FINANCIAL INCENTIVES FOR THERAPY COMPLETION: A RANDOMIZED CONTROLLED TRIAL WITH U.S. VETERANS

Study consent form submitted to University of Notre Dame Institutional Review Board
12 May 2023

CONSENT TO PARTICIPATION IN RESEARCH AND HIPAA AUTHORIZATION FORM

ABOUT THIS RESEARCH
You are being asked to participate in a research study that has been reviewed and approved by an Institutional Review Board at the University of Notre Dame.

Title of the Research Protocol: **Recovery Resource Council - Veteran Incentives**

Name of Principal Investigator: **Christopher Cronin**

IRB Protocol Number: **21-05-6633**

If you choose to participate in this research study, you may receive a monetary award while attending counseling sessions at Recovery Resource Council (RRC). Whether you are selected to potentially receive a monetary award or not, we are interested in the progress you make with RRC. For this reason, the research team will follow your progress over the next few years. This consent form will give you information about the study to help you decide whether you want to participate. Please ask any questions you have before agreeing to be in the study.

You were selected as a possible participant because you meet the eligibility criteria for RRC services.

TAKING PART IN THIS STUDY IS VOLUNTARY
Your participation in this research is completely voluntary. You can choose not to participate. Should you choose to participate, you can subsequently choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, does not have any penalty other than that you will no longer be eligible to receive any monetary awards. Your decision to participate or not to participate will not affect your relationship with RRC. If you decide to leave the study at any point after enrolling, the researchers will retain and analyze any data already collected from you up to the time of your withdrawal unless you specifically request otherwise.

WHAT WILL HAPPEN DURING THE STUDY?
During this intake session, you will be asked to respond to a brief questionnaire that all study participants are required to complete. All of your answers will be kept confidential, and your identifying information will never be attached to any published results. Once you complete the questionnaire, you will be entered into a lottery that will determine whether you will be offered the opportunity to receive a monetary award while attending counseling sessions at RRC. If the lottery does not assign you to potentially receive this monetary award, you will still have access to normal counseling services through RRC. Later, during each counseling session, therapists will ask a few basic questions to identify how conditions may have changed for you over time.

Whether or not you are selected to receive the possibility of a monetary award, you will be part of the study so that researchers can compare experiences of those who are selected and those who are not. To do this, the researchers will utilize administrative data that some government and private agencies already collect about you. You will never be contacted about this study outside of your interactions with RRC.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?
The risks involved with participation in this evaluation are low, but potential risks may include loss of confidential data. Your privacy is very important to us. Research-related survey questions will be answered using Qualtrics software, which is HITRUST certified - the industry standard for HIPAA security requirements. All confidential data used by the evaluation team will be stored

in a secure location. Only members of the evaluation team will have access to the data. Your data will be linked to administrative records from governmental and private agencies. Any data that is transferred for the purpose of linking with administrative records will be encrypted and password protected in transit. No one will be able to identify you in any published results from the study.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?
One benefit of participation in the study is the possibility of receiving a monetary award. The research team will use a fair lottery system to randomly assign participants to one of two groups: A or B. All participants face an even (50/50) chance of being assigned to each group. For individuals assigned to Group A, there is no possibility of receiving a financial award. For individuals assigned to Group B, there is a possibility of receiving a financial award while attending sessions at RRC. The financial award(s) will be given to participants as a gift card by RRC. Those who are not offered this opportunity will still have access to counseling and other resources at RRC that may be of assistance. There are also potential benefits to society that will result from your participation in the research, such as the stimulation of similar programs elsewhere.

HOW WILL MY INFORMATION BE PROTECTED?
Efforts will be made to keep your personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study or in databases in which results may be stored. Your personal information may be disclosed if required by law.

The research team will collect survey data using Qualtrics, which meets HIPAA security requirements. Merged survey and clinical data will be stripped of identifying information and stored securely in an encrypted form. Only members of the research team will have access to the data. In certain circumstances, other researchers may request access to de-identified information from this study. For example, researchers are often asked to make de-identified datasets available to other researchers so that other people can replicate their work and make sure it is correct. In these cases, your information may be made available to people outside the research team in a de-identified form. We will not make publicly available any pieces of information that could be tied back to you.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the University of Notre Dame Institutional Review Board or its designees, and (as allowed by law) state or federal agencies, especially the Office for Human Research Protections (OHRP), who may need to access the research records.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?
Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information that could identify you will be removed before any information is shared. Since identifying information will be removed, we will not ask for your additional consent.

WILL I BE PAID FOR STUDY PARTICIPATION?
Individuals who are randomly selected via lottery will have the opportunity to potentially receive a monetary award. No other compensation will be offered for study participation.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?
For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, please contact Notre Dame Research Compliance at 574-631-1461 or at compliance@nd.edu. For questions about the nature of the study, you can

contact the Principal Investigator, Chris Cronin (ccronin1@nd.edu). Other Investigators are Ethan Lieber (elieber@nd.edu) and Meghan Skira (skira@uga.edu).

HIPAA AUTHORIZATION

In order to participate in this research, you must authorize the creation, use, and disclosure of Protected Health Information (PHI) which has been described in a research protocol that has been reviewed and approved by an Institutional Review Board at the University of Notre Dame.

This authorization is voluntary and you may refuse it. If you refuse this authorization, your health care and relationship with Recovery Resource Council will not be affected. However, you will not be able to participate in this research study.

This form authorizes RRC to create, use, and disclose (share) certain protected health information (PHI) about you that the investigators will collect as a part of the research study. A description of the information to be created, used, and disclosed and the purposes for which the data will be used is included below.

The only persons who are authorized to use and disclose your PHI are the investigators listed on this form and others who are participating in the conduct of the research protocol. Those who are authorized and may receive this information are colleagues/collaborators, non-Notre Dame researchers, and the Office of Human Research Protections.

The information collected will be shared with identifiers and the investigators may continue to use and disclose PHI that we collect from you in this study indefinitely. You will not be given access to medical information about you that is related to the study until after the research is complete. After the study is completed and the results have been analyzed, you will be permitted access to any medical information collected about you in the study that is maintained in your medical record.

You may withdraw, at any time, your permission to provide this information to the researchers. To withdraw your permission, you will need to take one of the following courses of action:

a. If your information has already been given to the researchers, you should send a written and dated notice of this decision to the principal investigator of this research study. Upon receipt of this request, the researchers will destroy your information that was provided to them.
b. If your information has NOT already been given to the researchers, you should contact by telephone your counselor or a member of RRC's staff. With receipt of this request, your information will not be shared with the researchers.

Your decision to withdraw your permission to provide this information to the researchers will have no effect on your current or future medical care or your relationship with Recovery Resource Council, your doctor, or health care provider. The information about you that is used or disclosed in this study may be re-disclosed and is no longer protected under federal law.

Description of the **PHI to be created, used, and disclosed:**

☒ Your complete existing health record or limited information from your health record.
☒ Questionnaires, interview results, focus group survey, psychology survey, behavioral test results (e.g., memory and attention)

Your information will be used to learn more about your health condition and the care you receive for it.

The Enduring Families mental health program provides mental health services in the form of counseling. **It does NOT provide drug or alcohol treatment.** That said, because information about history with alcohol and drug use, as well as your mental health history, may be obtained by Notre Dame Researchers through RRC records, additional laws protecting this information apply. **By consenting to participate in the study, you are indicating that you understand that information related to your alcohol, drug, and mental health history will be created, used, and disclosed to Notre Dame researchers.**

PARTICIPANT'S CONSENT
Please select one of the following options:

▢ In consideration of all of the above, **I give my consent** to participate in this research study and to the use and disclosure of my PHI, my drug and alcohol-related diagnoses, treatment, or referral information, as well as information about my mental or behavioral health care. In addition, I recognize that in consenting, I agree that:

- I have access to and will provide my own personal email address.
- I am willing to fill out a W-9 if I am assigned to the group eligible to receive monetary rewards.
- I am willing to provide my Social Security Number.

▢ I do not agree to take part in this study.

By typing your name below, you acknowledge that your typed name will serve as your signature on this form.

_____
Text Box for Participant's Name

For the intake coordinator:

By typing your name below, you acknowledge that you were witness to the veteran giving consent to participate in research and that your typed name will serve as your signature on this form.

_____
Text Box for Intake Coordinator's Name