

## Appendix A. Participant Informed Consent

### STUDY FACT SHEET

**Study Title:** The Effects of Screening and Referral for Social Determinants of Health on Veterans' Outcomes

**Name of Study Lead (also called "Principal Investigator"):** Deborah Gurewich, PhD

Name of Study Lead at your VA (also call "Local Site Investigator"): (insert relevant name)

**1. What is the purpose of the study?** To understand how the Veterans Health Administration (VHA) can best help Veterans who have *resource needs*. *Resource needs* are also called social determinants of health. These are things like having trouble paying for housing or a hard time paying important bills, like electric or gas bills.

**2. Who is invited to participate?** You are eligible to participate if you

- a) have heart disease or cardiovascular disease (CVD) or are at risk for heart disease (for example, because you have high blood pressure), *and*
- b) get primary care at the Boston, Charleston, or Philadelphia VA Healthcare Systems.

**3. What does the study involve and how long will it last?** The study has two parts.

In **Part One**, someone from the research team will call you. They will want to talk for about 30 minutes. They will go over the study and answer any questions you might have. Next, they will conduct a brief questionnaire with you about your resource needs (for example, they will ask about your housing). Depending on your answers, you may be eligible for Part Two of the study. If you are not eligible for Part Two, that will be the end of your participation in the study.

If you are eligible for **Part Two** of the study, you will be contacted by phone two more times – eight weeks and six months after the first telephone call. During these calls, a researcher will conduct brief questionnaires with you about your resource needs. These phone calls should take only 5-10 minutes.

For Part Two of the study, you will be randomly assigned to one of three study groups: A, B, or C (see table on page 2). Being randomly assigned is like a flip of a coin for which group you would be placed in.

- **Group A:** Participants in this group will receive a postcard listing local and national VHA help lines that may help with resource needs.
- **Group B:** Participants in this group will receive a postcard and also a written list of resources (i.e., agencies and programs) tailored to each participant's specific resource needs.
- **Group C:** Participants in this group will receive a postcard, a written list of resources, and also be offered help from a social worker who is part of the research team. The social worker may contact you by phone to learn more about your resource needs and help you connect to agencies and programs. The social worker could contact the you by phone up to 5 more times.

If you are in Groups B or C, you might also be asked to participate in a phone interview. In contrast to the brief questionnaires described above, the phone interview will involve a longer list of questions and will take more time, we estimate 45-60 minutes. If you are selected for an interview, a member of the research team will contact you by phone between months 7 and 12. If you agree, the researcher will

then schedule a time that is convenient for you to conduct the interview. Before the interview begins, we will ask your permission to audio record the interview. If you do not want the interview recorded, that is Ok and you can still participate in the interview. During the interview you will be asked about your experience participating in the study. Veterans who participate in Part Two of study will be in the study for 12 months.

#### What Participants Will Receive by Study Group

Group A	Group B	Group C
<ul style="list-style-type: none"> <li>• Postcard listing local and national VHA help lines</li> </ul>	<ul style="list-style-type: none"> <li>• Postcard listing local and national VHA help lines</li> <li>• Resource sheet listing agencies and programs to address specific resource needs</li> </ul>	<ul style="list-style-type: none"> <li>• Postcard listing local and national VHA help lines</li> <li>• Resource sheet listing agencies and programs to address specific resource needs</li> <li>• Assistance from a Social Worker to help connect to agencies and programs</li> </ul>

**4. What are the benefits of participating?** People who participate in this study may have a better understanding of the resources that can help Veterans with resource needs. Your participation may also add much needed knowledge about resource needs among Veterans and how the VHA can better meet the needs of Veterans with resource needs.

**5. What are the possible risks or discomforts of participating?** Some people may feel uncomfortable or upset discussing resource needs during the telephone calls with research staff. You may choose to skip a question or stop the telephone call at any time. You can also withdraw from the study at any time. Some people may find the telephone calls inconvenient. We will make every effort to schedule phone calls when it is convenient for you and will try to keep them short. Finally, there is a general risk of loss of confidentiality, but we believe this risk is minimal.

**6. How will my private information be protected?** Information collected for this research study will be kept confidential as required by law and will not be shared with your care team. However, you are welcome to follow-up with your care team at any time during your participation this the study. The results of this study may be published for scientific purposes, but your record or identity will not be revealed unless required by law. We will store your information in ways we think are secure. We will store paper files in locked cabinets. We will store electronic files in computer systems with password protection and encryption. However, we cannot guarantee complete confidentiality. To help protect your personal information, we will assign you a study ID so that your identifiable information is not connected to you.

We will limit access to your personal information to members of the research team who need to review this information in order to conduct the study. In addition, a description of this study will be available at <http://www.ClinicalTrials.gov> as required by U.S law. This website will not include information that can identify you.

Your research records will be destroyed in accordance with the VHA Record Control Schedule ([www1.va.gov/VHAPUBLICATIONS/RCS10/rcs10-1/pdf](http://www1.va.gov/VHAPUBLICATIONS/RCS10/rcs10-1/pdf)). Records will be destroyed when allowed in the following manner: Paper records will be shredded; electronic records and audio recordings will be destroyed in a manner in which they cannot be retrieved.

Participating in this study will not affect your VHA healthcare including your healthcare providers' ability to see your records as part of normal care and will not affect your right to have access to your records during and after the study is completed.

**7. What are the costs of participating in the study?** You will not be charged for any activities or procedures that are part of this study.

**8. Do I have to take part in this study?** No. Participating in the study is voluntary and if you refuse to take part in the study, there will be no penalty or loss of benefits to which you are otherwise entitled to from the VHA. There are also no consequences if you decide to withdraw from the study. In this instance, for data already collected prior to your withdrawal, the research team may continue to review the data already collected for the study but will not collect further information from you.

**9. Who do I contact about this study if I have questions?** If you have any questions about the research study, concerns or complaints, you can contact the project manager at 857-364-2350. If you have questions about your rights as a study participant, or want to make sure the study is valid, you may contact the VHA Central Institutional Review Board toll free at 1-877-254-3130. This is the Board that is responsible for overseeing the safety of human participants in this study. You may call them if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

**10. Will I be compensated for being in this study?** As a thank you for your participation, you will receive a \$15 gift voucher to CVS for each brief questionnaire you complete and a \$25 gift voucher to CVS if you participate in a telephone interview.