Title of Project: Multi-site Pilot Trial of Strengths-based Linkage to Alcohol Care for Hazardous Drinkers in Primary Care (IIR 20-058)

NCT ID: NCT05023317

ICF Document Date (e.g., IRB approval date): 11/18/2022

Documentation of Verbal ICF
C2C Study (Aim 2)

Veteran's Name: _____Date: _____

Veteran Name meets inclusion criteria and does not meet the exclusion criteria for this study. Study purposes, procedures, risks, and benefits were reviewed utilizing the VA Central IRB approved Information Sheet v.1 date 11/18/2022.

Veteran was given the opportunity to ask questions. Questions asked and answered, Veteran voluntarily consented to participation in the research study and expressed comprehension and appropriate decision-making capacity at the time of consent. No protocol procedures were done prior to consent.

Study Team Member administered the informed consent.

Script for Obtaining Consent

Intro for calling a Veteran
Hello, this is [state your name] with the (Identify facility).
May I please speak to [state Veteran's first and last name]? If person answering the call is Veteran as them to confirm identify
Thank you. Would you please state your date of birth, so that I can make sure I am speaking to the right person [Confirm Veteran date of birth and continue with following script]

I am calling about a paid research study that we are conducting called C2C for Veterans. We recently mailed an invitation letter with some information about the study. You may recall receiving a large brown envelope. Have you received this letter?

[continue with script whether they received letter or not].

Is now a good time to provide you with more information?

SCRIPT:

The purpose of the research study is to adapt a new educational program, called Connect to Care (C2C), to help Veterans who drink alcohol and experience mental health symptoms learn more about their care options both within and outside the VA.

You are being asked to participate in this study because you are a Veteran who has had a visit in a primary care clinic within the past year, and your routine screening results during a visit suggest that you might benefit from learning about additional care options that are available to you.

If you agree to participate, you will be randomly assigned (like flipping a coin) to receive the C2C educational program or not. You will be asked to complete a baseline telephone interview at the start of the study and a follow-up telephone interview 3 months later. Each telephone interview should take approximately 45 minutes. During the interviews we will collect information on how you feel emotionally and physically, any substance use and how you feel about your care options.

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You will be compensated for your time. A check in the amount of $25 will be mailed to you 4-6 weeks after you complete the baseline interview and another check in the amount of $30 will be mailed to you 4-6 weeks after you complete the 3-month follow-up interview.

If you are assigned to the educational program, a coach will contact you by telephone to schedule an initial meeting with you. Should you choose to do so, you may have up to 5 contacts with your coach over a period of 7 weeks.

Your participation in this research study is voluntary. You may choose not to participate or leave the study at any time without penalty or loss of benefits to which you were otherwise entitled.
Are you interested in participating in this study?

If YES: I just need to go over a few more details and ask you some questions to make sure this study is right for you. Is it okay to proceed?

If NO: Thank you for your time and have a great day.

Do you agree to participate in this study? **Yes** **No**

Do you agree to be audiotaped? **Yes** **No**

Do you have any questions? (If yes, answer.)