STUDY ID#: 21-00596 **Form Version Date:** March 29, 2021

STUDY INFORMATION:

Study Title: Warrior Shield

Principal Investigator (Head Researcher): Robert Hirten MD

Physical Address: 1 Gustave L Levy Place, NY, NY 10229

Mailing Address: 1 Gustave L Levy Place, NY, NY 10229

Email: covid.hcw@mssm.edu (preferred); For urgent matters 212-824-8484.

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.

Due to the COVID-19 pandemic people are under increased stress. There are higher rates of anxiety, depression and other mental health conditions. It is unclear which interventions are effective at decreasing or improving these mental health effects. The purpose of this research study is see if a well-studied stress reducing and resilience building intervention can improve the well-being of health care workers during the COVID-19 pandemic.

If you choose to participate, you will be asked to:

- Download and install the eHive app on your phone.
- Connect your Apple Watch to the eHive app (if you don't have an Apple Watch you will be provided with one).
- Complete study surveys in the eHive app.
- Watch short videos each week that are in the eHive app to learn about the interventions we are using and how to apply them to your life.
- Download the HeartMath app and use the provided ear sensor which will be sent to you.
- Use the Heartmath app with the ear sensor for 5 minutes per day for 5 weeks.
- Apply the techniques you learn during these sessions to your day-to-day life.
- Continue to answer questions in the eHive app for 17 weeks after you begin the intervention.

As part of this study you will be given an Apple Watch, if you do not have one. The data that is collected from your Apple Watch includes the number of steps you take each day, your heart rate, your heart rate variability (calculated from your heart rate) and a general assessment of the total noise you are exposed to. All of these are already collected by Apple Watches.

It is possible that Apple and HeartMath may be collecting some data through the information you provide to the app or through the use of HeartMath. This does not include health information, which is protected by this research study. There are data specific to Apple and HeartMath terms and conditions which Apple and HeartMath have set up with you upon download and participation in the study application (or any application that you chose to download). We urge you to look over the terms of agreement with Apple and HeartMath to see what types of data they collect on their app users.

Similarly, the Apple Watch you will be loaned is designed to measure heart rate, ambient noise, location etc. This information is fed directly to Apple, as well as other apps that you authorize. It is important that you understand the data that will be shared and make whatever changes you wish to limit the sharing. Please note this sharing to Apple and HeartMath goes on even if you are not sending information to this project but are using their devices. We encourage you to read the Apple and HeartMath terms and conditions to learn more about how they might collect/use your data, prior to participating in this study. If you don't want to share information with Apple or HeartMath you should not participate in this project.

You will start using the HeartMath app and intervention after you have worn your Apple Watch for 7 days.

The main risks to you if you choose to participate are a loss of private information.

You may also benefit from participation in this research with reduced stress, increased resilience and other improvements in well-being.

If you are interested in learning more about this study, please continue to read below.

PARTICIPATION IN THIS RESEARCH STUDY:

This research study will be fully explained to you through the study app. 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 a healthcare worker in the Mount Sinai Health System.

Funds for conducting this research are provided by the Icahn School of Medicine.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last 17 weeks from the date you start the intervention portion of the study.

The number of people expected to take part in this research study in the Mount Sinai Health System is approximately 1000 subjects.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved. This study is site-less meaning there are no visits or in person contacts required.

1. You will download the eHive, complete the consent process and then answer questions about yourself.
2. You will link your Apple Watch to the study app. If you don't have an Apple Watch, we will send you an Apple Watch to use during the study.
3. You will download the HeartMath app after you receive it.
4. You will answer survey questions every day in the eHive app.
5. You will watch short videos each week in the eHive app.
6. You will use the HeartMath app for 5 minutes per day. You will do this for 5 weeks.
7. You will practice and use the techniques learned in these sessions when you encounter stress or feel stressed during the course of your day.
8 While the daily surveys are short there are longer surveys that will be asked prior to the intervention, and after 5, 7 and 17 weeks.

Data from your Apple Watch, or the Apple Watch provided to you, will be collected and includes your heart rate, heart rate variability, steps and overall noise exposure. These are already collected by the Apple Watch and the study App will automatically collect this information. You will receive notifications to complete surveys and reminders through the study App. These can be turned off by disabling App

notifications. Additionally, study coordinators may reach out to you periodically to answer any questions and reinforce what is learned during the sessions. This may be either by phone or email.

If there are any issues obtaining the data from your surveys or the eHive app, your Apple Watches, or using the HeartMath intervention a research coordinator may reach out to you to assist in troubleshooting the issue. Since this study is completely remote, research coordinators may reach out to you to check in on how the study is going. This will not be more frequent than every 1-2 weeks.

If you break or lose the Apple Watch you are not responsible for replacing it or having it repaired. You are responsible however for returning it at the end of the study. If you are not compliant with the study you will also be asked to return it to the study staff. To return the Apple Watch to the study staff you will mail it back to the study team using a provided shipping label or drop it off at Mount Sinai with the research team.

USE OF YOUR DATA AND/OR SPECIMENS:

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 for future research studies. You will not be informed of the details of specific research that is done with your medical information and biospecimens. That means that a research project might be done that you would not consent to if provided with the details of that research project.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study you will be responsible for the following things: Downloading the eHive app and the HeartMath app, wear your Apple Watch every day, practice with the HeartMath intervention and answer survey questions

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this research study, we will pay you with a $25 gift card at week 2 and 6 for your time and effort. Total compensation is for $50 of gift cards.

Tax law may require the Mount Sinai Finance Department to report the amount of payment you receive from Mount Sinai to the Internal Revenue Service (IRS) or other agencies, as applicable. Generally,

this reporting would take place if you receive payments that equal $600 or more from Mount Sinai in a calendar year. You would be responsible for the payment of any tax that may be due.

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

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be improved well-being, reduced stress or increased resilience from the HeartMath intervention.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

There are possible small risks related to participating in this study.

- 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.
- Privacy Risks - Your name and other information that could directly identify you (such as address, date of birth or social security number) will never be placed into a scientific database. However, because your genetic information is unique to you, there is a small chance that someone could trace it back to you. The risk of this happening is very small, but may grow in the future. Since the database includes genetic information, a break in security may also pose a potential risk to blood relatives as well as yourself. For example, it could be used to make it harder for you (or a relative) to get or keep a job or insurance. If your private information was misused it is possible you would also experience other harms, such as stress, anxiety, stigmatization, or embarrassment from revealing information about your family relationships, ethnic heritage, or health conditions.

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.

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.

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.

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 specimens or data have been stored as part of the research study, they too can be destroyed without your consent. More possible reasons for removal from the study include not being compliant with study related activities.

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 covid.hcw@mssm.edu.

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:

----------FOR IRB USE ONLY----------

Effective Date: 6/1/2021
End Date: 5/31/2022

- 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.

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.

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(s) involved in the research will collect your name, address and medical record number. The researchers will also get information from your medical record in the Mount Sinai Health System.

During the study the researchers will gather information by:

- Asking survey questions through the eHive app.
- Collecting data gathered by the Apple Watch.
- Assuring compliance with the HeartMath app through HeartMath's custom portal verifying the use and duration of practice sessions.

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 Principal Investigator may also use and share the results of these tests and procedures to treat you in collaboration with others in the Mount Sinai Health System.

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. I*f 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.

In all disclosures outside of Mount Sinai, you will not be identified by name, social security number, 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.

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

----------FOR IRB USE ONLY----------
Rev. 1.16.19 (amendment 02)

Effective Date: 6/1/2021
End Date: 5/31/2022

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