CEDARS-SINAI MEDICAL CENTER

CONSENT FORM FOR RESEARCH

Title: PILOT TEST OF A SUBSTANCE USE TREATMENT AND RECOVERY TEAM (START) FOR MEDICAL INPATIENTS WITH OPIOID AND ALCOHOL USE DISORDERS

SPONSOR: NATIONAL INSTITUTE ON DRUG ABUSE (NIDA-NIH)

PRINCIPAL INVESTIGATORS: ITAI DANOVITCH, MD, MBA; ALLISON OBER, MSW, PhD

STUDY CONTACT PHONE NUMBER AT CSMC: 310-423-5413

AFTER HOURS CONTACT (24 HOURS):310-423-5413

This research study is sponsored by NIDA. NIDA only pays Cedars-Sinai Medical Center for the costs associated with running the study; NIDA is not providing additional payment to Cedars-Sinai Medical Center or the researchers or providers for their participation in the study.

KEY INFORMATION ABOUT THIS RESEARCH STUDY

We are seeking your consent to take part in this research study. Your participation in this research is voluntary. If you choose to participate, you can stop at any time. Please consider the following summary, along with the more detailed information provided throughout this consent form.

- The purpose of this study is to evaluate whether a specially trained psychiatrist and care manager, both members of the Substance Use Treatment and Recovery Team (START), can help improve substance use care compared to standard care.

- The main procedures of this study include receiving either standard care or care from the START for alcohol or opioid use problems.

- Some patients will be assigned care with START. If you are in the START group, the case manager and psychiatrist will meet with you a few times during your hospital stay to discuss different options for receiving treatment problems with alcohol or opioids. START care will include therapy, focused discharge and follow-up planning to help you link to substance use treatment after you leave the hospital if you want it, and if appropriate and desired, well-established medications that can help reduce drinking and opioid use. Patients in START also will receive a weekly phone call by the care manager for one month after discharge to check in.

- Patients who do not receive START will receive standard care. Standard of care at this hospital may include being referred to speak with someone about alcohol or opioid use. It may also include being offered therapy and medications as part of regular medical care and referral to treatment after the hospital as part of regular hospital discharge planning.

- Regardless of whether you receive standard or START care, you will also be asked to complete a survey at the beginning of your hospital stay and another survey over the phone 1 month after you are discharged from the hospital. If you choose to take part in this study, the two surveys will last about an hour total. If you receive START care, talking to a care manager and psychiatrist will last about 2-6 hours while you are in the hospital and about 1 hour during the month after you leave.

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

- We will ask you for verbal permission to discuss your study participation in front of family members. You do not have to grant permission to include family members in these discussions.

- The possible benefit of taking part in this study is you may receive a more team-driven approach to care with your alcohol or opioid use.

- If you choose not to participate, you might still be offered medication for your alcohol or opioid use or you might be referred to a psychiatrist or care manager who is not part of the Substance Use Treatment and Recovery Team (START). You will not lose any services, benefits or rights you would normally have if you choose not to participate. Please discuss your choices with the researchers.

Please take time to read this entire form and ask questions before deciding whether to participate in this study. You are encouraged to talk with family members, friends, and/or healthcare providers before you make your decision.

1. WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

We are doing this study to test if a special Substance Use Treatment and Recovery Team (START) works better than standard care to help people with problems related to alcohol or opioid use start treatment in the hospital and get care after they leave.

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 alcohol or opioid use or because your doctor referred you.

The study will enroll up to 80 people in total.

2. WHAT WILL HAPPEN DURING THE STUDY?

Overview of study:

This is a randomized research study. That means you will be assigned to one of two groups by chance, like flipping a coin.

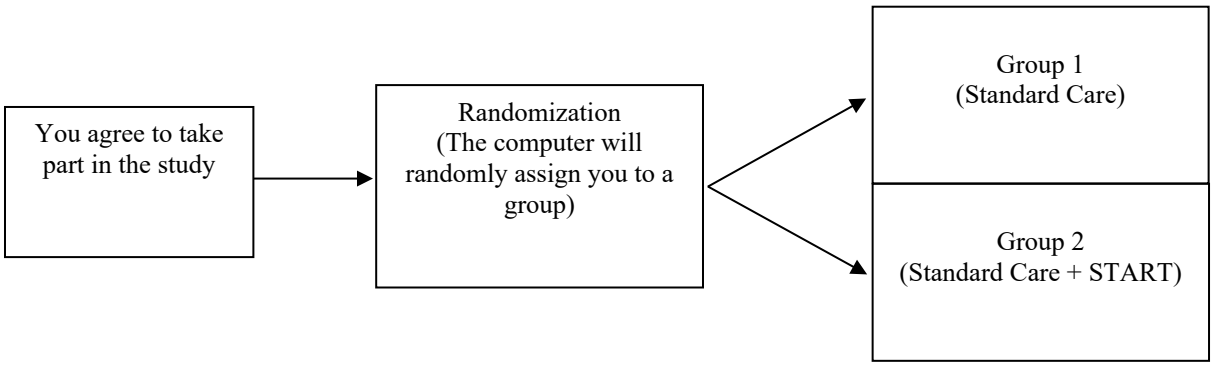
The two groups are:

- Group 1 (standard care). In Group 1 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 (standard care + START). In Group 2, a care manager and a psychiatrist 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.

A computer will randomly assign you to one of the study groups. Once you are put in one group, you cannot switch to another group. Neither you nor your doctor can choose the group in which you will be placed.

Being in either of these different groups could help your condition. This study will allow the researchers to learn whether one group results in better outcomes for people with an alcohol or opioid use disorder.

The picture below shows you how you will be assigned to a study group. Start reading at the left side and read across to the right.



Optional Additional Consent

Details of an optional additional consent are described in Appendix A of this consent form. You are not required to agree to this additional consent in order to take part in this research study.

How long will you be in the study?

We think you will be in this study for about 5 weeks. The total time includes an in-person or remote (phone or video call) interview (45-60 minutes) at the beginning of your hospital stay, the time you spend with START while you are in the hospital (2-6 hours, in-person or by phone or video), and a telephone interview (15-20 minutes) 1 month

after you leave the hospital. You may be contacted for these interviews over the phone by a member of the Survey Research Group (SRG) at the RAND Corporation.

What will the interviews include?
The interviews will include questions about your quality of life, employment, mental health, pain, and alcohol and drug use.

3. WHAT ARE THE POSSIBLE RISKS?

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 alcohol or opioid use disorder, your doctor will speak with you about any risks associated with specific medications.

4. ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this research study, there may or may not be direct benefit to you. The possible benefits of taking part in the research study are you may receive team-based treatment for your substance use. However, no benefit is guaranteed. It is possible that your condition may remain unchanged or even get worse.

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

6. WHY WOULD MY PARTICIPATION BE STOPPED?

Your participation in this study may be stopped at any time by the researcher without your consent for any reason, including:

- The study is stopped or suspended;
- Funding for the study is reduced, stopped or withdrawn;
- If it is in your best interest;
- The investigator will closely monitor your symptoms. At any time during the study, you or the investigator may discontinue your participation and choose other ways to treat your condition.

7. ARE THERE ANY OTHER OPTIONS?

Your participation is voluntary, so you have the right to decline to participate or to withdraw from this research study at any time without any penalty or loss of benefits to which you would be entitled outside of the study. Choosing not to participate will not affect the care you receive at Cedars-Sinai Health System.
If you 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 a psychiatrist or taking medication
- you may choose to take part in a different study at CSMC or elsewhere, if one is available
- you could decide not to be treated.

The researcher will discuss these options and their risks and benefits with you.

8. WILL MY INFORMATION BE KEPT CONFIDENTIAL?

We will do our best to make sure that the personal information collected as part of this study is kept private. However, we cannot guarantee total privacy. A copy of your research consent and authorization forms may be filed in your electronic medical record at CSMC. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other identifiable personal information will not be used. Organizations that may look at and/or copy your medical records for research oversight, quality assurance, and data analysis include: accrediting agencies, government and regulatory groups (such as Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), etc.), safety monitors, companies that sponsor the study, and authorized representatives of the sponsor.

Attached to this consent form is an “Authorization Form” that outlines with whom your information may be shared for the purposes of this research and under what circumstances.

We might share your information and/or research samples collected in this study 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 http://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. 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.

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 including research data in the medical record.

9. WHAT IF I BECOME ILL OR INJURED BECAUSE OF TAKING PART IN THIS STUDY?

Contact your study doctor at once if you feel that you are ill or have been injured because of taking part in this study. If it is a medical emergency, call 911 or go to an emergency room. Promptly notify your study doctor of your situation at the phone number listed on page 1 of this consent form.

Who pays for my research related illness or injury?

Cedars-Sinai has no plans to pay for costs associated with the treatment of research-related injury or illness. We will make every effort to seek reimbursement from your health plan. However, you will be responsible for any deductibles and co-payments required under your health plan and for any claims ultimately denied by your health plan. Financial assistance may be available under Cedars-Sinai's Charity Care Policy and Procedure. If you feel that you have had a research-related injury and need financial assistance, please contact the IRB Office at 310-423-3783. You do not waive any of your legal rights by signing this form.

10. FINANCIAL CONSIDERATIONS

Costs of Participation

Please review the attached Appendix C flowchart for a listing of items, drugs and services that will be billed to you and/or your insurance and those that will be covered by the study sponsor.

You will not be charged for tests or procedures related to the START project. Only items, drugs and services that are reasonable and necessary for your medical care

throughout the study will be billed to your insurance, including medications you decide to take for an alcohol or opioid use disorder. You remain responsible for all deductibles, co-pays, and balances under your health benefit plan. If your insurance company does not pay, you will be billed for those charges. You should check with your health benefit plan if you have questions or concerns about your insurance coverage.

Compensation for Participating

You will be given a $50 reloadable debit card after completing the first interview in the hospital. The same debit card will be reloaded with $50 which you can use after completing the follow-up interview by telephone one month after you've left the hospital. The total amount you will receive if you complete the whole study is $100. If you do not complete the entire research study, you will only be paid for the interviews you do complete.

Compensation will be managed by a private company to issue a debit card onto which your compensation for research participation will be loaded. The funds generally will be available within 1 business day after you complete each study visit. To be able to issue you a debit card, we will need to share your name, address, social security number, and date of birth with the private company contracted to issue and manage the debit card. All information is stored in a secure fashion and is deleted from the debit card system once the study has been completed and the funds on the card have been exhausted. The private company will not be aware of the nature of the study you are participating in will not share your information with any other third parties.

Financial Interest in the Research

The PI and institution have no potential financial conflict of interest with respect to this study.

11. WHAT IF I HAVE QUESTIONS OR PROBLEMS?

Please contact the researcher listed on the first page of this form for questions or concerns about the research.

If you have questions, problems, or concerns that you want to discuss with someone who is not associated with this study, or want to offer suggestions or feedback, please contact:

Cedars-Sinai Human Research Protection Program (HRPP)
Phone: (310) 423-3783
Email: ResearchConcerns@cshs.org

The Cedars-Sinai HRPP has been established to protect the rights and welfare of research participants. You may also contact the Cedars-Sinai HRPP if you want to offer input or obtain information regarding the study.

12. CONSENT PROVISIONS

If you sign this form below, it means that:
(1) You have taken the time to carefully read and understand the information presented in this informed consent form; you should discuss it with others, and if appropriate seek a second opinion to make an informed decision;
(2) The information concerning the research study and its involved procedures has been fully explained to you and your questions have been answered to your satisfaction;
(3) You have received and understand all the information you desire regarding your participation in the research study;
(4) You have considered the potential risks, any anticipated benefits and alternatives (and their relative risks and benefits) of participation;
(5) You are voluntarily agreeing to participate in this research study;
(6) You understand that by consenting to participate in the research, you are not giving up any of your legal rights;
(7) You understand that you have the right to be informed of significant new findings related to this research study which may affect your willingness to continue participating in this study.
(8) You have been provided with a copy of the “Experimental Subject’s Bill of Rights”, if applicable to this research study, and have been provided with an opportunity to ask questions regarding the Bill of Rights.

We will give you a copy of this signed and dated consent form and the Experimental Subject’s Bill of Rights.

SIGNATURE PAGE

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

SIGNATURE BY THE PARTICIPANT:

Consent for Main Research Study: *I hereby agree to participate in the research study described to me during the informed consent process and described in this informed consent form.* ***You will be given a signed copy of this form.***

Name of Participant (Print)	Signature	Date Signed

Optional Additional Consent: *I hereby agree to allow the study team to discuss the study and my health when I am not present, as described in Appendix A below.*

Name of Participant (Print)	Signature	Date Signed

Authorization for Use and Disclosure of Identifiable Health Information (Research):

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

Name of Participant (Print)	Signature	Date Signed

Authorization for Optional Additional Consent: *I hereby agree that my identifiable health information may be used and/or disclosed for the optional additional consent described during the informed consent process and described in Appendix A below:*

Name of Participant (Print)	Signature	Date Signed

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.*

Name of Investigator (Print)	Signature	Date Signed

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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.

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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 "**Pilot Test of a Substance Use and Recovery Team (START) for Medical Inpatients with Opioid and Alcohol Use Disorders**" 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
- ☒ 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, 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 is required by law to protect your private information. However, the recipients described above may re-disclose (or share) your information with other parties unless such sharing is prohibited by law.

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 additional consent you agree to.

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. The Research Team may not condition (withhold or refuse) treating you on whether you agree to this Authorization.

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

6. OPTIONAL ADDITIONAL CONSENT

In addition to the main research study, you have the option to agree to an optional additional consent as explained to you during the informed consent process. Your decision to agree to the optional additional consent does not impact your ability to participate in the main research study.

If you agree that your identifiable health information may be used and/or disclosed for the optional additional consent described in the informed consent process and above, you will be required to sign a second time in the signature section.

APPENDIX A: OPTIONAL ADDITIONAL CONSENT

INTRODUCTION

This Appendix is provided to you as a supplement to the main study consent form. In addition to the main study, you are also invited to provide this optional additional consent. **You do not have to agree to this optional additional consent to be in the main study. Your medical care at Cedars-Sinai Medical Center (CSMC) will not be changed in any way as a result of your decision.**

Before you make a decision, please read the rest of this Appendix and ask the researchers any questions to help you understand the additional consent.

This Appendix will be given with the study consent form. If you agree to this optional additional consent, then you will be asked to sign separate signature lines in the main consent form.

A. PURPOSE OF THIS OPTIONAL ADDITIONAL CONSENT

In this additional consent, we are asking for your permission to discuss study and health concerns with your family members when you are not present. The purpose of this is so we can help guide your family on how they can best support you through the study and help you achieve your goals.

B. POSSIBLE RISKS OR DISCOMFORTS OF THIS OPTIONAL ADDITIONAL CONSENT

You may feel some emotional discomfort in allowing us to discuss your health concerns with your family when you are not there.

C. BENEFITS OF THIS OPTIONAL ADDITIONAL CONSENT

If you agree to this optional additional consent, there may or may not be direct medical benefit to you. The possible benefits are that your family will be better informed of the study and your health concerns, and you may receive support and help from your family during your participation in the study. However, no benefit is guaranteed. It is possible that your condition may remain unchanged or even get worse.

APPENDIX B: Detailed Description of Common Medical Procedures Performed for Research Purposes and Associated Risks

The procedures listed below are often performed as part of routine care for a person with your condition. They are being repeated or performed more frequently as part of this research. However, the risks associated with each procedure should be comparable to what you would experience even if you were undergoing the procedure outside this research study.

Study Procedure	Related Risks
Physical Exam: Includes height, weight, vital signs (heart rate and blood pressure).	There are no physical risks associated with these procedures.
Concomitant Medications: You will be asked about your previous and current medications that you take.	There are no physical risks associated with these procedures.
Medical History Review: You will be asked about your medical and surgical history with attention to opioid and alcohol habits.	There are no physical risks associated with this procedure.
Questionnaires: You will be asked to complete questionnaires. We will ask you questions to evaluate your alcohol or opioid use. We think it should take about 45-60 minutes to complete the questionnaires. Questionnaires will ask you to respond to questions about your alcohol or opioid use and quality of life.	If you feel uncomfortable or embarrassed answering any question, you may skip it. The questionnaires will contain your name or other direct identifier.
Demographic Information: You will be asked about your age, gender, race, ethnicity.	There are no physical risks associated with these procedures.
Drug and alcohol screen: This is an assessment of your past or present use of drugs (such as, marijuana, cocaine, ecstasy). This can be completed by asking you to answer questions about your patterns of drug or alcohol use, or by having you complete a toxicology screen. A toxicology test checks blood, urine, or saliva for the presence of drugs or chemicals.	If you report a positive history of drug or alcohol use, this will be recorded as part of the study records. Study will follow all steps to protect the confidentiality of this information as outlined in the main consent form.
Assessment of Depression/Suicidality: As part of the research the study investigator may ask you questions, or ask you to complete questionnaires, to assess your overall quality of life, including coping mechanisms, instances of depression, or circumstances where you feel you may wish to harm yourself or others.	It is very important that you tell your researcher right away if you experience feelings or thoughts of harming yourself or others so that help can be provided. It is very important that you report any significant change in your condition to the investigator. The investigator will closely monitor your symptoms of depression. At any time during the study, you or the investigator may discontinue your participation in this study and may choose other ways to treat your condition.

APPENDIX C: Flowchart of Procedures – Medicare Coverage Analysis (MCA) Review

Procedures	Baseline visit	During course of hospital stay	1-month post-discharge
Eligibility	R		
Informed Consent	R		
Randomization	R		
Sociodemographic Data	R		
Mental health symptoms (PHQ-9, GAD 7); pain (PEG); substance use (WHO ASSIST, NSDUH) consequences of use (SIP-AD), service utilization (NSDUH, GAIN), stigma (SASS)	R		R
Satisfaction with START intervention[1]			R
Medication for alcohol or opioid use disorder [2]		S	
Therapy for alcohol or opioid use disorder [2]		S	
START Addiction Medicine Specialist (AMS) coordinates team-based care[3]		R	R
START Care Manager (CM)[3] coordinates team-based care		R	R

LEGEND
R = Research item/procedure done only for research purposes and covered by the study
S = Standard of care item/procedure that is part of regular care and billed to the patient/insurance

Footnotes:

1. Only for patients randomized to the START intervention arm of the study.
2. For both groups: Usual Care and Start intervention. Includes brief negotiated interview and addiction focused discharge planning and follow-up.
3. The START intervention utilizes established standard-of-care services and procedures (care manager, addiction medicine specialist, medication treatment, therapy, etc.) and helps integrate them into the patient's care in a systematic way. It is this planned coordination and integration that are the intervention, not the services themselves.