Principal Investigator's Name: Steven L. Sayers, Ph.D.

Complete VA Address: Corporal Michael J. Crescenz VA Medical Center MIRECC Suite, 2nd FL, MS 116, 3900 Woodland Avenue, Philadelphia, PA, 19104

Title of Study: Telephone Coaching of Family members of Veterans with Substance Abuse (Coaching-CRAFT Pilot)

Version Date and Version Number: 05/19/2016, Version 1

Name of Study Sponsor: VA Rehabilitation Research & Development (RR&D)

WHY AM I BEING ASKED TO VOLUNTEER?

You are being asked to voluntarily participate in a research study because your family member (_____) has been participating in a a study to help address his/her concerns about your alcohol or drug use. Your participation is voluntary, which means you can choose whether or not you want to take part. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The study doctor and/or a member of the research team will talk to you about the research study. You are encouraged to discuss this study and consent form with your family, friends, or family doctor. Please ask the study doctor and/or the research team about this form.

WHAT IS THE PURPOSE OF THIS RESEARCH STUDY?

The purpose of this research study is to see whether we can create a more effective way of helping family members encourage Veterans to consider starting treatment for alcohol or drug use. As your family member let you know, he/she has been talking with a Coach on the telephone as part of this study to improve his/her relationship with you, be supportive in your decisions about care, and encourage you to get help. Your part in the study, if you choose to be involved, is to give your own opinions about your relationship with your family member, if things changed between the two of you, and also to let us know whether you decided to get treatment for alcohol or drug use.

HOW LONG WILL I BE IN THE STUDY? HOW MANY PEOPLE WILL BE IN THE STUDY?

You will be involved with this study for one interview. You will have one telephone session with a study staff member from the Corporal Michael J. Crescenz VA Medical Center (CMCVAMC) in Philadelphia, PA. We plan to enroll 50 Veterans in this study from a range of VAs throughout the United States.

WHAT AM I BEING ASKED TO DO?

If you agree to be in the study, we will ask you to participate in one study interview, lasting about 60 minutes. This will be scheduled as soon as possible after we finish discussing the study and you consent to being in the study. This interview will cover the following information: your

contact information and address, your background, your relationship to your family member, amount of contact that you have with him/her, mental health symptoms you may have, and your use of alcohol and drugs. You will also be asked about any treatment you have received for mental health reasons, or alcohol and drug use. We will also gather information about your medical care over the last 12 months from your VA records.
All study procedures will be done over the telephone.

You will be paid $30 total by check for participating in this research interview. This check will be mailed out to you within two weeks of the interview.

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS?
There is a very small risk of a breach of confidentiality/privacy of your information or that your participation will become known to others, even if we are extremely careful about this. The research team will take steps to prevent a breach of confidentiality/privacy. Study plans to protect confidentiality are described further on in this consent form. You may become uncomfortable with some of the questions about mental health problems. You do not have to answer any questions that make you uncomfortable.

WHAT ARE THE POSSIBLE BENEFITS OF THE STUDY?
You will not benefit directly from participating in this research study. The information from this study will be helpful to other Veterans by helping us know how to help family members, and the Veterans they are concerned about, have positive discussions about getting treatment for alcohol and drug use problems.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT PARTICIPATE?
You have the choice not to participate in this research study. Participation is voluntary and you do not have to participate if you do not want to. There are no negative consequences to deciding not to participate in this study. If you choose to not participate in the study, you could be referred to the *Coaching Into Care* call center or other VA resources to offer continued work not associated with any research. You may wish to discuss your participation, or alternatives to participating, with your VA or non-VA Primary Care Physician.

WHO CAN SEE OR USE MY INFORMATION? HOW WILL MY PERSONAL INFORMATION BE PROTECTED?
Information that will be used: During the course of this study, we will collect personal information such as your name, address, social security/medical record number, telephone number, report of your feelings and symptoms, your relationship with your family member who also participated in this study, your report of treatment you have received, your use of alcohol and drugs, and other information that can personally identify you (i.e., some combination of age, birthdate). None of this identifying information is required, however, and you can decide to give only what you feel comfortable providing us.

Your name, social security/medical record number, and other identifying information will be used

only as necessary within the CMCVAMC. But other collected private information, such as your report of your feelings and symptoms, your relationship with your family member who also participated in this study, your report of treatment you have received, your use of alcohol and drugs may be disclosed to the study sponsor, VA's research division, Rehabilitation Research & Development (RR&D).

If you have an accident or reaction during the course of the study, your entire medical record may be used and disclosed as clinically necessary.

Internal monitors from the CMCVAMC Institutional Review Board (IRB), a research oversight committee, may inspect study records for quality assurance.

The results of this study may be published; however, you will not be identified by name or other personal identifiers. Further, your medical records will not be revealed unless required or authorized by law.

We will protect the privacy and confidentiality of your data by locking any paper records associated with the study in locked filing cabinets in a locked office at the CMCVAMC in Philadelphia, PA. The other responses to interviews as part of this study will be stored on a secure VA computer server.

The required records, including the investigator's research records, must be retained until disposition instructions are approved by the National Archives and Records Administration and are published in VHA's Records Control Schedule (RCS 10-1).

WHAT SHOULD I DO IF I HAVE BEEN INJURED OR EXPERIENCE A MEDICAL PROBLEM?

If you feel that you experience any negative consequence from your participation in this study you should inform the principal investigator and/or the study personnel immediately and should be encouraged to inform your VA or non-VA Primary Care Physician. It is important that you tell the study doctor, Dr. Steven. L. Sayers, if you feel that you have been injured because of taking part in this study. You can call the study doctor directly at (215) 823-5196. You may also contact the study doctor through the CMCVAMC's toll-free number: 1-800-949-1001 CMCVAMC's toll-free number: 1-800-949-1001 and connecting to extension 5196.

WHEN IS THE STUDY OVER? CAN I LEAVE THE STUDY BEFORE IT ENDS?

You understand that you do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled. . Even if you withdraw, we can continue to use information about you that has been collected up to that point. No information will be collected after you formally withdraw.

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped at any time without your consent because:

- The Principal Investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- The Sponsor or the Principal Investigator has decided to stop the study.

WHAT ARE MY RIGHTS AS A RESEARCH SUBJECT?

I have read or have had all of the above read to me. Dr. Sayers or a member of the research team has explained the study to you and answered all of your questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to you.

In case there are medical problems, research related injuries or questions, you have been told that you can call Dr. Sayers at (215) 823-5196 during the day, or the Veterans Crisis Line at (800) 273-8255 (press #1) after hours for emergencies.

In the event that you sustain injury or illness as a result of your participation in this VA approved research study, conducted under the supervision of one or more VA employees, all medical treatment (emergent as well as medical treatment beyond necessary emergent care) will be provided by the VA.

If you would like to discuss problems, complaints, concerns, or questions with someone who is not directly associated with your participation in this study or you have any questions regarding your rights as a research subject; if you feel that you have been injured, or you want to check the validity of the study and its personnel within the VA, you may contact the Research Compliance Officer at 215-823-7847 or the Patient Representative at 215-823-5803 from 8:00 AM to 4:30 PM Monday through Friday. These individuals are in Philadelphia, PA.

If you have concerns or complaints about the research study, you may contact the research staff involved with this study at (215) 823-5800, extension 5247; Dr. Sayers (PI) at (215) 823-5196.

As a Veteran, we value your input into how research is conducted at the CMCVAMC. If you would like to offer suggestions and opinions, or if you would like to participate in future discussions of research in Philadelphia, please call the Research and Development (R&D) Administrative Officer at (215) 823-6020 or R&D Associate Chief of Staff at (215) 823-5893.

There will be no cost to you for your participation in this study. However if you are receiving medical care and services from the VA that are not part of this study, and you are a Veteran described in federal regulations as a “category 7” Veteran, you may be required to make co-payments for the care and services that are not required as part of this research study.

You understand that in the event of injury resulting from the research procedures, eligible Veterans will be entitled to medical care and treatment for any sustained injury. Compensation

may also be payable under 38 USC 1151 or in some circumstances, under the Federal Tort Claims Act.

I voluntarily consent to participate in this study. I have read this consent document or it has been read to me; it explains what this research project is about and how and why it is being done.

If you want us to, we can mail you a copy of this consent form so that you have it for your records.