COVER PAGE

INFORMED CONSENT FORM FOR:

Relieving the Burden of Psychological Symptoms Among Families of Critically Ill Patients with COVID-19

NCT04501445

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Protocol Title: Relieving the Burden of Psychological Symptoms Among Families of Critically Ill Patients with COVID-19
Sponsor: Internally funded by the Rush University Medical Center 2020 Coronavirus Research Fund

Name of Participant: _____

RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent form will give you more detailed information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

The purpose of this study is to determine how you have been doing after your family member was hospitalized at Rush University Medical Center for COVID-19. If you agree to participate in this study, you will be asked to complete an online survey AND a 30-minute phone interview dealing with your ICU experience and how you have been doing.

Based on your survey responses and interest, you may be asked to participate in a support intervention with a psychologist by phone or video call once per week for up to six weeks. After which, you will be asked to complete a second online survey AND a 30-minute phone interview dealing with your ICU experience and how you have been doing. If you agree to participate in this study, your participation may last up to two months.

This study includes little risk. There may be a risk of loss of confidentiality if your medical information or your identity is obtained by someone other than the investigators, but extra care will be taken to prevent this from happening.

If an investigator is concerned for your safety based on your responses, he or she will inform you of the appropriate resources.

You may not directly benefit from taking part in this study, but we hope that knowledge gained from this study may benefit other family members of patients in an ICU.

Your only other option to participating in this study is not to participate.

Detailed Information: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

Why are you being invited to participate in this study?
You are being asked to take part in this study because you are a close family member or friend of a patient with COVID-19 who was treated at Rush University Medical Center.

How many participants will take part in this study?
Approximately 100 family members are expected to take part in this study at Rush University Medical Center.

What are the activities you will be doing if you participate in this study?
If you agree to participate, you will complete an online survey dealing with your ICU experience and how you have been doing, which will take about 15 minutes to complete. You will also complete a 30-minute phone interview dealing with these the same topics. Based on your survey responses and interest, you will be asked to participate in a support intervention with a psychologist by phone or video call once per week for up to six weeks. The phone or video calls may last 30-60 minutes each. At the end of the six-week period, you will be asked to complete a second online survey and a second 30-minute phone interview dealing with your ICU experience and how you have been doing. We will ask your permission to audio record phone interviews to assist in note taking.

What are the risks and discomforts of participating in this study?
This study includes little risk. There is a risk of loss of confidentiality if your medical information or your identity is obtained by someone other than the investigators, but extra care will be taken to prevent this from happening.

If an investigator is concerned for your safety based on your responses, he or she will inform you of the appropriate resources. All participants will be provided with the number to the national suicide hotline: 1-800-273-TALK. You may be referred for additional outpatient mental health services or a Rush mental health professional, reminded of the national suicide hotline number, and encouraged to visit a hospital emergency department if the severity of suicidal ideation increases.

Can you leave or be removed from this study?

You have the right to leave a study at any time without penalty.

The researchers and sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?

This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you sign this authorization.

By signing this document, you voluntarily authorize (give permission to) Dr. Jared A. Greenberg or his study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study Dr. Jared A. Greenberg or his study team will collect information about your mental health for the purposes of this research. Protected Health information (PHI) is your health information that includes your medical history and new information obtained as a result of this study.

Dr. Jared A. Greenberg or his study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- Monitoring agencies such as the National Institutes of Health

While you participate in the study you will have access to your medical record, but Dr Jared A. Greenberg is not required to release to your study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. The results of study tests/procedures performed as part of this study may become part of your medical record. Any study information in your medical record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings. Audio recordings will be destroyed after study completing.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed above.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Jared A. Greenberg 1725 W. Harrison St. Suite 054, Chicago IL, 60612. If the

authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. We will use coded names or identification numbers, with removal of all identifying information

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

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. This research study can be found by searching for the following Clinical Trial Registry Number NCT04501445.

What are the costs to participate in this study?

There are no costs to you for participating in this research. All costs for the required study will be paid for by the study sponsor.

Will you be paid for your participation in this study?

We will mail you a $50 Visa gift card after you complete the first survey and first 30-minute phone interview. If you complete the 6-week support intervention, we will mail you a second $50 Visa gift card after you complete the second survey and the second 30-minute phone interview,

Who can you contact for more information about this study?

Questions are encouraged. If you have further questions about this study, you may call Jared Greenberg MD at 312-942-7871 or email address jared_greenberg@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?

Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?

Taking part in this study is voluntary. If you choose not to participate in this study, your care at Rush University Medical Center will not change. You may choose not to participate at any time during the study. Leaving the study will not affect your care at Rush University Medical Center.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Jared Greenberg in writing at the address on the first page. Dr. Jared Greenberg may still use your information that was collected prior to your written notice. You will be given a signed copy of this document.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form. You will be given a signed copy of this consent.

SIGNATURE BY THE PARTICIPANT OR THE PARTICIPANT'S LEGAL REPRESENTATIVE]:

You can sign and either email to jared_greenberg@rush.edu
or fax to 312-942-3131 (Attention Jared Greenberg)
Otherwise, you can complete a phone consent with two study investigators.

Name of Participant	Signature of Participant	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:

I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature

SIGNATURE BY WITNESS/INTERPRETER:

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the participant or the participant's legally authorized representative] and the person signing the form has done so voluntarily.

Name of Witness/Interpreter

Signature of Witness/Interpreter	Date of Signature