Cover Page for Clinical Trials Document Posting

Official Title: Initiating Substance Use Disorder Treatment for Hospitalized Opioid Use Disorder Patients (ISTOP)

NCT Number: 03212794

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Description: ISTOP Study Informed Consent Form (ICF)

Partners HealthCare System
Research Consent Form

Subject Identification

General Template
Version Date: August 2016

Protocol Title: Initiating Substance use disorder treatment for hospitalized opioid use disorder patients: A randomized trial of recovery coaches.

Principal Investigator: Joji Suzuki, MD

Site Principal Investigator:

Description of Subject Population: Hospitalized patients admitted to Brigham and Women's Hospital and Brigham and Women's Faulkner Hospital

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

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

Why is this research study being done?

This research study is being done to help us understand if subjects will stay in treatment with buprenorphine after leaving the hospital if assigned to a recovery coach, compared to subjects not assigned a recovery coach. We are asking you to take part in this research study as you have been started on buprenorphine here in the hospital, and plan to continue this treatment after discharge. Up to 58 people will take part in this research study at Brigham and Women's Hospital and Brigham and Women's Faulkner Hospital.

How long will I take part in this research study?

The research study will last the length of your hospital stay and 6 months after you are discharged.

What will happen in this research study?

At the beginning of the study we will ask you questions to see if you are eligible to take part in the study. If you are deemed eligible to proceed with the study, you will be randomly assigned to one of two groups: Control Group or Treatment Group. The chance of being assigned to these groups will be like the flip of a coin, with a 50/50 probability.

Control Group
If you are assigned to the Control Group, there is no further study involvement other than to return for assessments 1, 3, and 6 months after discharge. During these assessments, we will ask you to fill out questionnaires.

Treatment Group
If you are assigned to the Treatment Group, you will be assigned a recovery coach, who is someone in recovery from substances and has received training to be a coach. While still in the hospital, you will meet your recovery coach, go over your plan after discharge, and go over the basics of how to maintain your sobriety by learning about relapse prevention skills. You will work together to come up with a treatment plan that is individualized for you. The recovery coach will review the treatment plan with you. After discharge, the recovery coach will continue to work with you to implement the treatment plan. The recovery coach will provide support and will be available to assist you in keeping your appointments, to share and suggest coping strategies, to reinforce relapse prevention skills, and to identify and link you to community programs. The recovery coach will spend approximately 2-3 hours with you each week on average. You will also return for assessments 1, 3, and 6 months after discharge. During these assessments, we will ask you to fill out questionnaires.

Payment
You will be paid $50 for completing the initial screening questions while in the hospital. You will also be paid $50 for each follow-up assessment done 1 and 3 months after discharge. You will be paid $100 for completing the follow-up assessment done 6 months after discharge. This would mean a total of $250 if you complete all study visits.

We may be using an approved, outside vendor (Forte Research) to make these payments to you via a reloadable credit card-based system, called Forte Payments. This secure system is similar to a gift card or credit card.

If you are paid by this system, you will be given a Forte Payments Visa card when you enroll in the study. Once the card is activated, the study team will add a payment after each paid visit you complete. The payment should be available to you within a day. You may use the card anywhere Visa cards are accepted, such as at a grocery store.

We will need to collect your Social Security number in order to make these payments, and it will be shared securely with the company that runs the card-based system. Payments like this are considered taxable income. If you receive more than $600, the payment will be reported to the IRS as income by the hospital.

If you provide a receipt for something like travel expenses and we can cover that, that is not considered taxable income. Reimbursement of expenses will not be made using the Forte Payments card.

Information Obtained from Medical Record

Whether you are in the Control Group or Treatment Group, we will obtain information about your hospitalization from your medical record at Brigham and Women's Hospital (BWH) and Brigham and Women's Faulkner Hospital (BWFH). This information includes: your demographics, reason for admission, physician notes from this hospitalization, medical history, and urine toxicology screens taken as part of your routine clinical care. This information will only be accessed during the time you are enrolled in this study.

Information collected in the study will remain separate from your medical record and will not impact your medical care at BWH or BWFH in anyway. Information collected during this study will only be reviewed by the staff conducting the research.

All information you provide through the questionnaire will be kept confidential and no identifying information (such as your name) will be noted on these. Instead, you will be assigned a study ID. The file linking your study ID to any identifiable information will be kept in a password protected document, only able to be accessed by the researchers conducting this study.

Certificate of Confidentiality from the National Institutes of Health

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you.

The Certificate cannot be used to resist a demand for information from personnel of the United

States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse or intent to hurt self or other.

What are the risks and possible discomforts from being in this research study?

Some individuals may be concerned about confidentiality. We will make every effort to insure your confidentiality. No information about you will be given to anyone else unless you give us your written consent. The information we get because of the study will not become part of your medical record. You will also be assigned a study ID so that your name is not associated with the responses you give.

Some individuals may experience psychological discomfort when completing the questionnaire or during discussions with the recovery coach. Some people may become nervous or upset when talking about their substance use. If so, you are free to omit an item, choose not to complete the questionnaire, or opt-out of a discussion. We strongly encourage you to inform a study staff member if you feel uncomfortable about a particular topic or would like to stop participating. You are free to discontinue the study at any time. If you would like a chance to talk more about your thoughts, Dr. Suzuki will be available to do so at no cost to you. Additionally, if you wish to receive additional support related to these matters after your discharge from BWH, Dr. Suzuki will be able to make the appropriate referrals.

What are the possible benefits from being in this research study?

The treatment provided by the recovery coach may benefit you by increasing the likelihood of remaining in treatment, reducing the use of substances, and reducing hospital readmissions.

This study hopes to provide information about how best to help individuals admitted to hospitals and started on buprenorphine.

What other treatments or procedures are available for my condition?

You do not have to take part in this research study to be treated for substance use disorder. Other treatments or procedures that are available to treat substance use disorder include:

- individual psychotherapy or group therapy
- medications, such as suboxone or methadone
- peer recovery services, like Alcoholics Anonymous (AA)

Talk with the study doctor if you have questions about any of these treatments.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will I be paid to take part in this research study?

You will be paid $50 for completing the initial screening questions while in the hospital. You will also be paid $50 for each follow-up assessment done 1 and 3 months after discharge. You will be paid $100 for completing the follow-up assessment done 6 months after discharge.

What will I have to pay for if I take part in this research study?

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Joji Suzuki, MD is the person in charge of this research study. You can call him at 617-732-5752 M-F 9am-5pm.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as "health information." In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so.

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in this study
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- Non-research staff within Partners who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- The Partners ethics board that oversees the research and the Partners research quality improvement programs.
- People from organizations that provide independent accreditation and oversight of hospitals and research
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers

- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
- Other:

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

_____	_____	_____
Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent Form Version: 11/13/18