
STUDY INFORMATION:

Study Title: Psychosocial Factors Related to Mental Health Outcomes and Resilience in the Face of COVID-19 Among Residents of New York City

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SUMMARY OF THIS RESEARCH STUDY:

In medicine there are many unanswered questions. A research study is when scientists try to answer a question about something that we don't know enough about. Participation in a research study may or may not directly help you or others. Participation is entirely voluntary. It is completely up to you whether or not you take part. You can also change your mind at any time, and it will not affect your ability to get medical care within the Mount Sinai Health System.

Prior research suggests that different people have different mental health outcomes in the wake of natural disasters and other forms of extreme stress. An improved knowledge of potential protective factors in particular – factors that increase someone's resilience to extreme stress – is essential to advance public health initiatives aimed at improving health outcomes. The COVID-19 pandemic is currently a source of significant stress to all New Yorker. Therefore, the goal of the proposed research is to conduct a longitudinal study of psychosocial factors that are associated with mental health outcomes and resilience among residents of New York City.

If you choose to participate, you will be asked to complete a set of surveys four times over the span of one year. We expect each set of surveys to take approximately one to two hours to complete The questions relate to your exposure to COVID-19-related stress, medical and psychiatric history, psychosocial and lifestyle factors, coping styles and symptom Our goal provide knowledge regarding mental health outcomes and protective resilience factors to COVID-19-related stress among residents of New York City. We hope this information will improve preparedness for future pandemics, natural disasters or other forms of extreme stress.

There will be no costs associated with participation and you will be compensated for your time.

The main risks to you if you choose to participate are loss of private information and discomfort answering questions related to mental and physical health symptoms or history.

Participating in this research will not benefit you. If you are interested in learning more about this study, please continue to read below.

PARTICIPATION IN THIS RESEARCH STUDY:

This research study can be fully explained to you by a member of the study team if you have any questions after reviewing this consent form. Please contact: DAC@mssm.edu or 212-241-6539. Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

You may qualify to take part in this research study because you are above the age of 18 and live in New York City or you have participated in a study at the Depression and Anxiety Center in the past. Funds for conducting this research are provided by Mount Sinai.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last 1 year. The number of people expected to take part in this research study at the Icahn School of Medicine at Mount Sinai is 1,500.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved:

- The study involves completion of surveys on Remote Electronic Data Capture system (REDCap) and all study procedures will be completed remotely (at home).
- You will be invited to complete an online survey via REDCap and will be re-contacted automatically three months later, six months later, and 12 months later for a total of 1 year. The study team expects each set of surveys to take approximately 1-2 hours to complete.
- Your first set of surveys will begin immediately after completing this consent form, if you choose to participate.

USE OF YOUR DATA AND/OR SPECIMENS:

If you have participated in a research study at the Icahn School of Medicine at Mount Sinai in the past, do you consent to allow the study team to use some of your previously collected research data for this project? This could include the results of brain imaging, genetics, laboratory testing and/or cognitive testing from previous study participation. Clinical information collected as part of these studies may also be used, such as medical or psychiatric history. **Please initial "Yes" or "No"**

_____**Yes,** I consent to the use of my previously collected data for the purposes of this study.

_____ **No,** I do not consent to the use of my previously collected data for the purposes of this study.

In the future, your identifiable information may be removed from the private information and/or samples that are collected as part of this research. After this removal, the information and/or samples could be used for future research studies or shared with other research teams, other academic institutions and for profit companies, for future research studies. You will not be informed of the details of specific research that is done with your medical information. That means that a research project might be done that you would not consent to if provided with the details of that research project.

You should also know that it is possible that products may someday be developed with the help of your specimens and data, and there are no plans to share any profits from such products with you, regardless of whether your identifiable information is removed.

The Principal Investigator will keep a code that links your identifiable information with your private information. The code will not be shared. Your data may be added to a large public repository, in which case, no identifiable information will be shared.

To do more powerful research, it is helpful for researchers to share information they get from studying human samples. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. If you agree to take part in this study, some of your health information might be placed into one or more scientific databases. There are many different kinds of scientific databases; some are maintained by Icahn School of Medicine at Mount Sinai or another institution, some are maintained by the federal government, and some are maintained by private companies. For example, the National Institutes of Health (an agency of the federal government) maintains a database called “dbGaP.” A researcher who wants to study the information must apply for permission to use the database. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with that from many other people. Researchers will always have a duty to protect your privacy and to keep your information confidential, but there are risks associated with data collection and sharing. They are described in more detail in the risks section.

Do you give the researchers permission to **contact you** in the future to collect additional information about you, discuss how your information might be used, or to discuss possible participation in another research project? **Please initial “Yes” or “No”**

_____**Yes,** I consent to be contacted in the future.

_____ **No,** I do not consent to be contacted in the future.

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YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for completing each set of surveys attentively and within 72 hours of receiving them.

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COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this research study, we will pay you $100 for your time and effort with Amazon e-gift cards. The amount is pro-rated for each set of surveys completed which means you will receive a $25 e-gift card for each set of surveys completed. The e-gift cards will be provided by email. Throughout the surveys, if you repeatedly fail attention checks or fail to complete the surveys within 72 hours, you will not be compensated for that set of surveys.

Study Task	Payment
Surveys (x4)	$25 e-gift card
Total	**$100**

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POSSIBLE BENEFITS:

You are not expected to get any benefit from taking part in this research study. Others may not benefit either. However, possible benefits to others include contributing to a greater understanding of the short- and long-term psychosocial effects of COVID-19. Please note that responses to the surveys may not be checked in real time. If you feel you may be at risk of hurting yourself or someone else, please call 911 or go to your nearest emergency room. The National Suicide Prevention Hotline can be reached at 1-800-273-8255. If you require assistance with COVID-19 or any physical or psychiatric issues please contact your treating provider. If you don't have a treating provider, please contact 1-888-NYC-WELL or text WELL to 65173. If you need immediate medical attention, please call 911.

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REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

- **Surveys:** You will be asked to complete a number of surveys about your experiences, behaviors, and symptoms. Answering these questions about how you feel may cause you some emotional discomfort as it can be difficult to think about your mental health and history. You have the right to refuse to answer any question that you do not wish to answer and to withdraw from participation at any time.
- **Loss of information:** Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.
- **Group Risks:** Although we will not give researchers your name, we will give them basic information such as your race, ethnic group, and sex. This information helps researchers learn whether the factors that lead to health problems are the same in different groups of people. It is possible that such findings could one day help people of the same race, ethnic

group, or sex as you. However, they could also be used to support harmful stereotypes or even promote discrimination.

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OTHER POSSIBLE OPTIONS TO CONSIDER:
You may decide not to take part in this research study without any penalty. The choice is totally up to you.

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IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the Principal Investigator.

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ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care at any of the Mount Sinai Health System hospitals or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff. If you decide you don't want your data to be used for research anymore, you can contact the researcher and ask to have your data removed from future use. If any data have already been shared without your identity, it won't be possible to retrieve them because no one will know who you are. Data that have already been used will not be affected by your decision. Any data that are still linked to your identity by a code the researcher has will be withdrawn so that no future sharing of your data will take place.

Withdrawal without your consent: The study doctor, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If data have been stored as part of the research study, they too can be destroyed without your consent.

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CONTACT INFORMATION:

If you have any questions, concerns, or complaints at any time about this research, or you think the research has harmed you, please contact the office of the research team and/or the Principal Investigator at phone number: 212-585-4640

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

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DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

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MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

What protected health information is collected and used in this study, and might also be shared with others? As part of this research project, the research team at the hospital involved in the research will collect your name, address, telephone numbers, dates directly related to you (birth, admission, discharge, date of death, etc.), social security number, and e-mail. The researchers may also gather information from your medical record at Mount Sinai hospital. During the study the researchers will gather information by:

- Completing the questionnaires explained in the description section of this consent.
- Researchers will also access previously collected data if you have participated in a study at the Icahn School of Medicine or with the Depression and Anxiety Center in the past. These data may include clinician administered interviews, self-reports, results of brain imaging, laboratory testing, genetics, and cognitive testing in addition to the protected health information listed above.

Why is your protected health information being used?
Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?
As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations:
(It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- The United States Department of Health and Human Services and the Office of Human Research Protection.

In all disclosures outside of Mount Sinai, you will not be identified by name, address, telephone number, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary, to complete their task. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information?
Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?
During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?

NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?
You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

Certificate of Confidentiality:

To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services. This is intended to ensure that your identity as a participant in this research study will not have to be disclosed as a result from a subpoena, for the

purpose of identifying you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings other than to the FDA or OHRP as identified above.
The research staff will not share any of your research information or biospecimens with anyone who is not a member of the research team, including any family members or friends, other than to those identified above. However, you should know that if we learn that you or someone else is threatened with serious harm, such as a child or an elderly person being abused, the investigators may notify the appropriate authorities if necessary to protect you or others. A Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. This means that you and your family must also actively protect your own privacy. If an insurer or employer learns about your research participation, and you agree that they can have your research information, then the researchers may not use the Certificate of Confidentiality to keep this information from them.

ADULT PARTICIPANT:
Your signature below documents your permission to take part in this research and to the use and disclosure of your protected health information. A signed and dated copy will be given to you.

_____	_____	_____	_____
Signature of subject	Printed Name of Subject	Date	Time

PERSON EXPLAINING STUDY AND OBTAINING CONSENT:

_____	_____	_____	_____
Signature of consent delegate	Printed Name of consent delegate	Date	Time

WITNESS SECTION:
When a witness is required to observe the consent process, it should be documented below (for example, when subject is illiterate, visually impaired, or this document accompanies a short form consent).

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

_____	_____	_____	_____
Signature of Witness	Printed Name of Witness	Date	Time