Northwell Health

Campus: Zucker Hillside Hospital

General Consent for Participation in a Research Study

Title: Project ReDUCE (Collaborative Care for Alcohol Use Disorders in the Patient-Centered Medical Home: Phase I & II)

Principal Investigator: Jon Morgenstern, PhD

Sponsor: National Institute on Alcohol Abuse and Alcoholism

Introduction
You are being asked to join a research study called, "Collaborative Care for Alcohol Use Disorders in the Patient-Centered Medical Home" or Project ReDUCE. Being in a research study is different from being a patient. When you are a patient, you and your doctor have freedom in making decisions about your healthcare. When you are in a research study, the researcher will follow the rules of the research study as closely as possible, while monitoring your health. The purpose of this research study is to explore different alcohol use treatment options, including a combination of medication and different types of counseling on drinking, in a primary care setting.

This consent form will explain:

- the purpose of the study
- what you will be asked to do
- the potential risks and benefits

It will also explain that you do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study.

Why is this research study being done?
The purpose of this research study is to develop and test a care model to treat excessive drinking and alcohol use disorders in the primary care setting. The goal of this research study is to increase the identification and treatment of problem drinking in the primary care setting. You are being asked to participate in this study because routine screening and assessment conducted at your primary care clinic indicates that you have recently exceeded healthy drinking limits as outlined by the National Institute on Alcohol Abuse and Alcoholism.

How many people will take part in this study?
This research study hopes to enroll 85 individuals.

How long will you be in this study?
The study will last for 12 weeks. If you choose to take part in this study, the first survey will last for approximately 30 minutes. You will then have follow up assessments also lasting approximately 30 minutes and occurring at weeks 4, 8, and 12 of the study. These research assessments can be completed in-person or via televideo based on your preferred method. We will also monitor your alcohol use in order see if the treatment is working via daily questionnaires. These questionnaires will be sent to your phone via text message. These treatment monitoring questions will take about 1 minute to complete. Depending on the treatments offered to you and your response to treatment, over the 12 week course of the study, you may be asked to make additional office visits for further assessment, counseling sessions, lab work, or consultation with study staff. These visits will not occur more than once per week. These visits will be to manage your treatment and will not require you to take part in research surveys.

What will happen in this research study?
You have already provided verbal consent to be screened for risky alcohol use as a standard of care at the 865 Northern Boulevard General Internal Medicine site, and you received a brief counseling session based on your screening results. Now, we are requesting written informed consent for your participation in this study, including confirming your eligibility. You have received and will receive the standard services detailed above, while at this clinic, regardless of your participation in this study.

If you agree to participate in this study, you will undergo an assessment in order to confirm your eligibility for this study and determine if this study is appropriate for you. For example, this study is for people who drink regularly, have concerns about their drinking, and who are willing to engage in efforts to reduce their drinking to safe levels. Once we determine that you are eligible to participate in this study, we ask that you not participate in any other type of formal substance abuse treatment outside of the study for the 12 weeks of the study so that we may be able to isolate the effects of our treatments as much as possible.

You may withdraw from the study at any time. If you choose to not participate in this study and at any time you feel that what is offered in this study is not addressing your problems sufficiently, you will be provided with referrals to community organizations or private practitioners for further treatment.

Depending on your level of need, you will be given the option to receive behavioral, medication, treatments or referral to a community alcohol treatment provider. In addition to the Brief Advice about your drinking that you already received as part of standard care at this primary care clinic, you may be offered other behavioral treatments, including four sessions of Motivational Enhancement Therapy or 12 sessions of Modified Behavioral Self-Control Therapy. You may be able to choose to receive medication treatment, which would include daily naltrexone (50mg) and bi-weekly meetings with a licensed medical professional to monitor appropriateness and safety of the medication treatment. You will be asked to choose a treatment from the options provided to you at the end of this appointment, and the treatment will be discussed in detail with a clinician at your next appointment as the second part of the consent process. During that time,

if you do not wish to continue with the treatment you chose, you will be free to choose a different option of the treatment choices provided for your level of need.

You will also be asked to complete a total of three assessments at week 4, 8, and 12, after your initial assessment. Assessments and behavioral treatments may be scheduled in-person or via televideo, depending on your preference. Each assessment entails completing questionnaires. Medication visits will occur in-person.

A summary of the study is provided in more detail below:

Week 0 Assessment: If you choose to participate in the study by signing this consent form, a trained research staff member will conduct a survey asking you questions about your alcohol use and a review of your medical chart as well as discuss your participation with your primary care clinical team (e.g., your primary care physician). The survey that you complete will last approximately 30 minutes. During this assessment, you will be evaluated for eligibility and, if you are deemed eligible, you may be offered treatment options in addition to the assessments based on your need. Treatments are described in more detail below. Once you choose from the treatment options available to you, you will be scheduled to meet with a clinician providing that treatment the following week (week 1).

Week 1-12 Treatment: At your week 1 appointment, you will learn in detail about the treatment option and can choose to participate or change your treatment choice to another option that was provided to you. If you choose to continue with your treatment choice, you will be asked to sign a separate consent form specific to the treatment that you will be doing with the clinician providing the treatment.

If you choose to receive medication treatment, you will meet with a licensed medical professional who will conduct a medical exam and review of your medical history as well as consult the primary care clinical team. You will learn about the medication, its side effects, and other relevant information. Participants enrolled in medication treatment will be seen weekly for the first two weeks until the medication dose is stable at 50mg, and then meetings will occur biweekly. Additional physician visits may be scheduled if you experience side effects or do not follow the recommended medication guidelines.

All participants already received one session of Brief Advice to discuss information about their drinking, which occurred as part of standard care at the primary care clinic. Some participants, who may also receive additional behavioral interventions, will meet with a Behavioral Health Specialist, who will be a licensed mental health professional, for treatment starting at week 1. Those who receive four sessions of Motivational Enhancement Therapy will have sessions at weeks 1, 2, 4, and 8. This treatment will focus on discussing reasons to reduce drinking and ways to do so. Those who receive 12 sessions of Modified Behavioral Self-Control Therapy will have weekly sessions starting at week 1. This treatment will focus on reasons and strategies to reduce drinking.

Week 4, 8, and 12 Assessments:
At week 4, 8, and 12 of the study, you will meet with a research assistant to assess your changes in drinking and progress in the study. These assessments will be approximately 30 minutes and can occur in-person or via televideo, based on your preference.

At your week 4 assessment, you may be offered alternative treatment depending on your progress and need. For instance, if you initially chose to receive medication, you may have the option to switch to a different medication or receive a behavioral intervention in addition. If you chose to receive a behavioral intervention, you may be able to switch to receiving a medication. You will be able to discuss these options with the study clinician providing your initially chosen treatment and make a decision on whether or not you wish to change your treatment choice.

Daily Online Questionnaires:
Starting at week 1, all participants will receive daily questions via text message to assess the previous day's drinking. As part of this study, you are agreeing to send and receive text messages on your mobile phone. You will receive text messages once a day. The texts you receive will contain a link that will direct you to a survey that will ask you questions about your drinking and will require a response from you. It will take approximately one minute to complete. You may not appreciate receiving a text message or its content at a particular time. If you do not wish to answer a particular question at the time you receive the message, you may skip it. The text messages will not identify you as someone who is taking part in a study on drinking reduction. The survey can only be opened by you using a unique code number. This unique code number will open the survey in your mobile web-browser. We will review all the ways to keep your phone secure if you decide to participate and are eligible.

In case we have trouble contacting you: To be in the study, we will ask you to provide the names and contact information of two people. The only reason we will contact them is to help us locate you if you move or are otherwise non-responsive to our outreach. No other information about you will be given to them nor will we ask your contacts any questions.

What are the risks of the research study? What could go wrong?
There is the risk of a breach of confidentiality of the study data. The study team has put measures in place to protect the confidentiality of study data to minimize risk.

We will be collecting minimal personal data. Only your contact information will be recorded and it will be kept separate from the study data collected. All study data will kept on the Northwell Health password-protected, secured computers in secure databases or in locked file cabinets.

Interviews/Questionnaires
Some of the questions we will ask you are personal. You may feel embarrassed or stressed. You may ask to see the questions before deciding whether or not to take part in this study. All questionnaires will be conducted in a private and confidential setting. You will be able to end the questionnaire at any time if you experience any discomfort.

Daily Online Questionnaires

If you do not have an unlimited text messaging plan, you may be charged for the text messages you send and receive in this study. We will not compensate you for any charges you incur for text messages. As with any mobile phone, there is a risk that messages that you send and receive can be read by unintended individuals. It is your responsibility to ensure your phone is appropriately secured and managed; however, we will provide you with ways to keep your messages confidential and your phone secured.

Permission to contact you once the study is over (Optional):

Sometimes, once the study is over, we realize we may have additional questions about your experience of change and being in the study. We are asking your permission to re-contact you after the study to ask you questions about your experience of change and being in the study. You may withdraw permission at any time—it will not affect your participation in the study.

I consent to being re-contacted after my participation in the study is completed:
□ Yes □ No **Initials:** _____ **Date**: _____

If you have any questions or believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator of the study, Dr. Jon Morgenstern at telephone number (516) 837-1694.

What are the benefits of this research study?

The possible benefits you may experience from the procedures described in this study include a reduction in problem drinking; however, this cannot be guaranteed. We expect that the findings of this research will help your primary care clinical team to recognize and treat excessive drinking and alcohol use disorders in primary care settings in the future.

If you do not want to take part in this research study, what are your other choices?

If you do not join this study, you have other choices for treatment. Talk to your doctor about your choices. Your other choices may include:

- Standard treatment
- Medication
- Counseling
- No treatment

Currently, there are agencies that provide information about drinking to the public. A variety of types of treatment for alcohol use, including inpatient and outpatient rehabilitation programs, outpatient counseling, self-help groups, and medications, may be available to you through community organizations, treatment centers, or private practitioners. Medications such as disulfiram (Antabuse) and naltrexone (ReVia) are approved by the FDA to help reduce alcohol use and are available by prescription from a physician. If you would like, we can provide you with a list of available services in the community for more information about drinking or treatment for alcohol use.

Are there any costs for being in this research study?
Because you will be receiving text messages as part of this study and may complete assessments using your smartphone, you may be subject to data overage usage charges per your smartphone data plan. If you choose to receive medication treatment as a part of this study, your insurance company may be billed for the cost of the medication and potential lab work costs. If you do not have insurance, or do not wish to have your insurance billed, the study will cover the costs of medication and bloodwork during the 12 weeks of the study.

All assessment and behavioral intervention visits and procedures will be given to you at no cost. Neither you nor your insurance company will be billed for these visits.

Will you receive any payments for participating in this research study?
You will be paid up to a total of $80 for your time for being in this study. If you do not complete the entire study, you will be paid $20 for each study assessment session that you have completed. Payment will be made at the end of each assessment or when you end your participation.

If the total payment you receive from Northwell Health, during this year, is equal to $600 or more, the payment is required to be reported to IRS. Although this study does not pay $600, if you participate in other Northwell Health studies, it is possible your payment could end up totaling $600. If this occurs, the payment you receive on this study will be reported to the IRS. In this case, you will be issued a 1099 form and be required to provide your social security number at that time for reporting purposes. You will also be responsible for reporting this income while filing your tax return.

What happens if you are injured while participating in this study?
If you are hurt from being in the study, you will receive medical care and treatment as needed from Northwell Health. However, you will be responsible for the costs of such medical treatment, directly or through your medical insurance or other forms of medical coverage. No money will be given to you.

What are your rights as a research participant?
Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study.

If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study, you may withdraw at any time without prejudice to your future care at Northwell Health. Follow-up examinations may be needed to assure your well-being.

Could you be taken off the study before it is over?
It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher, study sponsor or the Institutional Review Board (IRB—the committee that oversees research at this institution).

Reasons for withdrawal may include:

- failure to follow instructions,
- failure to show up for study visits,

- it is not in your best interest to continue on this study, or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data already collected will continue to be used. However, no new data will be collected.

What happens if new information is learned?
You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What information will be collected and used for this study?
If you agree to be in this study, we will collect information about your health and your alcohol use. We may collect the results of questionnaires and interviews. This information may include questions about the amount of alcohol you drink, how often you drink, any problems you have experienced because of drinking, and any reasons why you may have trouble accessing treatment services. If you drop out of treatment, we may ask you why, so that we can learn from your experiences. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study

Who else will see your information?
Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside Northwell Health, except as detailed below.

Investigators will share de-identified information collected from this research study with:
- study sponsor and/or its agents,
- data safety monitoring board,
- clinical staff not involved in the study who may be involved in the participant's treatment

The following reviewers may access your study and medical records to make sure that this study is being done properly:
- Representatives from federal and state government oversight agencies, such as National Institutes of Health, US Department of Health and Human Services (DHHS), or the New York State Department of Health. Representatives from Northwell Health Human Research Protection Program (a group of people that oversee research at this institution)

We will do our best to protect the privacy of your records, but it is possible that once information is shared with people listed on this form that it may be released to others. If this happens, your information may no longer be protected by the federal law.

In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records?
If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, please call the Human Research Protection Program at 516-321-2100.

How long will your health information be kept?
There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you can send a letter to the researcher at the following address:

Dr. Jon Morgenstern
1010 Northern Boulevard, Suite 311
Great Neck, N.Y., 11021

Your letter needs say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

We may write about this study and publish it in a scientific journal, however you will not be named and all participants' data will be combined such that no one participant is written about.

Will information about this study be available to the public?
We may write about this study and publish it in a scientific journal; however, you will not be named and all participants' data will be combined such that no one participant is written about. In addition, 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.

Does the investigator of this study receive money if you take part?
Funding for this research study is provided by the National Institute of Alcohol Abuse and Alcoholism. The investigators on this study receive money to conduct the study but do not financially benefit from your participation. The money they receive is to pay them back for the costs of conducting the research study. If your doctor is an investigator for this study s/he is

interested in both your healthcare and the conduct of this research. You do not have to take part in a research study conducted by your doctor.

Who can answer your questions about this study?
If you have any questions about the study, you may call Dr. Jon Morgenstern at (516) 837-1694. If you have questions about side effects or injury caused by research you should call Dr. Jon Morgenstern at (516) 837-1694. If you need emergency care, dial 911 or go to the nearest Emergency Room. If you have questions about your rights as a research participant, concerns about being in the study, or would like to offer input, you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516) 321-2100.

A signed copy of this consent form will be given to you.

Research Review Questionnaire

After reviewing the consent form for this study please answer the following questions by circling "True" or "False". The researchers doing this study want to be sure that you know what is involved in being in this research study. This questionnaire will help them make that decision. You may ask questions of the researcher and review the consent form again at any time.

This study will last for 12 weeks.	True False
I am being asked to participate in a research study.	True False
I will be required to take medication as part of this study.	True False
This study involves the use of a text messaging.	True False
I can withdraw from participating in this study at any time.	True False
There are no risks to me from participation in this study.	True False
My participation in this study is confidential and a unique code will identify me when I complete questionnaires online.	True False

[Signature Page Follows]

Summation/Signature

You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____ _____ _____
Witness's Printed Name Witness's Signature Date
(Note: A witness can be a member of the research team, but cannot be the same person signing consent as the investigator)

Investigator's Statement
In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study and to answer any further questions relating to it.

_____ _____
Investigator's signature **Date**

_____
Investigator's printed name