or performed *more frequently* for this study. These common procedures and their risks should be the same as when performed outside this study.

Study Procedure	Related Risks
Medications: We will ask you about your past and current medications. Talk with the study team about any non-study medications. Non-study medications include over-the-counter drugs, supplements and vitamins.	This does not have any physical risks.
Demographic Information: We will ask you about demographics, which may include your age, gender identity, sexual orientation, race and ethnicity.	This does not have any physical risks.

Medical History Review: We will ask you about your medical history. We will also ask about your opioid habits.	This does not have any physical risks.
Drug and Alcohol Screen: This is an assessment of your past and/or present drug use. A study team member will ask you questions about your drug or alcohol use.	We will record your history of drug or alcohol use in the study records. We will follow all steps to protect the confidentiality of this information as outlined in this consent form.
Screening of Depression/Suicidality: You will be asked questions about your overall quality of life. This includes coping mechanisms, times of depression or circumstances where you feel a wish to harm yourself or others. The study team may ask you questions or ask you to answer questionnaires.	Tell the study team right away if you have feelings or thoughts of harming yourself or others. This is so that the study team can help you. The study team will closely monitor your symptoms of depression.
Interviews: You will be asked to participate in two interviews. We will ask questions about your opioid use and quality of life. The interviews will take about 90 minutes total.	Some questions may make you feel uncomfortable or embarrassed. The questionnaire will have your name or another way of identifying you.

6. Benefits from Taking Part in the Study

Taking part in this research study may or may not have direct medical benefit to you. The possible benefits of taking part in the research study are you may receive more structured and targeted treatment for your substance use if you are in the START group. No benefit is guaranteed. It is possible that your condition may stay the same or even get worse.

We hope the information learned from this research study will benefit other individuals with opioid use disorders in the future by helping us learn better ways to deliver substance abuse treatment in hospitals.

7. Reasons Participation May Be Stopped

Your participation in this study may be stopped at any time. The researcher or the sponsor can stop your participation without your consent for any reason. Some reasons for stopping your participation include:

- The study is stopped or suspended.
- Funding for the study is reduced, stopped or withdrawn.
- It is in your best interest.

8. Choosing to Take Part and Other Options

Taking part in research is voluntary. You have the right to choose not to take part. You can stop taking part in this research study at any time. You can do this without any penalty or loss of benefits to which you would be entitled outside of the study. Your choice not to take part or to stop taking part will not affect the care you get at Cedars-Sinai.

If you decide to stop taking part, we will keep any data collected on you up to the time you choose to stop. Also, if you stop taking part, the study team may ask you whether you want to give further data from your routine medical care.

You can decide not to take part in this study. You have other choices. For example, you may choose:
- To be treated following the usual clinical approach which involves consultation with a social worker or an addiction medicine specialist or taking medication
- To take part in a different study at Cedars-Sinai or elsewhere, if one is available.
- To not be treated.

The study team will discuss these options and their risks and benefits with you. You may also choose to discuss these with your treating physician.

9. Confidentiality Protections

We will do our best to keep your personal information collected as part of this study private. But we cannot guarantee total privacy. We may put a copy of your research consent and authorization forms in your electronic medical record at Cedars-Sinai. Your personal information may be given out if required by law. Publications or presentations about this study at scientific meetings will not use your name and other identifiable personal information.

Organizations that may look at and/or copy your medical records for research oversight, quality assurance and data analysis include:
1. Accrediting agencies (agencies that grant official certifications to educational institutions)
2. Government and regulatory groups, such as the Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP)
3. The Institutional Review Board (IRB), which reviews research to protect people taking part in studies
4. Safety monitors, which monitors the safety of individual participants and the overall safety of the study
5. Companies that sponsor the study and authorized representatives of the sponsor

Attached to this consent form is an Authorization Form. It outlines with whom your information may be shared for this research and under what circumstances.

We might share your information and/or research samples collected in this study. It might be shared with other researchers at Cedars-Sinai, other academic institutions or third-party commercial entities for future research without additional informed consent from you. Information that identifies you will be removed and will not be shared with other researchers or anyone outside of Cedars-Sinai.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Protections from Forced Disclosures (Subpoenas) – Certificates of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate does not stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases and threats to harm yourself or others. The Certificate cannot be used to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate does not stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also does not prevent your information from being used for other research, if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

10. Research-Related Illness or Injury

We do not expect you will have any illness or injury from this research study. If you believe that you are ill or have been injured from this study, please contact the study team at the phone number listed on page 1 of this consent form.

11. Financial Considerations

Costs of Participation

The attached flowchart lists items, drugs and services that will be billed to you and/or your insurance and those that will be covered by the Study Sponsor. Review the flowchart for details.

For items billed to your insurance, you remain responsible for all deductibles, copays and balances under your health benefit plan. If your insurance company does not pay, you will be billed for those charges. If you have questions or concerns about your insurance coverage, you should ask your health benefit plan.

Payment

You will be given $50 for completing the first in-person interview and $50 after completing the second phone interview one month after you've left the hospital. After you leave the hospital, if you call us to schedule the second interview or to let us know you got a new phone number, and then complete the follow-up interview, you will be given an extra $5. The total amount you will receive if you complete the whole study is $100, with an option to receive up to $105 if you complete the extra step. If you do not complete the entire research study, you will only be paid for the interviews you do complete.

If you are a Cedars-Sinai employee, you should provide your employee identification number to the research team. This allows your payment to be processed through Payroll. For your own protection and to comply with tax laws, your payment for taking part will be reported to the IRS together with other payment you get from Cedars-Sinai.

Payment will be managed by an outside company. They will give you a debit card. Your payment for taking part in the research will be loaded onto the card. The money will generally be available within 4 weeks after you finish each study visit. You will need to share your name, address, social security number and birthdate with the outside company to get this debit card. Your information will be stored in a protected fashion. Your information will be removed from the debit card system once the study is finished and the money on the card has been used. The outside company will not share your information with any other third parties.

Financial Interest in the Research

The principal investigator and institution have no potential financial conflict of interest with this study.

12. Contact for Questions or Problems

Please contact the investigator for questions, problems or concerns about the research. Their contact information is on page 1 of this form.

You might have feedback, questions, problems, concerns or want to obtain more information about this study. If so, you can talk with someone who is not part of this study by contacting:

Cedars-Sinai Human Research Protection Program (HRPP)
Phone: 310-423-3783
Email: ResearchConcerns@cshs.org
Website: cedars-sinai.org/research/administration/office-of-research-compliance/review-board.html

The Cedars-Sinai HRPP protects the rights and welfare of research participants.

Experimental Subject's Bill of Rights

In accordance with California Health and Safety Code 24172, any person who is required to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks to the subject reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

AUTHORIZATION FOR USE AND DISCLOSURE OF IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH

1. USE AND DISCLOSURE OF HEALTH INFORMATION

If you agree to this Authorization, you give permission to the Sponsor, Principal Investigator, other investigators and their research team described in the Consent Form for Research ("Research Team") to use or disclose your identifiable health information ("private information") for the research study titled "Substance Use and Recovery Team (START)" which is described in the Consent Form for Research ("Consent Form") to which this Authorization is attached. In particular, you authorize the research team acting under the direction of the Principal Investigator to review your medical records and collect your private information from the following sources:

☒ Laboratory tests
☐ Pathology reports
☐ Imaging reports (e.g., x-rays or scans)
☐ Photographs or videos of your image
☒ Doctor/clinic records
☒ Hospital/medical records
☒ Mental health records
☒ Billing records

☒ Demographics, which may include age, gender identity, race, ethnicity, and/or sexual orientation

☒ Other tests or other types of medical information: Research study assessments

2. WHO WILL HAVE ACCESS TO YOUR PRIVATE INFORMATION?

Your private information will be used by and/or shared with the Research Team.

In addition to the research team, if applicable, the following parties may receive your private information and inspect your records:

- The reviewing Institutional Review Boards and Cedars-Sinai offices with authority to oversee research compliance.
- U.S. government agencies, such as the Food and Drug Administration and the Department of Health and Human Services.
- Researchers at other organizations who are participating in this research study.
- The Study Sponsor, its business partners, and Cedars-Sinai's business partners for matters related to research study oversight, conduct of the research, data analysis, use of research results in product development, and payment or reimbursement.

- Representatives from regulatory agencies in other countries may join in the review of your research records, including research-related medical reports and information, with the Sponsor and/or the FDA.

Cedars-Sinai takes steps to protect your private information when sharing it with the recipients described above. Though these steps and applicable law are meant to protect your private information, there is a risk that a recipient could share your private information without your permission.

3. WHEN WILL MY AUTHORIZATION EXPIRE?

By signing this document, you authorize the use and sharing of your private information until the end of the research study and any related optional sub-study you choose to participate in.

4. REVOKING AUTHORIZATION

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, the research team may still use or disclose private information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to the Principal Investigator of the research study by writing to the Office of Research Compliance and Quality Improvement, 6500 Wilshire Blvd, Suite 1800, Los Angeles, Calif. 90048 and/or emailing to ResearchConcerns@cshs.org.

5. NOTICE OF RIGHTS AND OTHER INFORMATION

You do not have to agree to this Authorization, but if you do not agree, you may not participate in the research study. Cedars-Sinai may not condition (withhold or refuse) the provision of standard of care treatment for you on whether you agree to this Authorization.

If you agree to this Authorization, please sign on the appropriate signature line on the Signature Page. You will receive a copy of this Authorization.

Flowchart of Visits and Procedures

R = Research item/procedure done only for research purposes and their costs are covered by the study. You are not responsible for the costs of these procedures.
S = Standard of care item/procedure that is part of regular care and billed to the patient/insurance. You and your insurance company will be responsible for these costs.

Procedures	Screening and Baseline	Services	Follow-up calls	Follow-up interview
	During hospital stay	During hospital stay	Weekly for 1-month post-discharge	At 1-month post-discharge
Eligibility Screening (Medications, Drug and Alcohol Screen)	R			
Demographic Information	R			
Informed Consent	R			
Randomization	R			
Baseline Interview (Medical History Review, Screening of Depression/Suicidality)	R			
START Addiction Medicine Specialist (AMS) and Care Manager (CM) offer consultative support services[1]		S		
START Addiction Medicine Specialist (AMS) coordinates care[1]		R		
START Care Manager (CM) coordinates care and provides 1-month follow-up services[1]		R	R	
Medication and therapy for opioid use disorder		S		
Hospitalization	S	S		
Follow-up Interview				R

Footnote: 1. Only for patient randomized to START

Signature Page

**Consent Form for Research and Authorization
for Use and Disclosure of Identifiable Health Information (Research)**

If you agree to take part in this study, you should sign and date on the signature lines below. You will be given a signed and dated copy of this form. This includes the "Experimental Subject's Bill of Rights," "Authorization for Use and Disclosure of Identifiable Health Information (Research)" and any optional sub-study descriptions, when applicable.

Signature by the Participant

Main Research Study: *I agree to take part in the research study described to me during the informed consent process and described in this informed consent form. My questions have been answered to my satisfaction.*

You will be given a signed and dated copy of this form.

Participant name (please print)	Signature	Date

Authorization for Use and Disclosure of Identifiable Health Information (Research): *I hereby agree that my identifiable health information may be used and/or disclosed in accordance with the "Authorization for Use and Disclosure of Identifiable Health Information (Research)."*

Participant name (please print)	Signature	Date

Signature by the Investigator

I attest that all the elements of informed consent described in this form have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Investigator name (please print)	Signature	Date

Witness

Signature of a witness is required when an English-speaking subjects who has been determined to have capacity to consent is unable to read or physically sign the consent form, but choses to indicate via a "mark" or verbally that he/she agrees to participate. The witness signs the consent form to confirm that an oral consent process occurred and that the individual verbally consented to participate in the research.)

Witness name (please print)	Signature	Date

To be marked at time of signature:
Consent obtained:
☐ *From English speaking individual who is not physically able to sign the consent document*