Information Sheet Template (Waiver of Documentation of Informed Consent)

VA Central IRB
VA Institutional Review Board for Multisite Studies

INFORMATION SHEET FOR LEVERAGING KNOWLEDGE OF CHRONIC MULTISYMPTOM ILLNESS (CMI) TO IMPROVE CARE FOR VETERANS POST-COVID

You are being asked to participate in a research study conducted by Veterans Affairs Health Services Research and Development (HSR&D). We are conducting a study to test if Concordant Care training for medical providers improves the health of Veterans with post-acute sequelae of COVID infection or "Long COVID." If you agree to participate in this study, we will ask you to complete a survey at two points about your experiences with your healthcare provider. 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.

WHY IS THIS STUDY BEING DONE?

Among patients with poorly understood medical conditions, our team has developed a provider communication approach that first validates the Veteran health experience, next, develops a shared understanding with the Veteran about the health concerns, and finally forms an action plan for managing the Veteran's health concerns. This is called Concordant Care. Preliminary data suggested that Veterans are more satisfied with their care when treated with Concordant Care. We don't know how well this approach helps improve care for Veterans with Long COVID. This study will help us adapt and examine Concordant Care among Veterans with Long COVID.

WHAT WILL HAPPEN IF I PARTICIPATE IN THIS STUDY?

Up to 240 veterans will participate in this study. This research study is expected to take about 4 years to complete. If you agree to participate, your participation in this study will last approximately 3 months and the following will occur:

1. You will review this information sheet. If you have questions please contact the study team at 973-676-1000, dial 201167.

2. 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.

3. Some Veterans in the study will receive a prompt to speak to their primary care provider about their Long COVID symptoms at an upcoming appointment.

4. A follow-up questionnaire will be completed at one point about 3-months from when you complete the baseline questionnaire. You may complete this questionnaire over the phone with a member of our study team, online through the secure internet platform, or mail it with a prepaid envelope we will provide to you. It will take approximately one hour

VA Central IRB
Effective Date: March 12, 2026

to complete each follow-up packet. You are free to skip any questions that you would prefer not to answer.

5. A follow-up medical chart review will also be done.

6. You may be invited to participate in an interview with a member of the study team. Approximately 10 participants may be asked to complete this interview. If you participate in the interview, you may decline to answer any questions that you would prefer not to answer. The interviews may be recorded and transcribed by a member of the study team.

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.

If you do not take part, you can still receive all the 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.

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 Distress: It is possible that some participants could find some of the questions in the questionnaire packets or interview upsetting.

   If you are experiencing emotional distress, you may contact the National VA CRISIS LINE at 1-800-273-8255 or 988 (Press 1). Someone will be available to talk to you 24 hours a day, every day of the year.

   For non-urgent distress, 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 8 am 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

VA Central IRB
Effective Date: March 12, 2026

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. 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 healthcare providers if you have any questions about the risks of your 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 veterans with Long COVID.

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 your social security number. Data that will be collected include your answers from the paper questionnaires or from the answers you inputted online. Collected data will also include audio recordings and transcriptions from interviews. If you enroll, data from screening will be used in data analysis.

   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 the unique identification number assigned to you. 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 (ID#). 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.”
   - This is a collaborative study being conducted at the VA New Jersey Health Care System, VA Portland Health Care System, VA Salt Lake City Health Care

VA Central IRB
Effective Date: March 12, 2026

System, Canandaigua VA, Michael E. DeBakey VA Medical Center, and Edith Nourse Rogers Memorial VA Medical Center. Study personnel at all sites may help with the study and have access to your data.

2. We may include information about your study participation in your VA medical record.

3. 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.

4. 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

5. Identifiers might be removed from the identifiable private information and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the participant or the legally authorized representative.

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 $225 for completing and returning questionnaires as follows and a possible interview:

- Baseline questionnaire packet = $75
- 3 months after baseline questionnaire packet = $100
- 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.

WHO CAN I TALK TO ABOUT THE STUDY?

In the event of a research related concern, the VA has resources available to you. If you should have a medical or other concern because of taking part in this study, please immediately contact:

- DURING THE DAY: Dr. Lisa McAndrew at 973-676-1000, dial 201167

VA Central IRB
Effective Date: March 12, 2026

- AFTER HOURS: VA New Jersey Health Care System Emergency Room at 973-395-7236 OR 973-676-1000, dial 201222
- VA Crisis Line: Phone: 800-273-8255 or 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 201167. You may also call the patient representative at 973-676-1000, dial 202169.

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.

VA Central IRB
Effective Date: March 12, 2026