STUDY INFORMATION:

Study Title: eHive: Decode Blood Pressure

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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.

> Hypertension (i .e. high blood pressure) is highly prevalent in adults worldwide and is the leading risk factor for cardiovascular diseases. However, the standard way to measure this condition is still quite cumbersome and requires a cuff-based device (you have likely experienced this cuff to measure blood pressure at the doctor's office). With the surge of more comfortable wearables like smartwatches and armbands, blood pressure monitoring at home is becoming easier and can thus have the potential, to help prevent and monitor not only hypertension but also many other cardiovascular health risks. In this study, we will test wearable devices to see how they measure blood pressure compared to a medical-grade oscillometric device. At home monitoring of blood pressure (BP) could lead to better health outcomes, but we do not know how accurate some of these measurements are.

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

- Download and install the eHive app on your phone.
- Connect a blood pressure monitor and two other wearable devices to the app and record your BP and wearable data twice daily.
- Complete study surveys in the eHive app.
- Watch short videos that instruct you how to use the BP monitor and wearable devices.

As part of this study you will be given three blood pressure devices, specifically the Withings BPM, Empatica E4, and Polar Verity. The data that is collected from the devices includes PPG signal (PPG signal can be used to detect blood volume changes in the microvascular bed of tissue). We will also collect accelerometer (ACC), heart rate (HR), inter beat interval (IBI), skin tone as defined by the Fitzpatrick scale, and blood pressure data from the devices.

It is possible that the BP device companies listed above may be collecting some data including, but also beyond what you share with the study. The data collected on blood pressure and from the wearable devices is a data feed that goes directly to the company's cloud system. It is important that you understand the data that will be shared and make whatever changes you wish to limit the sharing. Those are data specific to the terms and conditions which the companies have set up with you. We urge you to look over the terms of agreement with Withings, Polar, and Empatica to see what types of data they collect on their device users. Our study team retrieves the data we need for the study, from their cloud system to conduct the research. At this point, the data does not leave Mt. Sinai servers. We do not share your BP data associated with your identity in anyway that would allow you to be matched to it.

Briefly, the device companies listed here: Withings, Polar and Empatica may collect things like:

- **Identity data**, which means data which can directly identify you, such as your email address, birth date, name, phone number, delivery address, etc.
- **Activity data** which means your physical activities, such as number of steps, distance travelled, number of calories burned, your weight, heart rate, blood pressure, heart sound, temperature, etc.
- **Technical data** which means data necessary for the use of the Products and Services, such as Wi-Fi network, technical logs, date of Product activation, battery measurement, manufacturing ID, debug technical information, and website cookies.

We urge you to look at the terms and conditions yourself before you make a decision to join the study. You can find the links here: withings link, polar link, empatica link.

Study application: It is also possible that Apple may be collecting some data through the information you provide on the research platform. This does not include health information, which is protected by this research study. There are data specific to Apple terms and conditions which Apple has 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 to see what types of data they collect on their app users.

You will start using the eHive app after you have received your blood pressure and wearable devices in the mail. You will enter BP measurements for 7 days and then return the devices with the prepaid label contained in your packet.

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

There are no benefits to you if you participate in this study.

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 by contacting the study email address, made available to you in this app. 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 meet the eligibility criteria for this study; You are over 18, are fluent in English, not currently pregnant, have normal to high/normal blood pressure and are not on any medications for high blood pressure.

This study is funded by the Hasso Plattner Institute at Mount Sinai.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:

Your participation in this research study is expected to last approximately 1 week from the date you start.

The number of people expected to take part in this research study in the Mount Sinai Health System is approximately 30 participants.

The study will last for 1 week and take approximately 30 minutes to 1 hour to enroll, consent and learn how to take your blood pressure measurements properly at home and then 15 minutes each day for 6 more days.

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 remote, meaning there are no visits or in person contacts required.

1. You will download the eHive app, complete the consent process
2. You will answer survey questions every day in the eHive app.
3. You will watch short videos that provide instruction on how to use the BP and wearable devices.
4. You will link your BP and wearable devices to the study app once they arrive in the mail.
5. You will enter your BP measurements and wearable data twice a day for 7 days.

Data from your BP and wearable devices includes your PPG signal, ACC, IBI, HR and blood pressure data. You will receive notifications to complete surveys and reminders through the study App to enter the measurements. These can be turned off by disabling App notifications. Additionally, study coordinators may reach out to you periodically to answer any questions by email and reinforce the study procedures. It is important that you do not skip a day of entering data.

If there are any issues obtaining the data from your surveys, the eHive app or any of the devices, 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 may occur once a day at most or not at all.

USE OF YOUR DATA :

In the future, your identifiable information may be removed from the private information collected as part of this research. After this removal, the information will be used for future research studies and 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. That means that a research project might be done that you would not consent to if provided with the details of that research project.

To do more powerful research, it is helpful for researchers to share information they get from studying data. 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 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.

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 connecting the wearables and blood pressure monitor, entering the blood pressure measurements every day, once a day and answering survey questions.
You will be expected to mail the devices back with the return label attached in your kit at the end of the week.

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

If you agree to take part in this research study, we will pay you with $25 after your participation on the first day with the device readings. You will receive another $25 once we receive the devices back from you. The total compensation is for $50.

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.

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.

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, but learning more about how blood pressure is collected through these devices could have an impact on the health of people in the future.

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.
- 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.

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 bene fits 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 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 ehive.decodebp@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:

- 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 to 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 Withings BPM Connect, Empatica E4 and Polar Verity devices.

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

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.

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

Effective Date: 9/14/2021
End Date:8/2/2022

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