

Telehealth Referral to Improve Outcomes (TRIO) for Asymptomatic  
Hypertension in the Emergency Department  
PI: Kimberly T Souffront  
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**THE MOUNT SINAI HEALTH SYSTEM  
CONSENT FORM TO VOLUNTEER IN A RESEARCH STUDY  
AND AUTHORIZATION FOR USE AND DISCLOSURE OF MEDICAL INFORMATION  
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**STUDY INFORMATION:**

**Study Title:** Telehealth Referral to Improve Outcomes (TRIO2.0) for Uncontrolled Hypertension in the Emergency Department

**Principal Investigator (Head Researcher):** Kimberly Souffront, PhD, FNP-BC, RN

**Physical Address:** Mount Sinai Hospital [REDACTED], New York NY 10029]

**Mailing Address:** Mount Sinai Center for Emergency Research & Education, [REDACTED], New York, NY 10029

**Phone:** 212-824-8095

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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.

The purpose of this research study is to see if a nurse encounter plus a mobile device technology can improve primary care engagement and blood pressure control.

If you choose to participate, a member of the research team will ask you questions during your ED visits for a survey about hypertension awareness, treatment and perceived benefits of BP control. In 6 months and 12 months from today's visit, you will be contacted by a member of the study team to complete a survey about your experiences using the Vital Tech RPM, primary care and BP control. You will contact via the Vital Tech RPM mobile app.

The main risks to you if you choose to participate are possible loss of private information, mild discomfort completing survey questions and mild discomfort during the blood pressure reading.

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

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**PARTICIPATION IN THIS RESEARCH STUDY:**

This research study will be fully explained to you by a member of the study team. Feel free to ask all the questions you want before you make a decision about whether or not to participate. Any new

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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 were found to have at least two high blood pressure readings today and are being discharged. Funds for conducting this research are provided by Icahn School of Medicine at Mount Sinai, Mount Sinai West and Mount Sinai Morningside.

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.

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**LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE:**

Your participation in this research study is expected to last one-year.

The number of people expected to take part in this research study at Mount Sinai Hospital is 28; 10 at Mount Sinai West and 10 at Mount Sinai Morningside.

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**DESCRIPTION OF WHAT'S INVOLVED:**

If you choose to participate, you will be assigned a study group

- One group will get a blood pressure cuff PLUS a tablet.
- The second group will get a blood pressure cuff PLUS tablet PLUS a nurse encounter at 3-days.
  - The Mount Sinai nurse will speak to you virtually (via tablet) to assist with care coordination (making an appointment to see your primary care provider, if needed, reviewing your blood pressure readings, and/or discussing how to manage blood pressure).
- The third group will get a blood pressure cuff PLUS tablet PLUS a nurse encounter at 3-days and 7-days.
  - The Mount Sinai nurse will speak to you virtually (via tablet) at day 3 and day 7 to assist with care coordination (making an appointment to see your primary care provider, if needed, reviewing your blood pressure readings, and/or discussing how to manage blood pressure).
- The study treatment you will get will be chosen by chance, like pulling names out of a hat. You will have an equal chance of being given each study treatment. Neither you nor the study doctor will choose what experimental study treatment you get. You will have a one-in-three chance of being given each treatment.

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You will be given a blood pressure monitor and scale to take home with you when you leave the Mount Sinai emergency department, which you will use to measure your own blood pressure and weight at home.

You will be given a tablet to take home, which you will use to review information about how to control your blood pressure, the importance of controlling your blood pressure, and the importance of following up with your primary care provider. The research study staff will set up your account prior to you leaving the emergency department.

You will be contacted by a member of the study team at 6-months and 1-year using the Vital Tech Platform to discuss your blood pressure control and primary care engagement. You will also receive a text message from a coordinator about the follow up surveys. All participants will be contacted at 6 months and 12 months regardless of study group assignment.

You also have written instructions for its use attached to this consent form.

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**USE OF YOUR DATA AND/OR SPECIMENS:**

The private information collected as part of this research will never be used or shared for future research, even if the identifiable information is removed.

After the last patient (#48) has completed all study collection and the investigators have completed all data analysis, the information stored onto the tablet will be completely wiped and removed, which will take one year.

Do you give the researchers permission to **contact you** in the future to collect additional information about you? Please initial your choice:

Yes \_\_\_\_\_ No \_\_\_\_\_

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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 the following things:

- You will be asked to monitor your blood pressure:
  - At least once a day, at the same time, seated for 5-minutes, and continue this until you see your primary care provider.
  - You will be taught how to use this blood pressure monitor and scale before leaving the ED today and how to record your blood pressure readings and weight using the Vital Tech platform.
- You will engage in the Vital Tech Platform which provides information on blood pressure control and nutrition.

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- If you receive a nurse encounter, you will be asked to log onto the Vital Tech Platform to have a virtual encounter using your tablet. A text reminder (through the tablet) will be sent one day prior to your virtual encounter with the nurse.
- You will be asked to complete a survey on hypertension awareness and treatment at the beginning of this study, at 6-months, and at 1-year.
  - Each survey will take approximately 10-minutes to complete. All answers will be recorded using the VitalTech® Platform

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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 \$50 for your time and effort. You will receive \$50.00 cash during today's visit.

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 will not be paid for participating in this research study. Being in this research study will not lead to extra costs to you. You will not be reimbursed for time that may be required to complete the surveys.*

*If you agree to take part in this research study, we will provide you with a blood pressure cuff and tablet so that you can participate in the study. The tablet, BP cuff, and scale are free, and you can keep after the study ends.*

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**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 better blood pressure follow-up and management and more frequent opportunities to discuss your blood pressure with a health care provider. This potential benefit will only occur for up to 7 days and will stop after that. Other may benefit from the results of this study in the future as a way to help patients manage their blood pressure after an ED visit.

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**REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:**

- Risk of loss of private information; this risk always exists, but there are procedures in place to minimize the risk.

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- Economic risks (if you have to pay for additional mobile services to contact us) not with the tablet.
- Physical risks – you may be given a blood pressure monitor to measure your own blood pressure at home. This monitor is safe and effective, and harm caused by the monitor is extremely rare.
- For Women: Although pregnant woman are excluded from our study, you may become pregnant during the course of the study. The device used for this study is a blood pressure cuff. Blood Pressure cuffs are used in all adults, including pregnant woman during routine examinations. A blood pressure cuff does not pose harm or risk. Should you become pregnant, regardless of the outcome, the sponsor may withdraw you from the study. Your written consent will be obtained separately in the case that this happens.

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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.

*As with all patients seen in the Mount Sinai Emergency Department who have an elevated blood pressure, you will receive information in your discharge paperwork regarding follow-up with a primary provider to monitor your blood pressure. If you do not have a primary care provider, the phone number and address for a nearby Sinai-affiliated practice will be provided 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.

You may also 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 the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your

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authorization if you have an adverse event (a bad effect) from participating in the research study.  
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.

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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 212-824-8095.

If applicable, add: If you experience an emergency during your participation in this research, contact the study nurse at 212-824-8095

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.

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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 Mount Sinai Hospital involved in the research will collect your name, phone number, Emergency Department arrival and discharge dates, medical records number, Emergency Department visit numbers, blood pressure readings, and medical history from your medical record in the Emergency Department. Your private information (name, medical record number, Emergency Department visit number) will not be linked to your health information and will not be shared with Vital Tech.

During the study the researchers will gather information by:

- Completing the questionnaires and interviews explained in the description section of this consent.
- Reviewing your logged blood pressure readings from the home-based measurements.
- Reviewing your medical record from your current ED visit.

Why is your protected health information being used?

Your personal contact information is important to be able to contact you during the study if there may be any issues with your tablet and we need to speak to you. Your phone number will not be shared with Vital Tech. 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. *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.

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In all disclosures outside of Mount Sinai, you will not be identified by name, 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. Vital Tech will remove and wipe your health information from your tablet one-year after the last patient has completed data collection.

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.

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If you have not already received it, you will also be given The Hospital's Notice of Privacy Practices that contains more information about how The Hospital uses and discloses your protected health information.

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.

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**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.

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**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 [required if used for FDA documentation purposes]

**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

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