Information Sheet Template (Waiver of Documentation of Informed Consent)

VA Central IRB
VA Institutional Review Board for Multisite Studies

INFORMATION SHEET FOR COLLABORATIVE SPECIALTY CARE FOR GULF WAR ILLNESS

You are being invited to take part in a research study that is being funded by Veterans Affairs Health Services Research and Development (HSR&D). Before you decide to take part, it is important for you to know why the research is being done and what it will involve. This includes any potential risks to you, as well as any potential benefits you might receive. Taking part in this study is completely voluntary.

WHY IS THIS STUDY BEING DONE?

Research has found Problem-Solving Treatment and/or Health Coaching improve the disability from Gulf War Illness. We don't know the best way to deliver these treatments. By doing this study, we hope to learn if a clinic, that specializes in collaborative care for Gulf War Veterans, will improve their health and health care satisfaction. This study will also let us know how much Gulf War Veterans and their medical providers like this clinical model.

This is a collaborative study being conducted at the VA New Jersey Health Care System (VA NJHCS), VA New York Harbor Health Care System (VA NYHHCS), Roudebush VA Health Care System (Roudebush VAHCS), Michael E. Bakey VA Medical Center (Bakey VAMC) and Edith Nourse Rogers Memorial VA Medical Center (ENRM VAMC).

WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?

Up to 290 Gulf War Veterans will participate in this study. This research study is expected to take approximately 5 years to complete. If you agree to participate, your participation in this study will last approximately 9-12 months and the following will occur:

1. You will review this information sheet with a study team member and will be asked if you voluntarily agree to participate in this study. This process may take place over the phone with a study team member.

2. We will get the names of your VA primary care provider and mental health care provider. This name may be collected from your medical record or through a form you will complete. We will let your providers know about your participation in this study. Our specialty provider team will talk with your providers about treatment recommendations or current care. We may also contact your health care providers if we have any medical concerns during your participation in the study. We will ask your providers to tell us of any health concerns s/he may have about your participation. We highly encourage you to also reach out to your providers to ask about your participation in the study.

3. After you voluntarily agree to participate, you will be asked to fill out a questionnaire packet. Completing this questionnaire packet can be done either over the phone, over the internet through a secure internet platform, or mailed back to us in a prepaid envelope. You are free to skip any questions that you prefer not to answer.

4. You will also be "randomized" into one of two study groups: tele-CSC or e-consultation. Like flipping a coin, you will have about a 1 in 2 chance of receiving tele-Collaborative Specialty Care (tele-CSC) or e-consultation. Approximately half of the study participants will receive tele-CSC and the other half of study participants will receive e-consultation. Throughout the course of the study, you will be allowed to begin new treatments, continue with current treatments, or make changes to your existing medical regimen.

    a. **If you are in tele-CSC**, you will receive care from our specialty provider team. Our specialty provider team is made up of medical providers and mental health providers. They will review your medical chart and ask you about your experiences with Gulf War Illness and preferences for treatment. Treatment will include Problem-Solving Treatment sessions and Health Coaching sessions, and Pain Medicine Management check-ins. You will work with the specialty provider team to schedule these sessions and check-ins over a 6-month period. The sessions and check-ins can be completed either over the phone or through Veteran Affairs Video Connect (VVC) or other approved technological communication platforms. VVC, and other approved technological platforms, allow Veterans to connect with VA medical providers through video conference. The sessions may be audio recorded with a digital voice recorder or directly onto the computer. You will also be asked to follow some basic rules (i.e., not having anyone else in the room and shutting off other telephones so there will be no distractions). The specialty provider team may share their treatment recommendations for you with your primary care provider(s) and mental health provider.

    Problem-Solving Treatment: You will have 12 sessions of Problem-Solving Treatment. Each session will last about an hour. Before beginning this treatment, you will be provided a workbook. Over the course of this treatment, you will be taught a five-step problem-solving strategy. The workbook will contain worksheets that you may complete during sessions and at home in-between sessions.

    Health Coaching: You will also receive 6 sessions of Health Coaching. Each session will last about an hour. You will be provided a workbook and will discuss various health topics. Health topics include food and diet, social connection and relationships, working the body, sleep and recharge, and stress management.

You will also make goals for each topic discussed and be taught tips to assist you in reaching your health goals.

Pain Medication Management: You will work with a medical provider from the specialty team to discuss your past and current pain medication use, side effects, treatment preferences, medical conditions, etc. The medical provider may make recommendations regarding your pain medication regime. These recommendations will be shared with your primary care provider; your primary care provider will prescribe these medications. If you are pregnant or plan to get pregnant, you may not participate in this portion of treatment due to safety concerns.

At the specialty provider team's or PI's discretion, the treatment or protocol may vary to meet your needs (e.g., changing the order of the information given, having an additional session if feasible, etc.). Throughout the course of the study, you will be allowed to begin a new treatment(s), continue with current treatments, or make changes to your existing medical regimen.

b. **If you are in e-consultation**, the specialty provider team will review your medical record to create treatment recommendations. These treatment recommendations will be provided to you. The treatment recommendations will also be shared with your primary care provider. Treatment recommendations may include pain medication recommendations, health coaching with a local provider, and problem-solving treatment with a local provider. If your VA medical center does not have problem-solving treatment or health coaching available, we will recommend a similar treatment. If you are pregnant or plan to get pregnant, you may not receive pain medication recommendations due to safety concerns.

5. Follow-up questionnaires will be completed at two time points: at about 6-months and 9-months from when you complete the baseline questionnaire. These questionnaires are important because your responses on them help us to understand the effectiveness of the treatment being studied. You may complete these questionnaires over the phone with a member of our study team, on-line through the secure internet platform, or mail with a prepaid envelope we will provide to you. It will take approximately an hour to complete each follow-up packet. You are free to skip any questions that you would prefer not to answer.

6. A follow-up medical chart review will also be done to see if treatment recommendations were followed.

7. You may be invited to participate in an interview with a member of the study team. Approximately 40 participants may be asked to complete this interview. If you participate in the interview, you may not answer any questions that you would prefer not to answer. The interviews recordings may be recorded and transcribed by a VA-approved transcription company.

It is up to you to decide whether to take part in this study. Your participation in this study is voluntary; if you decide to take part, you may still withdraw at any time. If you do not wish to be in this study or leave the study early, you will not lose any benefits to which you are entitled. You can refuse to participate in any portion of the study and still take part in the rest of the study. For example, you may end treatment sessions, but continue completing the follow up questionniares.

If you don't take part, you can still receive all usual care that is available to you. Your decision not to take part will not affect the relationship you have with your doctor or other staff, and it will not affect the usual care that you receive as a patient.

If you decide to withdraw from the study prior to completion, data already collected prior to your withdrawal may still be reviewed and analyzed.

The Principal Investigator may stop you from taking part in the study at any time if she believes that it is in your best interest and/or the best interest of the study.

FUTURE USE OF DATA AND RE-CONTACT

With your permission, we would like your data or health information to be reused later for additional research purposes. If you agree, your data will be stored in a VA data repository, for future use. All the data in the repository will be coded and will reside on a secure server administered by the Information Resource Management (IRM). Future analysis of data stored within the data repository will only happen after further Institutional Review Board and/or other applicable approvals to ensure the protection of your individual privacy. **We will ask if you give your permission for Veterans Health Administration (VHA) to store your data collected from this study, including health information, in a research data repository.**

With your permission, we may also contact you in the future to invite you to take part in additional studies in the future. **We will ask if you give your permission for the Principal Investigator or a member of the study team to contact you to ask you to take part in additional studies in the future.**

ARE THERE ANY RISKS OR DISCOMFORTS?

Any procedure has possible risks and discomforts. The procedures in this study may cause all, some, or none of the risks or side effects listed.

1. Emotional Stress: It is possible that some participants could find some of the questions in the questionnaire packets or interview or treatment upsetting.

   If you are experiencing emotional distress you may contact the National VA CRISIS LINEby dialing 988 and then pressing 1 . Someone will be available to talk to you 24 hours a day, every day of the year.

   You may also call the NJ War Related Illness and Injury Study Center (WRIISC) and ask to speak with a mental health provider who is part of our study team at 1-800-248-8005. Mental health providers are typically (but not always) available Monday – Friday 8am to 4 pm eastern standard time.

2. Loss of Confidentiality: There is a risk that study information (data) could be connected to your name. This is called "loss of confidentiality." Data collected from the study, including audio recordings and transcriptions of sessions and interviews, will be maintained on the VA server with access limited to the study team. The methods and procedures used for data storage and security are consistent with those adopted by VA New Jersey Health Care System. If you complete your questionnaires online there are additional risks of loss of information. We are minimizing this risk by using a VA approved company that follows all the VA rules to keep your data secure. You may choose to complete your questionnaires on paper to reduce this risk.

3. Pain Medication Recommendations: All pain medications have potential risks. Any recommendations made by our specialty team provider will be reviewed and prescribed by your primary care provider. You should talk with your primary care provider about the risks of the medications they prescribe.

4. As part of Health Coaching and Problem-Solving Treatment, you will be encouraged to make changes to improve your health (e.g., increasing exercise, improving diet, practicing mindfulness). If and how you make these changes is your choice. There could be risks associated with any changes you make to your daily life. You should consult with your primary care provider or other medical provider to minimize any risks and address any concerns you may have about changes you may wish to make. We may also contact your health care provider.

5. There is always a chance that any procedure can harm you. The procedures in this study are no different. In addition to the risks described above, you may experience a previously unknown risk or side effect.

6. Risks of the usual care you receive are not risks of this study. Those risks are not included in this information sheet. You should talk with your health care providers if you have any questions about the risks of usual care.

ARE THERE ANY BENEFITS?

There may be no direct/personal benefits to you from your taking part in this research study. However, the information we get from this study might help us better understand how best to deliver care to Gulf War Veterans. It is possible you may experience a reduction in disability from your Gulf War Illness.

WHO WILL SEE MY INFORMATION AND HOW WILL IT BE PROTECTED?

The information collected for this study will be kept confidential.

1. Taking part in this study will involve collecting information, including private information about you. Private information may include the following: age, address, health information, (e.g., diagnoses, symptoms), treatment recommendations, your voice, and last four digits of your social security number. Data that will be collected include your answers from the paper questionnaires or from the answers you inputted into the online. Collected data will also include audio recordings and transcriptions from interviews and sessions with your specialty care team.

   If you decide to complete your questionnaires on the secure internet platform, your data will be temporarily stored on the secured internet platform server. This data will be identified only with your unique identification number, which you will be assigned. The data will be transmitted to us through encryption methods that are VA approved. This data will then be uploaded onto our secured shared network folder within the secure VA server.

   The methods and procedures used for data storage and security are consistent with those adopted by VA. This information will be protected in the following ways:

   - Data collected from the study will be maintained in a secured shared network folder within the secure VA server. Only members of the study team will have access to the shared network folder and its electronic files.
   - All paper copies will be kept in a locked cabinet in a locked office at one of the VA sites. Only members of the study team will have access to these cabinets.
   - All study information is coded with a “link” to the code. A “link” includes your name and the unique identification number. You will be assigned a unique identification number. The “link” will permanently reside in a password protected electronic file on the VA secure server. Only members of the study team will have access to this “link”.

2. Voice Recordings: A member of the study team may use a digital voice recorder or recorded directly onto the computer. We may record your sessions with the specialty care team and the interview, if you participate in these. The recordings may be used for data analysis. Recordings

will be downloaded and saved in a secured shared network folder within the secure VA server. If a digital voice recorder is used, after the audio recordings have been downloaded, they will then be deleted from the recorder. After the study is complete, the voice recordings will be stored on the shared network folder and then disposed of as per VA's policy. The recordings will be accessed only by the PI and members of the study team. **We will ask you if you verbally agree to the use of your voice as specified for the above-described purpose.**

3. Some of the data analysis will be completed by our collaborators including ENRM VAMC, Roudebush VAMC, VA NYHHCS, DeBakey VAMC, and Rutgers School of Public Health.

4. Audio recordings will be sent to an approved VA contract transcription service, for example the Centralized Transcription Services Program (CTSP), for transcription purposes. No identifiers will be transcribed, and you will be identified only by your Unique ID#.

5. We may include information about your study participation in your VA medical record; a note of consent will be placed in your electronic VA medical record.

6. There are times when we might have to show your records to people outside the research team. For example, someone from the Office of Human Research Protections, the Government Accountability Office, the Office of the Inspector General, the VA Office of Research Oversight, the VA Central IRB, our local Research and Development Committee, and other study monitors may look at or copy portions of records that identify you.

7. An exception to confidentiality is when the law mandates us to do so. Under the following circumstance we are required to break confidentiality and contact someone outside the treatment team:

    - If you are at risk to harm yourself or someone else
    - If a child or elder is at risk of harm or abuse

WILL I RECEIVE ANY PAYMENT IF I PARTICIPATE IN THIS STUDY?

You will be compensated for your participation in this study up to a total of $175 for completing and returning questionnaires as follows:

- Baseline questionnaire packet = $50
- 6 months after baseline questionnaire packet = $75
- 9 months after baseline questionnaire packet = $50
- You may or may not be asked to participate in a qualitative interview later. If you participate in this interview, you will be paid an additional $50

You will sign a voucher giving us permission to pay you. Due to limitations in the Financial Management System, payments made to you through Austin Financial Services Center generate

an Internal Revenue Service Form 1099 regardless of amount. You may mail to us the voucher with the completed questionnaires in the pre-paid envelopes provided. You should receive a check in approximately 6-8 weeks. If you are at the VA New Jersey Health Care System in person, you may receive cash.

WHO CAN I TALK TO ABOUT THE STUDY?

In the event of a research related injury, the VA will provide necessary medical treatment at no cost to you unless the injury is due to noncompliance with with study procedures or if the research is conducted by VA under contract with an individual or non-VA institution. If you should have a medical concern or get hurt or sick because of taking part in this study, please immediately contact:

- DURING THE DAY: Dr. Lisa McAndrew at 973-676-1000, dial 1+201167
- AFTER HOURS: VA New Jersey Health Care System Emergency Room at 973-395-7236 OR 973-676-1000, dial 1+201222
- VA Crisis Line: Phone:988 ; press 1. Available 24 hours a day, every day of the year.

If you have any other questions, comments or concerns about the research, call: Dr. Lisa McAndrew at 973-676-1000, dial 1+201167. You may also call the patient representative at 973-676-1000, dail 1+2169.

If you have questions about your rights as a study participant, or you want to make sure this is a valid VA study, you may contact the VA Central Institutional Review Board (IRB) toll free at 1-877-254-3130.