Partners HealthCare System
Research Consent Form

Subject Identification

Certificate of Confidentiality Template
Version Date: January 2019

Protocol Title: Pathways to Change

Principal Investigator: John F. Kelly, Ph.D.

Site Principal Investigator:

Description of Subject Population: Adults with an alcohol use disorder making a new recovery attempt.

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 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.

Key Information

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. Your decision won't change the medical care you get within Partners now or in the future.

The following key information is to help you decide whether or not to take part in this research study. We have included more details about the research in the Detailed Information section that follows the key information.

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Why is this research study being done?

This research is being done to obtain greater knowledge about the pathways followed in new recovery attempts for individuals with an alcohol use disorder (AUD). We are asking you to take part in this research study because you identified yourself as someone with an AUD and is making a new attempt to change your alcohol use. About 348 people will take part in this research study. We expect to enroll all subjects within the greater Boston, Massachusetts area.

How long will you take part in this research study?

If you enroll today, it will take you a total of 24 months (two years) to complete this research study. During this time, you will complete a baseline assessment, along with follow-up surveys every 3-, 6-, 9-, 12-, 18-, and 24-months.

What will happen if you take part in this research study?

If you choose to enroll, you will be required to come to our downtown Boston office at the MGH Center for Addiction Medicine (within 3-minute walking distance of two major subway stops) to complete your assessments. You will complete your questionnaires via the Harvard Catalyst's Electronic Data Capture (REDCap; project-redcap.org) and with a research coordinator. You will be asked about basic demographic questions, substance use history, mutual-help organization attendance, psychiatric symptoms, psychosocial functioning, treatment service utilization, quality of life, and recovery motivation/support.

If you are a participant from the San Diego area, all of your study visits will take place remotely. The questionnaires will be asked over Zoom, Skype, or phone call and through an online link that is sent to your personal device.

As a supplement to this research study, we are conducting an optional qualitative interview for a portion of study participants. The aim of this qualitative interview is to investigate the motivations, expectations, and experiences of individuals who do and do not participate in Mutual Help Organizations (MHOs) such as Alcoholics Anonymous and SMART Recovery. Additionally, we hope to assess how helpful individuals believe MHOs are in their recovery attempt and how MHOs and other recovery resources might be improved and adapted to better fit the needs of individuals currently seeking recovery from an Alcohol Use Disorder.

MHO attendance is not required to participate in this qualitative interview. We plan to include individuals following a variety of recovery pathways.

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Study staff will reach out directly to a pre-determined number of interested individuals via email or phone call to offer them the opportunity to participate in this qualitative interview and schedule an interview time. The interview will be approximately 30-60 minutes in length and will be conducted via Zoom or over the phone and will be recorded. This is done purely for data summarization purposes and once the data are transcribed, the recordings will be deleted. Participants will be compensated an additional $50 following completion of the interview.

You are not required to participate in the optional qualitative interview in order to participate in the Pathways to Change Study. You can still take part in the original research study whether or not you choose to participate in this additional qualitative interview. Signing this form does not guarantee that you will be able to participate in the qualitative interview.

Do you consent to participate in the qualitative interview if selected?

[ ] YES [ ] NO Initial _____

You will receive text/email reminders about upcoming appointments through REDCap's automated email feature and integrated Twilio SMS and voice call services. Both REDCap and Twilio are secure services for these appointment reminders.

Text messages by mobile/cell phones are a common form of communication. The Recovery Health research study involves sending you text messages that are relevant to the research study. Texting over mobile/cell phones carries security risks because text messages to mobile/cell phones are not encrypted. This means that information you send or receive by text message could be intercepted or viewed by an unintended recipient, or by your mobile/cell phone provider or carrier.

Below are some important points about texting in this research study.

- Text messages are not encrypted, and therefore carry security risks. This research study and Partners Healthcare are not responsible for any interception of messages sent through unencrypted text message communications.

- You will be responsible for all fees charged by your carrier's service plan for text messaging. This research study and Partners Healthcare are not responsible for any increased charges, data usage against plan limits or changes to data fees from the research texts.

- Text messaging should not be used in case of an emergency. If you experience a medical emergency, call 911 or go to the nearest hospital emergency department.

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- You may decide to not receive text messages with staff associated with this research study at any time. You can do this in person at your upcoming visit, by calling 617-643-5927, or by emailing recoveryhealth@mgh.harvard.edu.

- Your agreement applies to this research study only. Agreeing to other texts from Partners Healthcare, for example appointment reminders, is a separate process. Opting out of other texts from Partners Healthcare is a separate process as well.

- It is your responsibility to update your mobile/cell phone number with this research study in the event of a change.

I have had the chance to ask questions about texting with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted text communications associated with this research study.

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

The risk of participating in this study is expected to be very small because your privacy is protected by law. We may report medical information if you need medical help, if we feel you might be in danger of harming yourself or others, or if there is any suspicion of child abuse or elder abuse.

It is possible that you may experience some discomfort during scheduled assessments from the questionnaires, as they ask for some sensitive personal information. However, you are free not to participate in any aspect of the study that makes you uncomfortable.

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

You will gain no direct benefit from participation in this study. However, this study has the potential to contribute valuable information about recovery pathways for individuals with alcohol use disorder, and may provide additional support for mutual-help organizations.

What other treatments or procedures are available for your condition?

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This study does not provide any treatment to you. Rather, we will ask you about your experiences with various treatments that you have been receiving or have received. You do not have to take part in this study to be able to obtain mental health services.

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

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

Dr. John F. Kelly, Ph.D., is the person in charge of this research study. You can call him at 617-643-1980, Monday-Friday, 9am-5pm. You may leave a message at this number and he will return your call. You can also call research staff at 617-643-9850, Monday-Friday 9am-5pm with questions about this research study. If you have questions about the scheduling of appointments or study visits, call research staff at 617-643-9850.

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
- Any pressure to take part in, or to continue in the research study

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Detailed Information

How may we use and share your samples and health information for other research?

The samples and information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example your name, medical record number, and date of birth) and use these de-identified samples and data in other research. It won't be possible to link the information or samples back to you. Information and/or samples may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

No. The research study we are doing is only a stepping stone in understanding recovery from alcohol use disorder. Therefore, no information about the results of this research study or the results of your individual participation in the research study will be given to you or your doctor. Tests done for the research using your samples will not be useful in directing your medical treatment. The results of the tests will not be placed in your medical record.

Can you still get medical care within Partners if you don't take part in this research study, or if you 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.

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 you do if you 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.

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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 you be paid to take part in this research study?

You will be compensated up to $455 for completing the questionnaires. That is $15, $25, $30, $35, $40, $45, and $55 for the baseline, 3-, 6-, 9-, 12-, 18-, and 24-month assessments, respectively. Additionally, you will be compensated $20 for each of the computer-based REDCap surveys you complete at each assessment. Finally, in order to help offset the cost of travel, you will be compensated $10 per assessment for coming to our offices. In order to receive payment for this study, we will need your Social Security Number (SSN). We need to collect this information in order to comply with tax reporting obligations. This information is confidential and protected, and will be stored securely and redacted when no longer required.

	Computer-based REDCap Surveys	In-Person Study Visits with Staff	Travel Reimbursement
Baseline	$20	$15	$10
3-Month Follow-Up	$20	$25	$10
6-Month Follow-Up	$20	$30	$10
9-Month Follow-Up	$20	$35	$10
12-Month Follow-Up	$20	$40	$10
18-Month Follow-Up	$20	$45	$10
24-Month Follow-Up	$20	$55	$10
Total:			Up to $455

As a supplement to this research study, we are conducting an optional qualitative interview for a portion of study participants. Participants will be compensated an additional $50 following completion of the qualitative interview.

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

There are no costs to participate in this research. All questionnaires and surveys will be provided to you by study staff members.

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What happens if you are 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 beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable 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 information and why:

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study

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- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside Partners, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain completely 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 identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable 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 identifiable 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 identifiable 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, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable 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.
- I have had the chance to ask questions about texting with staff associated with this research study. I have been informed of the risks and other information covered above and consent to the use of unencrypted text communications associated with this research study.

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Signature of Subject (choose one):

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

Subject	Date	Time (optional)

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. **I understand that I am eligible to be compensated for my participation but am choosing not to be.**

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)

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