PRINCIPAL INVESTIGATOR: Joyce Chung, MD

STUDY TITLE: Mental Health Impact of COVID-19 Pandemic on NIMH Research Participants and Volunteers

You are being asked to take part in a research study at the National Institutes of Health (NIH).

IT IS YOUR CHOICE TO TAKE PART IN THE STUDY

This study is entirely voluntary, and you are not required to participate. If you join this study, you may change your mind and stop participating in the study at any time and for any reason. In either case, you will not lose any benefits to which you are otherwise entitled. If you do choose to leave the study, please inform the study team.

WHY IS THIS STUDY BEING DONE?

This is an on-line study. The purpose of this study is to learn about how stressors related to the COVID-19 virus affects mental health symptoms like anxiety and mood over time. We are asking you to join this research study because you participated in other research studies at NIH or have expressed an interest in this study because you heard about it through an advertisement or website. We hope the study will help us better understand the experiences of NIH/NIMH patients and others during this difficult time.

WHAT WILL HAPPEN DURING THE STUDY?

We will ask you to complete questionnaires every two weeks using the study website for up to 6 months. The questions will focus on COVID-19, your mental health history and symptoms, stress, physical health, substance use, and day to day activities. After you consent, you will be able to complete and submit the online study questionnaires. Every two weeks, you will be notified by the study team by email when it is time to repeat the questionnaires. When the study ends, you will be asked to complete a set of end-of-study questionnaires. The entire study will be conducted online. If you have already participated in other NIH/NIMH studies, we may access and link your new responses to previously collected information that we have about you in our research records including assessments of behavior, mental health, medical conditions, labs and neuroimaging.

HOW LONG WILL THE STUDY TAKE?

If you agree to take part in this study, your involvement is expected to last up to 6 months, and we would like the option to re-contact you in the future. It will take approximately 20 minutes each time for you to complete the survey.

HOW MANY PEOPLE WILL PARTICIPATE IN THIS STUDY?

We plan to have approximately 10,000 people participate in this study.

IRB NUMBER: 20MN085
IRB APPROVAL DATE: 05/15/2020
WHAT ARE THE RISKS AND DISCOMFORTS OF BEING IN THE STUDY?

The primary risk to subjects for this study would be a breach of confidentiality. We plan to take extensive precautions to protect the confidentiality of your data.

You may find it difficult to answer questions about the mental health impact of COVID-19 on yourself or others. If a question or questions are upsetting to you or making you more worried, you do not have to answer them.

WHAT ARE THE BENEFITS OF BEING IN THE STUDY?

You will not benefit from being in this study.

Are there any potential benefits to others that might result from the study?

The results of the study may benefit society in general if we better understand the mental health impact of pandemics such as COVID-19 through real time assessments of individuals from a wide range of backgrounds and clinical histories.

STORAGE, SHARING AND FUTURE RESEARCH USING YOUR DATA

As part of this study, we are obtaining data from you. We will remove all the identifiers, such as your name, date of birth, address, or medical record number and label your data with a code so that you cannot easily be identified. However, the code will be linked through a key to information that can identify you. We plan to store and use these data for studies other than the ones described in this consent form that are going on right now, as well as studies that may be conducted in the future. We may share your coded data with other researchers. These researchers may be at NIH, other research centers and institutions, or commercial entities. If we do this, while we will maintain the code key, we will not share it, so the other researchers will not be able to identify you.

The future studies may provide additional information that will be helpful in understanding mental illness and mental health, or other diseases or conditions. This could include studies to develop other research tests, treatments, drugs, or devices, that may lead to development of a commercial product by the NIH and/or its research or commercial partners. There are no plans to provide financial compensation to you if this happens. Also, it is unlikely that we will learn anything from these studies that may directly benefit you.

If you change your mind and do not want us to store and use your data for future research, you should contact the research team member identified at the bottom of this document. We will do our best to comply with your request but cannot guarantee that we will always be able to destroy your data. For example, if some research with your data has already been completed, the information from that research may still be used. Also, for example, if the data have been shared already with other researchers, it might not be possible to withdraw them. In addition to the planned use and sharing described above, we might remove all identifiers and codes from your specimens and data and use or share them with other researchers for future research at the NIH or other places. When we or the other researchers access your anonymized data, there will be no way to link the specimens or data back to you. If we do this, we would not be able...
to remove your specimens or data to prevent their use in future research studies, even if you asked, because we will not be able to tell which are your specimens or data.

NIH policies require that your clinical and other study data be placed in an internal NIH database that is accessible to other NIH researchers for future research. These researchers will not have access to any of your identifiers. We cannot offer you a choice of whether your data to be placed in this database or not. If you do not wish to have your data placed in this database, you should not enroll in this study.

**How long will your data be stored by the NIH?**

Your specimens and data may be stored by the NIH indefinitely.

**Risks of storage and sharing of data**

When we store your specimens and data, we take precautions to protect your information from others that should not have access to it. Even with the safeguards we put in place, we cannot guarantee that your identity will never become known or someone may gain unauthorized access to your information. New methods may be created in the future that could make it possible to re-identify your and data.

**COMPENSATION**

You will not receive compensation for participation in this study.

**CONFIDENTIALITY PROTECTIONS PROVIDED IN THIS STUDY**

**Will your information be kept private?**

We will do our best to make sure that the personal information in your record will be kept private. However, we cannot guarantee total privacy. Organizations that may look at and/or copy your records for research, quality assurance, and data analysis include:

- The NIH and other government agencies which are involved in keeping research safe for people.
- National Institutes of Health Intramural Institutional Review Board

When results of an NIH research study are reported in medical journals or at scientific meetings, the people who take part are not named and identified. In most cases, the NIH will not release any information about your research involvement without your written permission. However, if you sign a release of information form, for example, for an insurance company, the NIH will give the insurance company information from your medical record. This information might affect (either favorably or unfavorably) the willingness of the insurance company to sell you insurance.

Further, the information collected for this study is protected by NIH under a Certificate of Confidentiality and the Privacy Act.

**Certificate of Confidentiality**

To help us protect your privacy, the NIH Intramural Program has received a Certificate of Confidentiality (Certificate). With this certificate, researchers may not release or use data or information about you except in certain circumstances.
NIH researchers must not share information that may identify you in any federal, state, or local
civil, criminal, administrative, legislative, or other proceedings, for example, if requested by a
court.

The Certificate does not protect your information when it:

1. is disclosed to people connected with the research, for example, information may be used
   for auditing or program evaluation internally by the NIH; or
2. is required to be disclosed by Federal, State, or local laws;
3. is for other research;
4. is disclosed with your consent.

The Certificate does not prevent you from voluntarily releasing information about yourself or
your involvement in this research.

The Certificate will not be used to prevent disclosure to state or local authorities of harm to self
or others including, for example, child abuse and neglect, and by signing below you consent to
those disclosures. Other permissions for release may be made by signing NIH forms, such as the
Notice and Acknowledgement of Information Practices consent.

Privacy Act

The Federal Privacy Act generally protects the confidentiality of your NIH medical information
that we collect under the authority of the Public Health Service Act. In some cases, the Privacy
Act protections differ from the Certificate of Confidentiality. For example, sometimes the
Privacy Act allows release of information from your record without your permission, for
example, if it is requested by Congress. Information may also be released for certain research
purposes with due consideration and protection, to those engaged by the agency for research
purposes, to certain federal and state agencies, for HIV partner notification, for infectious disease
or abuse or neglect reporting, for quality assessment and medical audits, or when the NIH is
involved in a lawsuit. However, NIH will only release information from your medical record if
it is permitted by both the Certificate of Confidentiality and the Privacy Act.

PROBLEMS OR QUESTIONS

If you have any problems or questions about this study or about your rights as a research
participant, contact the Study Coordinator, Alison Gibbons, alison.gibbons@nih.gov, 240-665-
0697, or the Principal Investigator, Joyce Chung, M.D., joyce.chung@nih.gov, 301-443-84. Other researchers you may call are: Maryland Pao, M.D., 301-435-5770. You may also call the
NIH Clinical Center Patient Representative at 301-496-2626, or the NIH Office of IRB
Operations at 301-402-3713, if you have a research-related complaint or concern.

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By clicking below, you are attesting that:

- you are 18 years of age or older;
- have read the explanation about this study;
- consent to participate;
- and give permission for your previous NIMH research data, if applicable, and your new data to be used by NIH researchers and coded and shared with other researchers for future research.