Participant Name: _____ **Date**:_____

Title of Study: CSP #2028: Epidemiology, Immunology and Clinical Characteristics of COVID-19 (EPIC3) within the Veterans Health Administration

Site Principal Investigator: [INSERT SITE PI] **VA Facility:** [INSERT SITE NAME]

Principal Investigators for Multisite Study: Dr. Jennifer S. Lee, MD, PhD, Dr. Jennifer Ross, MD, MPH

KEY SUMMARY INFORMATION ABOUT THIS STUDY

You are being invited to take part in a research study that is being funded by the VA Cooperative Studies Program. 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.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this research is to gather information about the **S**evere **A**cute **R**espiratory **S**yndrome **Co**rona**v**irus **2** (SARS-CoV-2 or Coronavirus) infection and the disease the virus causes, **Co**rona**vi**rus **D**isease 20**19** (COVID-19) in people with and without the infection. By doing this study, we hope to learn new important information about SARS-CoV-2 infections and potentially severe outcomes of COVID-19, so that we can find better ways to manage and treat it in the future. We also hope to learn what makes some people more susceptible to infection so that we can help better inform Veterans on how to lessen their risk of infection.

This study consists of several required and optional components. Your direct participation in this research will last up to approximately 24 months.

We may collect the following types of information and samples from participants:

- Blood samples, saliva/spit, stool, and nasal, nasopharyngeal (NP), and oropharyngeal (OP) swabs
- Leftover samples such as blood, sputum/phlegm, saliva/spit, stool, urine, nasal, throat, pharyngeal, and rectal swabs, tissue(s), and cerebrospinal fluid (CSF), from other tests your doctor may order
- Genetic information from your samples
- Survey data, collected over the phone or in person
- Information from your medical records related to your health, including concurrent and past conditions, and medications

All data collected from participants will be stored in a data repository (long term storage and sharing of study data) and all biospecimens and related data will be stored in a biospecimen repository (long term storage and sharing of study biospecimens and related data).

There are two optional study components that you will be asked to opt in or opt out of:

1. Enroll in a participant registry so that we may contact you about future research; and
2. Provide permission for whole genome sequencing of information from your samples.

Participant Name: _____ **Date**:_____

Title of Study: CSP #2028: Epidemiology, Immunology and Clinical Characteristics of COVID-19 (EPIC3) within the Veterans Health Administration

Site Principal Investigator: [INSERT SITE PI] **VA Facility:** [INSERT SITE NAME]

Principal Investigator for Multisite Study: Dr. Jennifer S. Lee, MD, PhD, Dr. Jennifer Ross, MD, MPH

We are recruiting participants from 3 different settings: (1) inpatient setting; (2) outpatient setting (including the emergency department); and (3) VA Community Living Centers and other medium or long-term care facilities. We are recruiting participants who have been tested for COVID-19 and we are interested in enrolling those who test negative OR positive for COVID-19. We hope to recruit up to 9,000 total Veterans to participate in this study from several different VA medical centers across the United States.

This study does not involve treatment or the use of any investigational drugs or vaccines. You may still join a research study to receive an experimental drug or vaccine. If you join another VA study that involves treatment or the use of any investigational drugs or vaccines for SARS-CoV-2 or COVID-19, we will obtain related data from your medical records or will ask that the study share that data with us.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The most important reason for volunteering is to benefit Veterans and society as a whole. You will not benefit directly from being in this study. Your participation may benefit others in the future by contributing to the researchers' understanding of SARS-CoV-2 infections and potentially severe outcomes of COVID-19, so we can try to find better ways to manage and treat it in the future.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

This is not a treatment study, so you will not receive treatment. You may also not want to provide the samples or data being requested.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The persons in charge of the study are Dr. Jennifer S. Lee at the VA Palo Alto Healthcare System and Dr. Jennifer Ross at the VA Puget Sound Healthcare System. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study their contact information is:

Dr. Jennifer S. Lee, MD, PhD
Associate Chief of Staff, VA Palo Alto
Chief Medical Officer, VA Palo Alto CSPCC
Associate Professor of Medicine, Stanford Medicine
VA Palo Alto Bldg 101, B2 (Research Admin Office)
3801 Miranda Avenue
Palo Alto, CA 94304

Contact Number: (650) 493-5000

Dr. Jennifer M. Ross, MD, MPH
Acting Assistant Professor, International Clinical Research Center
Departments of Global Health and Medicine (Infectious Disease), University of Washington
Attending Physician, Seattle VA Medical Center
VA Puget Sound Bldg. 1, Room 219
1660 S. Columbian Way
Seattle, WA 98108
Contact Number; (206) 764-2128

[INSERT LSI CONTACT INFORMATION AS APPLICABLE]

DETAILED INFORMATION ABOUT THE STUDY

WHAT IS THE PURPOSE OF THIS STUDY?

COVID-19, the human disease caused by SARS-CoV-2 infection, has developed into a global pandemic. The clinical portrait of COVID-19 is not fully known yet but understanding the clinical course of infection is crucial to caring for Veterans with and without infection. The purpose of this research is to gather data to answer questions about SARS-CoV-2 (the virus) and COVID-19 (the disease caused by the virus) while also gathering clinical specimens for future study as questions emerge about this new pathogen.

HOW LONG WILL I BE IN THE STUDY?

This research study is expected to take approximately 5 years. Your direct participation in the project will last up to approximately 24 months. Participation in the data and biospecimen repositories will be indefinite. Participation in the registry, if you choose to participate, will also be indefinite.

WHAT WILL HAPPEN IF I TAKE PART IN THE STUDY?

In this study, for those with and without SARS-CoV-2 infection or COVID-19 disease, we will:

1. Ask you to complete the following questionnaires administered over the phone or in person. You can skip any question you do not want to answer. If you already agreed to this procedure earlier by telephone, we are asking you if we can deposit the baseline questionnaire data into the data repository (see procedure 7).

a. A one-time (baseline) questionnaire about socio-demographics, personal and family medical history, lifestyle factors, and COVID-19-pertinent exposures and potential risk factors (approximately 45 minutes).

b. A recurring symptom questionnaire about any signs and symptoms you may be experiencing, according to the questionnaire collection schedules described below (approximately 10 minutes).

c. A recurring vaccination questionnaire about SARS-CoV-2 vaccines you may have ever received, according to the questionnaire collection schedules described below (approximately 5 minutes).

d. A recurring long-term symptom questionnaire about general health and recovery status, according to the questionnaire collection schedules described below (approximately 10 minutes).

2. Collect clinical data from your medical records now and in the future for information related to this infection and concurrent and past conditions and medications. These include but are not limited to: vital signs; radiologic imaging of lung and other body sites; other clinical data about cardiopulmonary and infectious disease clinical status and clinical support required; treatments initiated on hospital admission; discharge diagnosis(es) and location after discharge and clinical follow-up plan. We will also collect information about whether you have sickle-cell anemia and your HIV/AIDS status. If you already agreed to this procedure earlier by telephone, we are asking you if we can deposit the clinical data into the data repository (see procedure 7).

3. Collect blood samples. The total amount of blood collected at one sitting will be up to 50mL (about 10 teaspoons). The total number of blood samples collected depends on the duration of your illness and the participant group in which you are enrolled. During the first 6 months that you participate in the study, no more than 500 mL (about 2-1/4 cups) total of blood will be collected. For comparison, a typical blood drive donation is 470 mL (about 2 cups) in one day. We will, as feasible, coordinate with your primary care provider the collection of blood during at the same time blood is drawn for your clinical care to minimize discomfort to you.

4. Collect saliva/spit, stool, and nasal, throat, and pharyngeal* swabs according to the biospecimen collection schedules described below.

*Pharyngeal swabs reach deeper than typical swabs of the nose and throat. Nasopharyngeal swabs involve swabbing the area of the nose that is at a depth equal to the distance from the nostrils to the outer opening of the ear. Oropharyngeal swabs involve swabbing areas of the tonsil and the back of the pharynx.

5. Collect leftover clinical samples such as blood, sputum/phlegm, saliva/spit, stool, urine, nasal, throat, pharyngeal, and rectal swabs, tissue(s), and CSF from other tests your doctor may order.

6. You have the option of self-collecting capillary blood spots and mini-vials as well as self-collected nasal swabs, saliva samples, and stool samples. You can either conduct the collection yourself or conduct the collection with guidance from study staff using VA-compliant methods (e.g. in-person or by telephone, VA Video Connect, etc.). The blood collection process involves finger or arm pricks and collection of blood with sponge heads or mini-vials*. These self-collecting kit takes very small amounts (less than1 milliliter) of capillary blood (from the tiny blood vessels just under your skin). The nasal swab involves swabbing the front of both of your nasal passages. The saliva sample involves collecting saliva into a tube. The stool collection process is what is usually done at home for clinical use (collecting a small sample when you go to the bathroom). If you are conducting self-collection at your home, the specimen collection kits will be sent to you, along with a pre-paid return envelope for returning the samples to the VA medical center by mail.

   *The device that collects a mini-vial of blood is the Tasso-SST kit. The Tasso-SST kit is an investigational blood collection device that has not been approved by the U.S. Food and Drug Administration (FDA) for clinical care. The VA Central IRB has determined that the Tasso-SST device can be used for research because it does not pose more than minimal risk to the participant.

7. Place all the data and biospecimens collected during the study into data and biospecimen repositories for future research.

8. (Optional) If you agree, we may contact you about future research by adding you to our participant registry.

9. (Optional) If you agree, we may conduct whole genome sequencing using your biospecimens.

Timing of symptom questionnaire and sample collections:

Note that the actual time points for all groups listed below may vary depending on how well you are feeling, if study staff are able to contact you, and other logistical matters (e.g., availability of supplies).

For all groups, it is possible that you may move into a different participant group at some point during the study. This consent form covers all study procedures in any of the 3 participant groups, for the length of time you are enrolled in the study, which will not exceed 24 months.

If you are enrolled as an Inpatient:

You will be asked to: complete the baseline, flu-related symptom, and vaccination questionnaires at time of enrollment, and complete the flu-related symptom, vaccination, and long-term symptom questionnaires, on days 3, 7, 14, 21, and 28, and at months 3, 6, 12, 18, and 24.

Sample collection times may vary depending on the type of sample being collected. Blood, saliva/spit, and stool will be collected on days 0, 3, 7, 14, 21, and 28 and at months 3, 6, 12, 18, and 24. Nasal or pharyngeal swabs will be collected on days 0, 3, 7, 14, 21, and 28. Whenever possible on or near these days, leftover clinical samples will also be used for this research study.

If you are enrolled as an Outpatient:

You will be asked to: complete the baseline, flu-related symptom, and vaccination questionnaires at time of enrollment, and complete the flu-related symptom, vaccination, and long-term symptom questionnaires, on days 3, 7, 14, 21, and 28, and at months 3, 6, 12, 18, and 24.

Sample collection times may vary depending on the type of sample being collected. Blood, saliva/spit, and stool will be collected on days 0, 3, 7, 14, 21, and 28, and at months 3, 6, 12, 18, and 24. Nasal or pharyngeal swabs will be collected on days 0, 3, 7, 14, 21, and 28. Whenever possible on or near these days, leftover clinical samples will be used for this research study.

If you are enrolled as a CLC resident:

You will be asked to: complete the baseline, flu-related symptom, and vaccination questionnaires at time of enrollment, and complete the flu-related symptom, vaccination, and long-term symptom questionnaires at months 3, 6, 9, 12, 15, 18, 21 and 24.

Blood will be collected on day 0, and at months 3, 6, 9, 12, 15, 18, 21 and 24.

WHAT IS EXPECTED OF ME IF I TAKE PART IN THIS STUDY?

If you decide to take part in the study, the following will be expected of you**:**

- Keep your study appointments. If you miss an appointment, please contact the investigator or research staff to reschedule as soon as you know you will miss the appointment.

- Complete your questionnaires as instructed.
- Provide biospecimens.
- Ask questions as you think of them.

You may be asked to complete and sign a VA Form FL10-212 which authorizes the study team to obtain your medical records from your non-VA healthcare provider(s).

WHAT POSSIBLE RISKS OR DISCOMFORTS MIGHT I HAVE IF I TAKE PART IN THIS STUDY?
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 below. Rare, unknown, or unexpected risks also may occur.

Being a part of this study means that more samples may be taken than are needed for normal care. Whenever possible these samples will be taken at the same time as clinical samples to reduce the extra procedures.

The blood collections at the VA will involve a needle stick which will cause a sharp, but quick, pain. There may be bruising at the site of the needle stick. The home collection involves a small skin puncture and collecting drops of blood that accumulate.

The nasal, throat, and pharyngeal swabs may be uncomfortable, but should not cause any lasting discomfort or bruising, though there is a slight chance of nose bleeds with aggressive swabbing.

You might find completing the questionnaires inconvenient or the questions personal.

If whole genome sequencing is done, there is a small chance that the results will show a genetic condition that could affect your future health. There is usually considerable uncertainty about the implications of any research DNA test result for individual health. For these reasons we would not attempt to identify you or inform you of any results from DNA testing.

Pregnant women can be a part of this study. There are no additional risks to pregnant women or their fetuses who are a part of this study.

Although every effort will be made to protect your research study records, there is always a small risk that unauthorized personnel could get access to the personal information in your medical records or other information researchers have stored about you.

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.

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

WHAT ARE THE POSSIBLE BENEFITS OF THIS STUDY?

You will not benefit directly from being in this study. Your participation may benefit others in the future by contributing to the researchers' understanding of SARS-CoV-2 infections and potentially severe outcomes of COVID-19, so we can try to find better ways to manage and treat it in the future.

HOW WILL MY PRIVATE INFORMATION BE PROTECTED?

Taking part in this study will involve collecting private information about you. This information will be protected in the following ways: All information about you will be handled in confidence and only the people responsible for your care, specimen processing, and who are working on this study will know that you were a part of the study. We will review your medical records and keep limited information about you on a secure file. All research information and samples will be labeled only with a study code so that they cannot be directly linked to you personally. Some samples may require special handling and testing because of the suspected SARS-CoV-2 infection.

These samples may be sent to an approved VA laboratory with appropriate biosafety capabilities with your information, but the identifying information will be removed as soon as possible and replaced with the study code for long term storage. Study personnel will have access to the key that links your personally identifiable information with this code.

Data will be stored and maintained on VA servers by research study staff. Only VA-approved staff will have access to the data and biospecimens.

By signing this consent document, you give your permission for information gained from your participation in this study to be published in medical literature, discussed for educational purposes, and used generally to further medical science. You will not be personally identified; all information will be presented as anonymous data.

Information about your participation in this study will be added to your medical record upon your enrollment into the study; this information may be accessed by the people responsible for your care such as your clinician. We may share personally identifiable information with the National Center for Health Statistics' National Death Index to obtain updated active statuses among registry members. We will also send de-identified study data (no individually identifiable information will be shared) to Leidos Biomedical so that they may improve the Flu-related symptom questionnaire.

There are times when we might have to show your records to other people. 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, US Treasury, VA Austin, and other study monitors may look at or copy portions of records that identify you.

A description of this study will be available on http://www.ClinicalTrials.gov. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

If you participate in the registry, we may use contracted organizations used for research recruitment and maintenance of registry contact information. Professional survey organizations or location specialists, that are used to search for updated contact information, already have access to and maintain computerized lists of millions of SSNs at their organizations. They use the SSN to link our information with their information. The lists they have may include your most recent addresses and telephone numbers. Many organizations use a professional survey organization to keep up with their members in this way, although they may not tell you about it. Professional survey organizations may also be used to administer telephone questionnaires or mailed surveys. We place very strict rules on how your SSN is used by these entities.

WHAT ARE THE COSTS TO ME IF I TAKE PART IN THIS STUDY?

You will not be charged for any treatments or procedures that are part of this study. If you usually pay co-payments for VA care and medications, you will still pay these co-payments for VA care and medications that are not part of this study.

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WILL I BE COMPENSATED FOR MY PARTICIPATION IN THIS STUDY?

Those agreeing to participate will be paid for completing study questionnaires and sample collections. The amount of compensation may vary based on the participant group in which you are enrolled, the course and duration of your illness, and how many follow up visits are completed.

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: 11/26/2021
Per PI/SC Amend 12
LSI Approval Date: N/A

LSI Verification Date: N/A

If you are enrolled as an Inpatient:
You will be paid $150 for all study procedures that occur during your time as an inpatient, through discharge from the hospital. After discharge, you will be paid $50 for each follow up visit. Depending on the length of your hospital stay, follow up visits can occur on days 3, 7, 14, 21 and 28 and at months 3, 6, 12, 18, and 24. The amount of compensation an Inpatient participant could receive ranges from $150 to $650.

If you are enrolled as an Outpatient:
You will be paid $100 for all study procedures that occur during your isolation period, which covers data collection for approximately 14 days, or until 7 days after the last COVID-19 associated symptom (whichever is longer). After isolation, you will be paid $50 for each follow up visit. Depending on the length of your isolation period, follow up visits can occur on days 3, 7, 14, 21, and 28 and at months 3, 6, 12, 18, and 24. The amount of compensation an Outpatient participant could receive ranges from $100 to $600.

***If you are enrolled as a CLC resident*:**
You will be paid $100 for all study procedures that occur during the baseline visit. You will be paid $50 for each follow up visit. Follow up visits can occur on months 3, 6, 9, 12, 15, 18, 21 and 24. The amount of compensation a CLC resident participant could receive ranges from $100 to $500.

[INSERT DESCRIPTION OF METHOD(S) OF PAYMENT AVAILABLE AT LOCAL SITE]. VA recordkeeping requires that you will receive an IRS Form 1099 for your payment, which will be subject to taxes and withholding.

You consent to the release of personally identifying information about you, such as your name, address, phone number, and SSN, to the [INSERT VA FACILITY NAME & OTHER AFFILIATE INSITUTIONS] and the VA Financial Services Center, located in Austin, Texas, so that they may provide compensation to you.

WHAT WILL HAPPEN IF I AM INJURED BECAUSE OF MY BEING IN THE STUDY?
If you are injured as a result of taking part in this study, the VA will provide necessary medical treatment at no cost to you unless the injury is due to non-compliance by a study participant with study procedures or if the research is conducted for VA under contract with an individual or non-VA institution.

No further compensation is available should an injury occur. You do not give up any legal rights or release the VA from any liability by signing this form.

If you should have a medical concern or get hurt or sick as a result of taking part in this study, call:

DURING REGULAR BUSINESS HOURS:

[INSERT SITE PI AND CONTACT INFORMATION/TELEPHONE #]

DO I HAVE TO TAKE PART IN THE STUDY?

The decision to participate in this study is completely voluntary on your part. Refusal to take part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue taking part at any time without any penalty or loss of benefits. You may withdraw and still receive the same standard of care that you would otherwise have received. If you do not provide your consent, we will not use your medical information.

If you decide to withdraw from this study, investigators may continue to review data which has already been collected prior to your withdrawal. We will not collect any further information, except from public records, such as survival data. Any specimens already used cannot be withdrawn.

WHO DO I CONTACT ABOUT THIS STUDY IF I HAVE QUESTIONS?

If you have questions, complaints, or concerns about the research or related matters, please contact the site investigator at [INSERT INFO], the site study staff [INSERT INFO], or the multi-site Principal Investigator [INSERT INFO], you may contact your VAMC's patient advocate at [INSERT SITE PT ADVOCATE INFORMATION].

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). This is the Board that is responsible for overseeing the safety of human participants in this study. You may call the VA Central IRB toll free at 1-877-254-3130 if you have questions, complaints or concerns about the study or if you would like to obtain information or offer input.

DOES THIS STUDY INVOLVE GENETIC RESEARCH AND HOW WILL MY GENETIC INFORMATION BE PROTECTED?

This study or future research may include genetic testing and whole genome sequencing (optional). Genetic information can be used to understand how inherited factors influence who gets sick and how sick one becomes.

Genetic testing means researchers: 1. may look at a single gene (short lengths of DNA) to identify variations or mutations that lead to a genetic disorder; 2. may look at an entire chromosome (much

longer lengths of DNA that may include many genes), to see if there are large genetic changes (like an extra chromosome) that cause a genetic condition; or 3. may look at the amount or activity level of proteins (proteins encoded by DNA) that can indicate changes to the DNA itself that result in a genetic disorder.

If you agree, we may also conduct whole genome sequencing using your biospecimens. Whole genome sequencing looks at all of a person's genes (DNA). It is mostly used for research purposes but may increasingly be used to guide clinical care by predicting disease susceptibility and drug responses.

Federal laws and policies provide you with protection from discrimination by health insurance companies, group health plans, and most employers based on your genetic information. A federal law called the Genetic Information Nondiscrimination Act (GINA) generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information obtained from this study.
- Health insurance companies and group health plans may not use your genetic information obtained from this study when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information obtained from this study when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. It also does not prohibit discrimination on the basis of already known genetic disease.

FUTURE USE OF DATA AND BIOSPECIMENS

By enrolling in this study, you are agreeing to the storage, sharing, and use of your biological specimens and research data for future use in research studies related to this new infection and other health conditions. Researchers or laboratories that access your biological specimens and data for future research use may be national or international and affiliated or unaffiliated with the VA.

Specimens will not be used for commercial purposes. Your biospecimen and any data that are produced from your biospecimen will be used for research purposes only. An IRB will review any future research proposals and help researchers determine if results should be shared. If so, you would be contacted to see if you wanted to know your results. If there are future plans to share research information generated from your biospecimen with you, we will only do so with your permission.

Future studies will also need to be reviewed and approved by an IRB and other oversight committees.

TISSUE BANKING

We will use the biologic specimens to look at how the body fights infections and how different treatments work in the body of those with and without SARS-CoV-2 infection. These tests will be conducted at a protocol-approved research laboratory, following applicable enhanced precaution standard operating procedures (SOPs). All specimens collected for this study will be handled and banked in accordance with federal regulations.

The storage (bank) area will be maintained at a VA approved biospecimen repository and any approved laboratory with an appropriate biosafety level and enhanced precaution SOPs. Identifiers will be removed from the biospecimens before they are used for future research studies or distributed to another investigator for future research studies.

We will also use the specimens to analyze your DNA to see how your immune system is able to fight the infection, if you have the infection. If you do not have the infection, we will try to find out what makes some people more susceptible to infection. Since storage (banking) of tissues, organs and other biologic specimens for future genetic testing is still undergoing development, the risks of genetic testing are unknown.

You have the right to withdraw your consent in the future and have your specimen(s) destroyed. In this case, you would need to notify the investigator of your decision. If you decide to withdraw your consent after identifiers have been removed from your specimen(s), you will not be able to withdraw your specimen(s) because they cannot be linked back to you.

CERTIFICATE OF CONFIDENTIALITY

We have obtained a Certificate of Confidentiality from the Federal Government. This helps protect your privacy by allowing us to refuse to release your name or other information outside of the research study, even by a court order. The Certificate of Confidentiality will not be used to prevent disclosures to local authorities of child abuse or neglect, or harm to self or others. The Certificate does not prevent you or a member of your family from releasing data about yourself or your involvement in this study.

Participant Name: _____ **Date**:_____

Title of Study: CSP #2028: Epidemiology, Immunology and Clinical Characteristics of COVID-19 (EPIC3) within the Veterans Health Administration

Site Principal Investigator: [INSERT SITE PI] **VA Facility:** [INSERT SITE NAME]

Principal Investigator for Multisite Study: Dr. Jennifer S. Lee, MD, PhD, Dr. Jennifer Ross, MD, MPH

FUTURE CONTACT (OPTIONAL)

Please read each sentence below, think about your choice, and mark "**YES**" or "**NO**". **No matter what you decide to do, your decision will not affect your medical care or your participation in the study already described.**

May the study contact you for future research?

☐ **YES** The study may contact me about future research by adding me to the registry.

☐ **NO** The study may not contact me about future research by adding me to the registry.

You have the right to withdraw your permission allowing future contact at any time. If you want to stop allowing the use of your contact information, please call the study team at 1-800- [INSERT PHONE NUMBER] to let us know.

FUTURE WHOLE GENOME SEQUENCING (OPTIONAL)

Please read each sentence below, think about your choice, and mark "**YES**" or "**NO**". **No matter what you decide to do, your decision will not affect your medical care or your participation in the study already described.**

May the study conduct future whole genome sequencing?

☐ **YES** The study may use my biospecimen(s) for whole genome sequencing.

☐ **NO** The study may not use my biospecimens for whole genome sequencing.

You have the right to withdraw your permission allowing future whole genome sequencing at any time. If you want to stop allowing the use of your biospecimens for whole genome sequencing, please call the study team at 1-800- [INSERT PHONE NUMBER] to let us know.

AGREEMENT TO PARTICIPATE IN THE RESEARCH STUDY

A research staff member has explained the research study to you. You have been told of the risks or discomforts and possible benefits of the study. You have been given the chance to ask questions and obtain answers.

FOR VA CENTRAL IRB USE ONLY

PI/SC Approval Date: **11/26/2021**
Per PI/SC Amend 12
LSI Approval Date: **N/A**

LSI Verification Date: **N/A**

Participant Name: _____ **Date**:_____

Title of Study: CSP #2028: Epidemiology, Immunology and Clinical Characteristics of COVID-19 (EPIC3) within the Veterans Health Administration

Site Principal Investigator: [INSERT SITE PI] **VA Facility:** [INSERT SITE NAME]

Principal Investigator for Multisite Study: Dr. Jennifer S. Lee, MD, PhD, Dr. Jennifer Ross, MD, MPH

By signing this document below, you voluntarily consent to participate in this study. You also confirm that you have read this consent, or it has been read to you. You will receive a copy of this consent after you sign it.

I agree to participate in this research study as has been explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date

The participant is unable to give informed consent. I, as the legally authorized representative of the participant, give consent for their participation in this study.		
_____ Name of Legally Authorized Representative	_____ Signature of Legally Authorized Representative	_____ Date

Indicate below your authority to act as the participant's legally authorized representative:

- ☐ Spouse
- ☐ Parent
- ☐ Adult Child (18 years of age or over) for his or her parent
- ☐ Adult Sibling (18 years of age or over)
- ☐ Grandparent
- ☐ Adult Grandchild
- ☐ Guardian appointed to make medical decisions for individuals who are incapacitated
- ☐ Other per local or state law

Specify: _____

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PI/SC Approval Date: **11/26/2021**
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LSI Verification Date: **N/A**