Consent and Authorization Document

Research Study Title: Research on the Epidemiology of COVID-19 in Essential Response Personnel (RECOVER) Study

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Background: You are being asked to be in a research study conducted by the University of Utah. This study is being done to help understand the risks of infection and the immune response against SARS-CoV-2, the virus that causes COVID-19.

If you decide to join this study,

1. You will be asked to fill out surveys about your work and health, collect nasal swab and/or saliva samples, and give blood samples a few times each year.
2. You will be asked to allow us access to your health record at University of Utah.
3. The most common risk of joining is brief pain and bruising when you give your blood sample.
4. We will do everything we can to protect your privacy. But there is still a very small chance that an unauthorized person could access your information.
5. You may benefit by knowing the results of frequent COVID-19 testing. You are also contributing to help researchers understand the risks of SARS-CoV-2 infection and the progress of the illness.
6. Being in this study is completely voluntary. You can withdraw (quit) at any time.

This is a consent form. It tells you important information about a research study to help you decide whether or not you would like to take part in the study. Please read this form carefully before agreeing to participate. A member of our study team will also talk to you about this study. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part. For you to be in the study, you must provide your consent. We will also give you a copy of this form to keep.

COVID-19: Coronavirus disease 2019 (COVID-19) is the name of the illness caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Common COVID-19 symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, sore throat, and new loss of taste or smell. COVID-19 symptoms may range from mild to very severe, and some people may have no signs or symptoms at all. Older adults and people of any age who have underlying chronic medical conditions might be at higher risk for severe illness from COVID-19.

Purpose: We are asking people who work as essential responders, including healthcare and health facility workers, emergency first responders, and other frontline workers to be in a research study to learn more about COVID-19. The purpose of this study is to learn the following:

- How many people get sick with COVID-19
- What symptoms are common if they have COVID-19
- How long it takes to recover from COVID-19
- How many people become infected with SARS-CoV-2 but do not become sick

- How well people are protected from getting COVID-19 again after having it once
- If and when a vaccine becomes available, how well it protects people from infection

Procedure: The study is being done by the University of Utah in collaboration with the Centers for Disease Control and Prevention (CDC) and Abt Associates Inc. Different healthcare centers and universities across the United States will help with this CDC-funded study.

Up to 550 essential responders in Utah will participate in this study. Up to 3,000 adults across the country age 18 and over will be asked to take part in this study.

This study is expected to last for two years. If you choose to take part this study, we will ask you to do these steps each year:

Planned Surveys: Enrollment and Quarterly
When you enroll, we will send you an online survey with questions about yourself, your work, and your health. The first survey should take about 15 minutes. About every 3 to 4 months, we will ask about changes in your work and health and about important questions related to the pandemic. For example, we will ask for your opinion about the COVID-19 vaccine before and after it becomes available. Each follow up survey should take about 10 minutes, but may vary. Answers are entered into a secure electronic database. If we do not receive your survey, we will follow-up by phone. Your answers to survey questions will be kept confidential. Your employer will not have access to your answers.

Weekly Checks for COVID-19 Symptoms
Once per week, we will send you a text message to ask if you have had any symptoms develop that may be related to COVID-19. We will follow-up by text and phone if we are unable to get a reply.

Nasal Swab or Saliva Sample Collection
Once per week, at the same time as the symptom reporting, we will ask you to collect a nasal swab or saliva sample from yourself. A courier will collect the sample from your home or workplace and send it to a CDC-designated laboratory. You also have the option to bring it to a designated FedEx drop off site. During the study year, the type of sample may change as we learn better or easier ways to collect samples.

If you develop COVID-19 symptoms such as cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, sore throat and new loss of taste or smell, we ask that you contact study staff right away and collect a sample. We ask that you collect a sample whether or not you have already collected your weekly sample. To help us learn the best way to test for SARS-CoV-2, we may ask for more than one sample type, such as an extra nasal swab and a saliva sample. Please note, collecting these samples does not replace medical care, and you should seek medical attention if you need it.

When you join the study, you will be given self-swabbing kits and instructions for how to collect, store and send the sample or have it ready for courier pick up.

Please note that if you are found to have an infection, even if you don't have symptoms, you will be asked to follow your institution's policy for COVID-19 infection including staying home from work for the recommended time. We will also follow the rules and guidance of your local public health authority. If

they require that SARS-CoV-2 test results and your contact information must be reported, we will do so and notify you of this.

Illness Surveys
If you become sick with COVID-19 symptoms during the study, we will contact you to respond online, text, or by telephone to questions about your illness. In your weekly text message, we will ask if you are still sick. In about a week after your illness begins, we will send you a text or a link to an online survey with questions about your illness at that time. If your illness requires hospitalization, we will contact you or your primary emergency contact if you cannot be reached. After your illness is over, we will send you a link to an online survey with questions about your illness including any medical visits, days of work missed, and use of medications. Answers are entered into a secure electronic database. Your answers to survey questions will be kept completely confidential. Your employer will not have access to your answers.

Blood Sample Collection
We will collect a 20 ml (about 4 teaspoons) blood sample from you every three months until the study end. This will tell us if you were infected with SARS-CoV-2, even if you had no symptoms or the virus was not found in your swab samples.
If you develop a SARS-CoV-2 infection, we will collect a blood sample at approximately 4-weeks after symptom onset. If you receive a vaccine for COVID-19 during the study, we will now ask to collect a 20 ml (about 4 teaspoons) blood sample approximately four weeks after each vaccination dose. If one of these extra blood collections occurs, the next planned blood sample collection will then be changed to occur about 3 months after the illness sample. We will schedule a time for you to come to the University of Utah to collect the blood samples.

Medical Records
Study staff will look at your relevant medical records at the University of Utah or other Utah health care systemsto learn more about your health, your medical history, and medical visits that may be related to COVID-19 or influenza during the study period. Examples include: diagnoses for chronic medical conditions, vaccine and billing records, doctor visits for respiratory illnesses, treatment you received, and medications you may be taking. We will also collect sensitive information that may impact the severity of symptoms in those who contract COVID-19, such as HIV status, alcohol use/abuse, and drug use/abuse. We will enter the information into a secure computer database. Your employer will not have access to information we collect from your medical history or medical visits during the study. We will not be able to see all the information in your EHR. We will use a computer program to find only the data that we need for the study.

Notes from counselors or doctors in specialized clinics who treat mental health conditions or substance use disorders are usually private and not part of the EHR. We will only be able to see these types of notes if they are part of your EHR.

Giving access to your health information is voluntary. You get to choose. No matter what you decide, now or in the future, it will not affect your medical care. You can change your mind at any time in the future. However, if you choose not to give us access to your health information now, we will not be able to enroll you in the research study.

Notify Study Staff of COVID Vaccination
We are asking participants who receive a COVID-19 vaccine to contact the study staff at (385) 399-0295 or RECOVER@utah.edu with the date you were vaccinated and details about the vaccine by sending a photo or copy of the face sheet, vaccine box, or vaccination record. When a vaccine becomes available to your occupational group and geographic area, if you have not previously notified us that you have been vaccinated, we will send a short survey to ask if you have been vaccinated or when/if you intend to. Answers to all surveys are entered into a secure electronic database. If we do not receive your survey or been notified previously that you have received your vaccination, we may follow-up by phone. Your answers to survey questions will be kept confidential. Your employer will not have access to your answers.

Vaccination verification
If a COVID-19 vaccine should become available during the study period and you are vaccinated at University of Utah or one of our clinics, we will look into our records to confirm your vaccination status. We will also verify prior to influenza vaccination. If a COVID-19 vaccine should become available during the study period and you are vaccinated outside the University of Utah health system, we will check with other Utah health systems, Utah Department of Health, and/or state vaccine registries. We will also verify prior influenza vaccination.

Other Clinical Trials
Enrollment in preventive treatment or vaccination programs may impact some of our study goals to understand how many people get SARS-CoV-2 infections and symptoms. In the future, if you are offered and decide to join a new trial of investigational COVID-19 vaccines or drugs that may prevent infection, we ask that you contact the study staff to withdraw from this study. If you choose not to take part in the study, it will not affect your job/employment or the care you receive at University of Utah or at any other medical provider.

Sample Usage
Nasal swab or saliva samples. Your samples will be sent to the Marshfield Clinic Research Lab to find out if you have been infected with SARS-CoV-2 and/or influenza. If your sample confirms SARS-CoV-2 infection, we may do more tests on your sample. Please note, this test is not meant to take the place of any tests that your provider may order as part of your medical care. The results from the research test will not affect your medical care. The test results will be shared with you and the research study staff. We will follow your institution's and local public health authority's rules and guidelines for reporting COVID-19 test results.

Blood samples. Your blood samples will be sent to the CDC and/or a CDC-designated research labs and will be tested for proteins in the blood called antibodies. More than one type of test for antibodies may be used. The first type of test we will use on all blood samples tells us if you were infected with SARS-CoV-2 , even if you had no symptoms. The test results will be shared with study investigators but are for research purposes and may not be available for a long time. We will share your test results with you when/if they are provided to us by the CDC.

An additional antibody test may be used to determine how well your immune system responds if you were infected or vaccinated. Your blood samples may also be tested for concentrations of per- and polyflouroalkyl substances (PFAS), chemical contaminants that are widespread in the general population

of the United States and which might impact how well your immune system responds if you were infected with SARS-CoV-2. These test results will be shared with study investigators, but the tests we will use are for research purposes only. This means we are not currently allowed to share your results back to you. If this changes during the study period, you may receive results from your antibody testing at that time.

Future Sample Usage

If there are leftover nasal/saliva samples collected to test for COVID-19 or serum samples collected to test for the presence of antibodies to SARS-Co-V-2 that the researchers do not need for this study, we plan to store them for future testing by CDC or a CDC-designated research partner to discover new ways to identify other respiratory infections and evaluate the body's immune response to respiratory infections with your consent. This sample bank with be managed by the CDC. Your research samples may also be shared with other research institutions to test for other respiratory infections and evaluate the body's immune response to respiratory infections. If we do, we will not include any information that could identify you. Sample banking is voluntary and will not affect compensation for participation in this study. Any results from future research will not be reported back to you due to identifying your information with the samples.

Tissue or blood samples obtained from you in this research may help in the development of a commercial product by the University of Utah, CDC or its research partners. There are no plans to provide financial compensation to you should this occur.

☐ I agree with the future use of the remaining samples.
☐ I do not agree. After the completion of this study, I would like the remaining sample to be destroyed.

If you choose to withdraw consent to sample banking please contact the research team at RECOVER@utah.edu.

Risks: We expect the risks for being in this study to be small. Getting blood drawn may cause minor pain when the needle is inserted, very occasionally fainting, and some possible bruising afterward.

Although all information on you, your health, samples you provide, and testing results will be kept in a secured data base, there is a risk that an unauthorized person could get access to this data. We believe the chance this will happen is very small and we will do everything we can to protect your privacy. We have protections in place to safeguard your identity and health information.
Your employer may also have rules that require you to notify them if you become aware that you tested positive for Covid-19, and may require you to take time off which may impact your income, sick time/paid time off bank. We will not notify your employer, but you should check with your organizational rules related to this.

There may also be other risks that we currently do not know about. We will tell you about any new information that may affect your health, welfare, or choice to stay in this research study.

Benefits: You may benefit by knowing if you test positive for COVID-19 on your weekly sample. You may use this information to protect other people from getting infected. Please note that you may not know the results for a week or more. Although the molecular tests for COVID-19 used in this study are highly accurate, they are not perfect. It is unlikely, but a negative test result can occur even if you are infected. In addition, a negative test result will not tell you if you have been infected in the days since you collected your sample.

Your participation in this study also has a chance to teach us a lot about COVID-19 and SARS-CoV-2. If so, that could benefit you, or someone you know, in the future.

Alternative: The alternative is not to participate in this study.

Contact: If you have questions, complaints or concerns about this study, you can contact Dr. Sarang Yoon at (385) 399-0295. If you think you may have been injured from being in this study, please call Dr. Sarang Yoon at (385) 399-0295. Dr. Yoon or one of her colleagues can be reached at this number Monday through Friday during normal working hours.

Institutional Review Board: Contact the Institutional Review Board (IRB) if you have questions regarding your rights as a research participant. Also, contact the IRB if you have questions, complaints or concerns which you do not feel you can discuss with the investigator. The University of Utah IRB may be reached by phone at (801) 581-3655 or by e-mail at irb@hsc.utah.edu.

Research Participant Advocate: You may also contact the Research Participant Advocate (RPA) by phone at (801) 581-3803 or by email at participant.advocate@hsc.utah.edu.

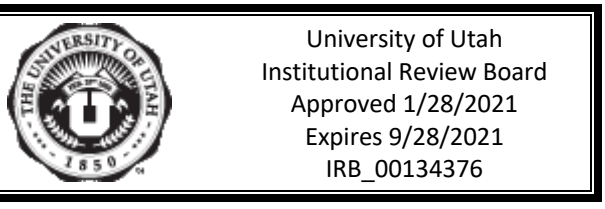
Discontinuation: Being in this study is completely voluntary, meaning you can choose whether or not you want to be a part of it. If you choose not to take part in the study, it will not affect your job/employment or the care you receive at the University of Utah or at any other medical provider. Even if you do take part in the study, you can quit at any time. You are free to withdraw consent and stop being part in this study at any time without providing a reason.

Costs: There is no cost to you or your insurance for taking part in this study. You may incur charges from your cell phone service provider for message/data rates that apply to messages sent for this study.

Compensation: Up to $400.00.

$75 will be given if you complete the total swab series.
$15 will be given if you complete the acute illness swab series.
$20 will be given per blood draw (every 3 months).
$50 will be given per convalescent COVID-19 blood draw.
$50 will be given per convalescent influenza blood draw.
$50 will be given per post-vaccine blood draw (up to 2 times).
$25 per referral with up to two referrals (only those that end up eligible and participating in the study).

Payments will likely be disbursed on a quarterly basis.



Funding: Funding for this study has been provided by Centers for Disease Control and Prevention and Abt Associates Inc.

New Findings: During the course of the study, we may find new information that could be important to you. This includes information that may cause you to change your mind about being part of the study. We will notify you if any significant new information becomes available which may affect your health, safety, or willingness to continue in this study.

AUTHORIZATION FOR USE OF YOUR PROTECTED HEALTH INFORMATION

The information collected from your medical record and that you provide in the online/paper surveys or interviews, emails and phone calls will be part of study data shared with research partners at the Centers for Disease Control and Prevention, Abt Associates, and Marshfield Clinic Research Lab. These organizations will be involved in data collection and management for the study. We will not disclose any information that could identify you, such as your name, telephone number or email, with any other party for any other purpose without your permission.

People inside and outside of the University of Utah may need to see your information for this study. The researchers in this study will be looking at your personal health information and will need to disclose it to our research partners (Abt Associates, Marshfield Laboratory, CDC) for the purposes of lab testing, data analysis, and preparing articles for publication.

We will also follow the rules and guidance of your state public health authority. If they require that SARS-CoV-2 test results and your contact information must be reported to the state public health authority, we will do so and notify you of this. The state public health authority requires us to report all test results to them. The test results will be uploaded to the state public health system. Your information will be kept confidential. While we cannot disclose a positive test to your employer, we do encourage you to follow the employee health guidelines about reporting a positive test and taking the steps appropriate to prevent passing the virus to co-workers and patients.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

However, you or the researcher may choose to voluntarily disclose the protected information under certain circumstances. For example, we may disclose medical information in cases of medical necessity, or take steps (including notifying authorities) to protect you or someone else from serious harm, including child or elder abuse. Additionally, if you request the release of information about you in writing (through, for example, a written request to release medical records to an insurance company), the Certificate does not protect against that voluntary disclosure. This certificate does not prevent the researchers from releasing information about you to prevent serious harm to you or someone else. Moreover, federal agencies may review our records under limited circumstances, such as a Department of Health and Human Services request for information for an audit or program evaluation [or as required by the Food and Drug Administration].

By agreeing to participate in the study, you also grant permission to researchers at the University of Utah to use and/or disclose (release) your health information for the purpose of this research.

We will collect individually identifiable health information about you for the purpose of this research. This includes information we will get from:

- Study visits
- Your responses to study surveys or questionnaires
- Testing your blood and nasal swabs
- Your electronic health record (EHR)

The University of Utah researchers will use your health information to conduct the research study named above. Others at the University of Utah may access your health information to help coordinate or oversee the research. This may include employees of any of the organizations that make up the University of Utah.

We may disclose (release) the health information described above to others outside of The University of Utah who are involved in conducting or overseeing research, including:

- Research collaborators
- Data coordinating centers
- The study sponsor
- Sponsor representatives and vendors
- Government oversight agencies, such as the Office for Human Research Protections or the Food and Drug Administration

The University of Utah research staff may request records, such as information related to hospitalizations and care received outside of the University of Utah, for eligibility, safety, and/or recruitment purposes. The University of Utah research staff may also disclose (release) the health information listed above to an outside provider to coordinate management of your care.

State and federal privacy laws protect your health information. We will do our best to protect your confidentiality by using standard security measures as required by law. We will also remove or separate information that identifies you (such as your name or address) from the rest of your health information whenever possible. Everyone with access to your information has received training in the protection of sensitive information. Still, there is a small chance your information could be released accidentally. There are also certain situations where we may be required by law to release your information. Once your information has been given to others, it may no longer be protected by state or federal privacy laws. It will be protected by other rules and agreements with the recipients. However, there is still a risk that a recipient could share your information without your permission.

The University of Utah may also use and disclose your information to other researchers, including researchers outside The University of Utah, for future research purposes. These may include left-over blood specimens which will be stored in a CDC-designated laboratory in case future testing related to immune responses to flu and other respiratory viruses or potential pathogens is needed. Future testing will not include genetic testing.

You are free to withdraw your consent or stop being a part of this study at any time. The decision will not affect in any way your current or future medical care or your employment. The investigator may stop you from taking part in this study if they decide it is in your best interest or if you do not follow study instructions.

If you decide you want to stop sharing your health information for this study, you need to tell us in writing. You can tell us by writing to:

Dr. Sarang Yoon
375 Chipeta Way, Suite A
Salt Lake City, UT 84108

When we receive your request, we will stop using and disclosing (releasing) your health information. We may continue to use information we collected before we received your request. If we have already disclosed (released) your information to someone else, we will probably not be able to get it back.

To protect your confidentiality, we will use a study assigned identification number instead of your personal information on study forms whenever possible. We will store your data in locked files and secured computers on the internal site networks. If information from this study is presented publicly or published in a medical journal, you will not be identified by name or by any other personally identifiable information. Your information will be summarized with information from many other people and will not be linked to you personally.

AUTHORIZATION

What if I decide to Not Participate after I sign the Consent and Authorization Form?

If at any point you not do want to participate and you do not want us to use your health information please let us know. You can contact us over the phone or you can tell us in writing. You will be withdrawn from the research study. If you change your mind, we will not be able to collect new information about you. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

This authorization does not have an expiration date.

CONSENT

Thank you for taking the time to consider being in our study and for reviewing the consent form.

If after reviewing the consent you agree to participate in the study and allow us to use the information we collect from you and your medical record, and agree for us to share it with our study collaborators for the conduct of this study, we will just ask you to verbally acknowledge that you have read this consent form, had all of your questions answered, and freely agree to participate in this research project:

I confirm that I have read this consent and authorization document and have had the opportunity to ask questions. I give permission to be contacted in the future for research purposes. I agree to take part in this research study and authorize you to use and disclose health information about me for this study, as you have explained in this document.

Electronic signature of person obtaining consent	**Date**