CoV-PICS Telephone Consent

Hello_____,

My name is **[insert name]** from Barnes-Jewish Hospital at Washington University in St. Louis-School of Medicine. I received your name and telephone number from Barnes-Jewish Hospital.

This is a research study conducted by Dr. Chris Palmer, a physician in the Barnes-Jewish Hospital Intensive Care Unit. We are inviting you to participate in this research study because you Tested positive for COVID-19 and were admitted to the ICU for your care.

The purpose of this study is to determine if virtual patient visits, such as a phone call or video visit, could replace an in-person visit when caring for patients who may be experiencing symptoms related topost-intensive care syndrome. This syndrome may present health problems that remain after critical illness. They may present when the patient is in the intensive care unit or after the patient returns home. These problems can involve the patient's body, thoughts, feelings or mind. They may show up as weakness, problems with thinking, problems falling or staying asleep or nightmares, or feeling depressed or anxious.

The current study focuses on the ability of you to communicate information about your symptoms to your caregivers; and the ability of the caregivers to interpret the information you provide without ever meeting in-person. All appointments will be done virtually. Suggestions for care to address any symptoms you may be having will be shared with you and your primary care physician, if you so desire. Because this research is being done only to determine the feasibility of using a virtual clinic to provide care to patients similar to you, the clinicians will not be allowed to order labs, make referrals or prescribe any treatments. This will need to be done by your primary care physician.

You should carefully consider the information we are providing and discuss it with the research team. You should understand why you might want to participate, or why you might not want to participate. You may choose to participate or not. Your participation in this study will be completely voluntary and will not impact your medical care in any way.

Under certain circumstances, the investigator might decide to end your participation in this research study earlier than planned. This might happen for no reason or because in our judgment it would not be in your best interest you to continue.

If you agree to take part in this study, your involvement will last for approximately 6 months, during the time you are having your ICU follow-up appointments conducted via a video call, rather than an in-person visit at the Washington University School of Medicine campus.

As part of this research study, the research team will access your medical record. Your medical record contains private, protected health information, which is information that can personally identify you. Specifically, we will access/use information such as your name, date of birth, diagnosis, your hospital stay and your hospital discharge instructions. We will also collect information about your participation in the virtual clinic including questionnaires you will complete as part of your care.

We will ask you to perform two tests of your physical strength. These two tests are optional and will be performed under the visual guidance of a physical or occupational therapist. One will assess your ability to sit and stand out of a chair 5 times. The second will involve you standing next to a wall, stepping in place while raising your knees to a certain height. The therapist will measure the number of times you can do this in two minutes. This is called a two minute step test.

You will also be asked to complete surveys about any symptoms related to your stay in the intensive care unit you may be experiencing such as memory loss, decreased strength and ability to perform physical tasks, changes in your mood, and changes in your diet. Your answers will help the clinicians form suggestions for future treatment that will be shared with you and your primary care physician. . You are free to skip any questions that you prefer not to answer.

At the end of your study period, you will be asked how you liked having your follow-up care being provided with a video conference rather than having several in-person visits with your various providers.

We would like to use the data we are obtaining in this study for studies going on right now as well as studies that are conducted in the future. These studies may provide additional information that will be helpful in understanding the effects of conducting post-ICU care during a video call rather than through several in person visits with each specialized provider. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data you give up any property rights you may have in the data.

We will share your data with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These researchers may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

Your data will be stored without your name or any other kind of link that would enable us to identify which data are yours. Therefore, it will be available for use in future research studies indefinitely and cannot be removed.

Identifiers may be removed from your private information your medical record data and information we collect from you during this study and used for future research or shared with others. If this occurs, we will not ask you for additional consent.

Approximately 80 people will take part in this study.

You will not have any cost for being in this study and you will not be paid. You and/or your medical/hospital insurance provider will remain responsible for your regular medical care expenses.

You will not benefit personally. We hope that, in the future, other people might benefit from this study because we will be able to compare the characteristics of the symptoms found in patients with COVID-19 with those who have not been told they have COVID-19.

The risks of doing the optional sit/stand test and two minute step test include feeling short of breath, feeling unsteady, or possibly falling. If you do not feel you could safely perform these tasks by yourself without assistance, let the physical or occupational therapist know before the tests are started, so that the tests are not performed.

Another risk of participating in this study is that confidential information about you may be accidentally disclosed. We will keep the information you provide confidential by directly entered the information you provide into a secured database. We will keep all electronic documents on secured servers that are password protected and have various state of the art firewall protections withy frequent upgrades of these protections. Access to these electronic research files will be restricted to members of the research team and will be controlled by the principal investigator. Any report or article that we write will not include information that can directly identify you. However, federal regulatory agencies and Washington University, including the Washington University Institutional Review Board (a committee that reviews and approves research studies) and the Human Research Protection Office may inspect and copy records pertaining to this research activity.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

As part of this study we will generate Protected Health Information, or PHI. PHI is health information that identifies you and is protected by law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this study you must give the research team permission to use and disclose your PHI as explained earlier in our conversation. The research team will follow state and federal laws and it is possible that other people may become aware of your participation in this study and may inspect records pertaining to the research. This could include university representatives, to complete university responsibilities, and government

representatives (including the Office for Human Research Protections and the Food and Drug Administration), to complete federal or state responsibilities, and the NIH.

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in earlier in our conversation. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this letter. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you do not provide authorization for us to use your PHI it will not affect your treatment or the care given by your health provider, insurance payments or enrollment in any health plans, or any benefits to which you are entitled. However, it will not be possible for you to take part in the study. If you agree to take part, you authorize the use of your PHI for this research, and your authorization will not expire. You may later change your mind and not let the research team use or share your information.

In order to revoke your authorization, you will need to complete a withdrawal letter. Please contact the Human Research Protection Office for more information on how to revoke your authorization or contact the research team to request the withdrawal letter. If you revoke your authorization, the research team may only use and share information already collected for the study. Your information may still be used and shared as necessary to maintain the integrity of the research, for example, to account for a participant's withdrawal from the research study or for safety reasons. You will not be allowed to continue to participate in the study.

Can we contact you by email?
We would like to contact you by email for the purposes listed below. Some of these emails may contain health information that identifies you.

- To schedule telephone follow-up appointments
- To send reminders about scheduled follow-up appointments

Only the research team will have access to your email communications. We will only communicate by email to send you the information listed above. If you have any questions or need to contact us for an urgent or emergent situation, please contact the research team member identified at the top of this document.

You should be aware that there are risks associated with sending your health information via email.

- There is always a risk that the message could be intercepted or sent to the wrong email address. To avoid sending messages to the wrong email address, the first email we send you will be a test message to ensure we have the correct email address.
- When using any computer you should be careful to protect your username and password. Make sure you log-out before getting up from the computer.
- If you share a home computer with other family members, and do not want them to know you are participating in this study make sure you provide an email address that only you can access.
- Your employer will have access to any email communications sent or received on any electronic devices used for work or through a work server.

Do you agree to allow us to send your health information via email?

_____Yes _____No

The following privacy protections will be enacted for all email communications involving PHI: 1) a test email will be sent to you to verify your identity by asking you to confirm receipt. The email will be sent in a secure manner, i.e., [secure] in the subject line; 2) The body of the email will instruct you to send all information as a response and to not remove the "[Secure] from the subject line; 3) we will document your agreement to provide information over email in your research record.

After electronic informed consent is obtained, a member of the research team will send a copy of the approved consent to you for your records.

We encourage you to ask questions. If you have any questions about the research study itself of feel you have been harmed, please contact: Beth Taylor, 314-215-7384. If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office at 1-(800)-438-0445 or email hrpo@wustl.edu. General information about being a research participant can be found on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research participant or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

Do you agree to participate in this study?

[If the individual states, "no"]
Thank you for your time and consideration. **[End the call]**

-OR-

[If the individual states, "yes"]

Obtain participant's e-mail address.