

HIC#2000020382

INFORMATION SHEET FOR PARTICIPATION IN A RESEARCH STUDY**YALE UNIVERSITY**

Study Title: Financial Incentives, Randomization with Stepped Treatment (FIRST) Implementation Sub-study

Principal Investigator: David Fiellin, MD, Yale University School of Medicine, 367 Cedar Street, ESH-A, Rm 401A, New Haven, CT 06510

Research Study Summary:

- We are asking you to join a research study.
- The purpose of this research study is to get your feedback on your experiences in contingency management, the rewards program, while participating in the FIRST Trial
- Study activities will include your participation in a one-time telephone interview. The interview will contain questions on how well you liked the techniques we used to help you address your alcohol use. Some examples of questions include: Was the number of sessions acceptable? How did you like the rewards? Would you refer a friend to the FIRST Trial? With your permission, we will be audio recording the session.
- Your involvement will require about one hour.
- There may be some risks from participating in this study. You may become tired or uncomfortable in answering the questions. There is also the possible risk of loss of confidentiality, however we have put safety measures in place. We will not use your name on the interview or on the recording.
- The study may have no benefits to you. However, your participation may help us to design better studies in the future.
- Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with your health care provider.
- If you are interested in learning more about the study, please continue reading, or have someone read to you, the rest of this document. Ask the study staff questions about anything you do not understand. Once you understand the study, we will ask you if you wish to participate; if so, we will continue with the study procedures described in this form.

Are there any costs to participation? Will I be paid for participation?

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You will not have to pay for taking part in this study. You will be paid \$50 for taking part in this study.

How will you keep my data safe and private?

All of your responses will be held in confidence. Only the researchers involved in this study and those responsible for research oversight (such as representatives of the Yale University Human Research Protection Program, the Yale University Institutional Review Boards, and others) will have access to any information that could identify you that you provide. We will share it with others if you agree to it or when we have to do it because U.S. or State law requires it. For example, we will tell somebody if we learn that you are hurting a child or an older person.

You will be given an anonymous study ID which will be used for the interview and for the recording.

When we publish the results of the research or talk about it in conferences, we will not use your name. If we want to use your name, we would ask you for your permission.

We will also share information about you with other researchers for future studies, but we will not use your name or any other identifiers. We will not ask you for any additional permissions.

What if I want to refuse or end participation before the study is over?

Taking part in this study is your choice. You can choose to take part, or you can choose not to take part in this study. You also can change your mind at any time. Whatever choice you make will not have any effect on your relationship with your health care provider. You do not give up any of your legal rights by giving your verbal agreement to participate.

Who should I contact if I have questions?

Please feel free to ask about anything you don't understand.

If you have questions later or if you have a research-related problem, you can call the Principal Investigator at **203-737-3347**.

If you have questions about your rights as a research participant, or you have complaints about this research, you call the Yale Institutional Review Boards at (203) 785-4688 or email hrpp@yale.edu.

What Information Will You Collect About Me in this Study?

The information we are asking to use and share is called "Protected Health Information." It is protected by a federal law called the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA). In general, we cannot use or share your health information for research without your permission. If you want, we can give you more information about the Privacy Rule. Also, if you have any questions about the Privacy Rule and your rights, you can speak to Yale Privacy Officer at 203-432-5919.

The specific information about you and your health that we will collect, use, and share includes:

- Research study records

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- Records about phone calls made as part of this research
- Records about your study visits

How will you use and share my information?

We will use your information to conduct the study described in this consent form.

We may share your information with:

- The U.S. Department of Health and Human Services (DHHS) agencies
- Representatives from Yale University, the Yale Human Research Protection Program and the Institutional Review Board (the committee that reviews, approves, and monitors research on human participants), who are responsible for ensuring research compliance. These individuals are required to keep all information confidential.
- The Principal Investigator
- Co-Investigators and other investigators
- Study Coordinator and Members of the Research Team

We will do our best to make sure your information stays private. But, if we share information with people who do not have to follow the Privacy Rule, your information will no longer be protected by the Privacy Rule. Let us know if you have questions about this. However, to better protect your health information, agreements are in place with these individuals and/or companies that require that they keep your information confidential.

Why must I agree to the use of my information?

By giving permission for the use of your health information, you will allow researchers to use and disclose your information described above for this research study. This is to ensure that the information related to this research is available to all parties who may need it for research purposes. You always have the right to review and copy your health information in your medical record.

What if I change my mind?

The authorization to use and disclose your health information collected during your participation in this study will never expire. However, you may withdraw or take away your permission at any time. You may withdraw your permission by telling the study staff or by writing to Dr. David Fiellin, Yale University School of Medicine, 367 Cedar Street, ESH-A, New Haven, CT 06520.

If you withdraw your permission, you will not be able to stay in this study but the care you get from your doctor outside this study will not change. No new health information identifying you will be gathered after the date you withdraw. Information that has already been collected may still be used and given to others until the end of the research study to insure the integrity of the study and/or study oversight.